Buoy, 9 m.p.h. for upbound vessels and 12 m.p.h. for downbound vessels.

(ii) Between Stag Island Upper Junction Lighted Buoy and Harsens Island Rear Range Light, 12 m.p.h. for both upbound and downbound vessels.

(iii) Between Harsens Island Rear Range Light and St. Clair Cut-off Channel Lt2, F1R, 10 m.p.h. for both upbound and downbound vessels.

(2) In the Detroit River:

(i) Between the black turn buoy (lat. 42°22.0′ N., long. 82°54.0′ W.—Lake St. Clair), and Fighting Island South Light, 12 m.p.h. for upbound vessels and 14 m.p.h. for downbound vessels.

(ii) Between Fighting Island South Light and Detroit River Light 12 m.p.h. for both upbound and downbound vessels.

(3) [Revoked]

* * * * *

[Regs., Mar. 21, 1973] (Sec. 7, 40 Stat. 266; 33 U.S.C. 1)

[FR Doc.73-6144 Filed 3-29-73;8:45 am]

Title 47—Telecommunication

CHAPTER I—FEDERAL COMMUNICATIONS COMMISSION

[FCC 73-315]

PART 0—COMMISSION ORGANIZATION

Delegation of Authority to Chief, Safety and Special Radio Services Bureau

Order. In the matter of amendment of Part 0 of the Commission's rules to delegate authority to the Chief, Safety and Special Radio Services Bureau to act on requests for waivers of Part 97 as they relate to amateur radio space stations.

1. Since 1961 six amateur communication satellites have been placed into orbit. The newest satellite, OSCAR 6, was launched on October 15, 1972, and has been successfully transmitting amateur radiocommunication since that date.

2. In order to allow the operation of an amateur radio space station on board a satellite, it is necessary that a number of rules contained in Part 97 of the Commission's rules be waived. Therefore, to facilitate the orderly and efficient regulation of amateur radio space stations, while they are in their present experimental stage, delegated authority is granted to the Chief, Safety and Special Radio Services Bureau to act on such waiver requests of the provisions of Part 97. Waivers granted under this delegated authority will be limited to rules regarding station location, authorized emissions, station control, identification, logging, and operator privileges.

3. Authority for the rule adopted herein is contained in sections 4(i), 5(d) and 303 of the Communications Act of 1934, as amended. Since this change involves only a matter of internal Commission organization, the prior notification requirement of 5 U.S.C. section 553 is not applicable.

4. *It is ordered,* effective May 3, 1973, that § 0.331 of Part 0 of the Commission's rules is amended as set forth below.

(Secs. 4, 5, 303, 48 Stat., as amended, 1066, 1068, 1082; 47 U.S.C. 154, 155, 303)

Adopted: March 21, 1973.

Released: March 26, 1973.

FEDERAL COMMUNICATIONS COMMISSION,[1]

[SEAL] BEN F. WAPLE,
Secretary.

In Part 0 of Chapter I of Title 47 of the Code of Federal Regulations, § 0.331 (b)(24) is added to read as follows:

§ 0.331 Authority delegated.

* * * * *

(b) * * *

(24) To act on requests for waivers of the requirements of Part 97 of this chapter when it is shown that such a waiver is required, taking into account the state of the radio art, to allow the operation of an amateur radio space station. Waivers will be limited to the following areas: Station location, authorized emission, station control identification, logging, and operator privileges.

* * * * *

[FR Doc.73-6139 Filed 3-29-73;8:45 am]

[Docket No. 18703; FCC 73-327]

PART 1—PRACTICE AND PROCEDURE

Tariffs and Evidence

Memorandum opinion and order. In the matter of amendment of Part 61 of the Commission's rules relating to tariffs and Part 1 of the Commission's rules relating to evidence.

1. The Commission has before it several petitions requesting reconsideration of our final report and order released herein on October 13, 1970 (see 35 FR 16247), wherein we adopted certain tariff and evidentiary rules (25 F.C.C. 2d 957 (1970)). These petitions were filed on or about November 12, 1970, by two domestic carriers, American Telephone & Telegraph Co. (AT&T) and the Western Union Telegraph Co. (WU), and by two international carriers, Western Union International, Inc. (WUI), and RCA Global Communications, Inc. (RCA). In addition, an opposition to the AT&T, WU, and WUI petitions was filed by the National Retail Merchants Association (NRMA).

2. In essence, the petitioners raise both legal and policy objections to the rules. Insofar as the legal issues are concerned, it is argued:

(a) That section 203(d) of the Communications Act, as amended, sets forth the one and only basis upon which the Commission may reject a tariff filing; that is, for failure to give "lawful notice of its effective date" and that, therefore, the Commission is without power to reject tariff filings for violation of the Commission's rules.

(b) That the requirement that tariff increases and data in support thereof be filed 60 days prior to the effective date of such proposed increase is contrary to the requirements of section 203(b) of the Communications Act which puts a limitation of 30 days' notice which the Commission may require of any proposed tariff revision including increased rates.

(c) That the requirement for data to support new or reduced rates, as distinguished from increased rates, is an unlawful attempt to place the burden of proof on the carrier with respect to new or reduced rates and that section 204 places such burden on the carrier only with respect to increased rates.

3. The objections raised in the petitions on policy grounds relate to such matters as:

(a) The propriety or wisdom of including various requirements with respect to the filing of data and forecasts in those instances where there are competing carriers;

(b) The need to keep data confidential in those instances where there is actual active competition between carriers;

(c) The alleged reliance on cost data to the exclusion of other considerations;

(d) The need for and usefulness of 3-year projections as well as the other detailed data required;

(e) The advisability of substituting a provision which would permit the carrier to cure or rectify deficiencies in their filings rather than subjecting such filing to rejection;

(f) The alleged requirement for data that is not reasonably required to facilitate an understanding or evaluation of any particular filing;

(g) The need for exemptions from rules for tariff changes involving routine alterations on the basis that it is not necessary that the Commission have a detailed analysis of routine changes; and

(h) The need to formulate rules closely related to the diverse situations of each of the various kinds of carriers, such as, for example, certain rules for domestic landline carriers, certain rules for the domestic miscellaneous carriers and other rules for the international voice carrier and the several international record carriers.

DISCUSSION

LEGAL ISSUES

4. We shall address the legal objections first. In this connection we note that many of the matters raised in the petitions for reconsideration merely repeat arguments set forth in previous pleadings. We have considered such arguments fully in our final report and order and find no basis for changing our original decision thereon. Insofar as the petitioners' first contention is concerned, that we have power to reject tariffs only for failure to provide a 30-day effective date on tariff filings, it is sufficient to note that we and the courts have held to the contary. We have held that we can reject tariffs even when the effective date shown on the tariff provides the full 30 days' notice where, for example, there is lack of authorization to perform the service offered in the tariffs. "In Re AT&T Private Line Rate Case," Dockets 18128 and 18684, FCC 72-619, 36 FCC 2d

[1] Commissioner Johnson concurring in the result; Commissioner Reid and Hooks dissenting.

484 (July 17, 1972); "Press Wireless, Inc.," 21 FCC 311; 511 (1956); aff'd. 264 F. 28 372 (D.C. Cir. 1959). Moreover, subsequent to our final report and order and the filing of the petitions for reconsideration, the U.S. Court of Appeals for the District of Columbia has summarized the powers and duties of regulatory agencies to reject tariffs in the following language:

> We recognize, however, that an agency has the power and in some cases the duty to reject a tariff that is demonstrably unlawful on its face. Thus, an agency will reject a tariff that conflicts with a statute, agency regulation or order, or with a rate fixed in a contract sanctioned by statutes; similarly, a tariff will be rejected if it is unlawful without prior agency approval, and approval has not been obtained." "The Associated Press v. FCC et al.," 448 F. 2d 1095 (1971) (D.C. Cir.).

5. In connection with the above-stated language of the court, it is to be noted that we have never construed the provisions of section 203(d) as limiting the Commission's powers of rejection solely to tariffs that fail to give notice of their effective date. Rules relating to the filing of tariffs have been in effect during almost the entire period the Commission has existed. These rules, now incorporated as Part 61 of the Commission's rules, set forth numerous requirements with respect to tariffs in addition to notice of effective date. Failure to comply with these rules has always been recognized as grounds for rejection. Petitioners have not heretofore challenged the power of the Commission to reject a tariff which fails substantially to comply with rules governing such minor matters as letters of transmittal, number of copies, prepaid postage, erasures, alterations, etc., none of which is expressly mentioned in section 203(d) of the Act as grounds for rejection. In light of all of the foregoing, we cannot accept as valid a challenge to the authority of the Commission to reject a tariff which is in patent violation of any of the provisions of Part 61 of the rules. Accordingly, we reiterate our position, for the reasons set forth above and in paragraphs 47 through 52 of our final report and order that we have ample authority to reject a tariff for failure to comply with these rules (see 25 FCC 2d 957; 973–975).

6. Fears are expressed in the petitions to the effect that the Commission will exercise power arbitrarily in the rejection of tariffs. In the more than 2 years that the rules have been effective, out of many thousands of filings made, there have been but few rejections based upon failure to comply with our rules. Section 61.69(c) states that failure to comply with our rules constitutes "grounds" for rejection. However, the rule does not mandate that we reject all tariffs that do not comply fully with our rules. Section 61.69(c) means that tariff filings are subject to the exercise of reasonable judgment in implementing the rejection provisions. As the record shows, we have not invoked this power lightly, frequently, or in an arbitrary fashion. Thus, we reject the contention that we will abuse our discretion in exercising our authority to reject tariffs for rule violation. Furthermore, in the light of the experience since the rules became effective, we must reject as unfounded in fact the allegations that retention of our rules will invite incessant petitions for rejections by the public or protracted court tests of every significant filing not rejected.

7. We have dealt fully with the second legal argument challenging the validity of the 60 days' notice requirement for rate increases and data in support thereof, in paragraphs 37 through 43 of our Final Decision and Order (See, 25 FCC 2d 957; paragraphs 969–971). We note that no arguments of any significance in addition to those already considered have been made on this point. Accordingly, we reaffirm our conclusion that we have ample authority under sections 4(i), 4(j), and 203(b) of the Act to require the submission of tariffs and data in support of proposed increases 60 days in advance of the effective date of such increases.

8. As to the third and final legal issue raised, i.e., the power of this Commission under section 204 to require submission of detailed supporting data in connection with new or changed tariff material (not involving a rate increase), we believe that petitioners have misconstrued the effect of section 204 and have misunderstood both the purpose and effect of our rule (§ 61.38) and the legal authority upon which it rests. Petitioners first premise their argument on the contention that section 204 sets forth the one and only situation under which carriers have any burden of proof in any proceeding involving questions of lawfulness of their tariffs, i.e., only at hearings involving a charge increased or sought to be increased. For reasons which we shall state, we disagree with this basic contention.

9. Section 204, enacted in 1934, does not say, as the petitioners appear to contend, that it is only in cases of increased rates that a carrier has any burden of proof.[1] Subsequent to the passage of section 204, the Administrative Procedure Act was enacted with the provision that "Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. 556(d) Thus, it would appear clear that in any tariff proceeding in which the carrier seeks a rule or order from the Commission approving or prescribing a charge, regulation, classification, or practice the carrier would have the burden of proof irrespective of whether increased rates are being sought. In addition, we have repeatedly held that the burden of proof is on the carrier in tariff proceedings (where increased rates are not being sought) involving questions of lawfulness of "like and contemporaneous communication service between the same points at different charges to different users." "Private Line Rate Case," 34 FCC 217, at page 317 (1961); "Telpak Case," 38 FCC 370, 381–382 (1964); "Telpak Sharing Case," 23 FCC 2d 606, at page 625 (1970). On review of our Telpak decisions, the U.S. Court of Appeals for the District of Columbia Court affirmed our decisions including our holding therein on burden of proof in the aforementioned types of cases. "American Trucking Association, Inc. v. FCC," 126 U.S. App. D.C., 236, 377 F.2d 121 (1966), cert. denied, 386 U.S. 943 (1947). Accordingly, we reject the basic contention made herein that carriers have the burden of proof in tariff or rate proceedings only where increased rates are being sought.

10. Furthermore, it is our view that questions of burden of proof in rulemaking cases involving the lawfulness of tariffs are largely academic. Under our procedural rules carriers are required to open and close in such cases and, irrespective of where the the burden of proof lies, we must make our decision on the basis of reliable, probative, and substantial evidence of record whether adduced by the carriers or other parties. Additionally, contrary to the contentions, we do not view the requirements in our tariff rules for the submission of data to support new or changed tariffs, as having any effect whatsoever on whether or to what extent a carrier may have the burden of proof in any rate or tariff proceeding. In this respect petitioners misconstrue the purpose and effect of our rules. As the reviewing court held in "The Associated Press case, supra, the purpose of our rules is "to provide the Commission with the information necessary to decide whether an investigation and suspension of proposed rates should be ordered" and referred to the decision by the U.S. Supreme Court in "American Farm Lines v. Black Ball Freight Service," 397 U.S. 532 (1970), holding that similar rules of the Interstate Commerce Commission are "mere aids to the exercise of the agency's independent discretion." Thus, the purpose and effect of our rules in this regard is not to impose new burdens of proof on carriers but is to provide us with information by which, in the reasonable exercise of our discretion, we can determine the orderly and proper procedures to follow in the solution of the difficult and complex problems increasingly presented in tariffs filed with us by the carriers. In short, the purpose of the rules is to elicit information and data which will facilitate the Commission's judgment as to whether such proposed tariffs present questions of lawfulness which warrant our investigation and hearing.

POLICY OBJECTIONS

11. We have also given careful consideration to the aforementioned policy objections raised by petitioners and it is our conclusion that such objections do not warrant any revisions in our final decision or any substantive changes in our rules. Although extended discussion of such objections is not warranted, it

[1] The relevant provisions states that: "At any hearing involving a charge increased or sought to be increased, after the organization of the Commission, the burden of proof to show the increased charge, or proposed increased charge, is just and reasonable shall be upon the carriers * * *" 47 U.S.C. 204.

may be useful to touch briefly upon the principal reasons for our conclusion.

12. We recognize that, in competitive situations, the requirement of our rules that a carrier must submit cost and other data to support new or revised competitive tariffs may make it necessary for such carrier to make public certain information about its operations that it would not ordinarily want to reveal to its competitors. However, disclosures of this nature are inherent characteristics of the regulatory requirements imposed by the Communications Act on carriers subject to our jurisdiction. Carriers must, for example, make public their prices through tariffs filed with us and they must adhere to such prices until changed on proper advance public notice; and, with certain limited exceptions, carriers' contracts, agreements, arrangements, statistics, tables, and figures contained in annual and other reports filed with the Commission must be made public. 47 U.S.C. 412. Moreover, carriers have the obligation under the Act to supply such information as the Commission may need to enable it to carry out its regulatory duties. 47 U.S.C. 218, 219. Our own recent experience under these rules, has been that the submission by carriers of the required cost and other data to support competitive tariff filings has been helpful to us in determining the most orderly and effective regulatory steps to be taken and procedures to be followed in administering the Communications Act and implementing our policy and objective thereunder of maintaining such competition on a full and fair basis. (See e.g., proceedings in Dockets 18684, 19129, 19419, and 19546.) We have found that it is particularly important to obtain the data required by our rules where questions are raised as to whether a new or reduced rate competitive service is being cross-subsidized by other services and whether there is factual support for allegations of anticompetitive impact from such rates. Thus, the value of our rules as a regulatory tool in the public interest far outweigh any supposed detriment to the private interests of carriers who desire to keep such data from their competition. Moreover, petitioners have made no persuasive showing that, as a general rule, the submission of the kind of data we require will, in fact, reveal sensitive data that actually affords competitors any advantage over the filing carrier in the marketplace.

13. Much concern was expressed in the petitions that our rules seem to place too heavy reliance on cost data to the exclusion of other considerations (e.g., value of service) which allegedly may also support proposed rates, particularly competitive rates. However, our requirement for the submission of cost data does not mean that we intend to consider only cost as support for tariff filings, to the exclusion of other factors or principles. On the other hand, the carriers themselves generally stress that their revenues must exceed their costs, and our established regulatory policies are to regard costs either as directly controlling in the fixing of rates or as benchmarks from which to measure any departures, from costs with a clear and persuasive showing required for such departures. "Private Line Rate Case," 34 FCC 217, at page 231 (1963). Subject to the foregoing, carriers are free to submit any data they wish, in addition to cost, to support their tariff filings and appropriate consideration will be given thereto.

14. With respect to our requirement that the carriers furnish 3-year estimates with respect to the effects of new or changed tariff provisions on the carriers' traffic and revenues, it is true that no carrier can foretell with complete accuracy what will happen over a future 3-year period, particularly in a field as dynamic as interstate and foreign communications. On the other hand, it appears to us that responsible management would not ordinarily undertake to make new or revised service or rate offerings unless and until it has surveyed the potential market and made some assessment of what it may expect will be the results of such offering. Under these circumstances we find it reasonable to have a general rule, subject to waiver in appropriate cases, that the Commission be furnished with such projections to assist it in discharging its statutory duties.

15. With respect to the advisability of adopting a new rule which would allow the carriers to cure or rectify deficiencies in their filings, before rejection, we believe that such a rule would unreasonably inhibit the ability of the Commission to take on its own motion or in response to pleadings filed by the public, prompt and effective action to prevent patently defective tariffs from becoming effective. Moreover, any rejection of tariffs for violation of our tariff rules is always without prejudice to the prompt refiling by the carrier of appropriate revisions in full compliance with the rules.

16. As to the contention that the data required by the Commission's rules should be limited to data that would be reasonably needed by the Commission to understand and evaluate tariff filings, we believe that our rules do just that and no more. The data required by § 61.38 is the minimum which we believe is required for us to make necessary decisions with respect to most, if not all, tariff filings that are subject thereto.

17. As to the argument that a de minimis exemption should exist for certain kinds or levels of tariff filings and that a need exists for expanding or increasing the categories of items exempted from the requirements of the rules, we dealt fully with this matter in paragraph 26 of our final decision. Experience gained since the effective date of our rules indicates that there has been no great difficulty on the part of most carriers in complying with the requirements of our rules. Accordingly, we do not believe that we should revise our rules to allow for any further exemption at this time. With regard to the possibility of exemptions for so-called "routine" tariff changes, we indicated in paragraph 26 of our final decision that if it becomes apparent after experience has been gained that certain types of routine changes do not require all or part of the support required by our rules, then waiver of the rules would be granted or new rules would be promulgated. Based on our experience we believe that we should continue to handle any such "routine" exemptions by waivers made upon specific application by the carriers rather than by any rule changes at this time.

18. The contentions that the diverse requirements of the various kinds of carriers dictate different application of the rules as to each class of carriers are not sufficiently supported by probative factual data for us to conclude that any significant benefit would accrue to the carriers or to the public by making this kind of revision in our rules. It may be true that one class of carriers may have problem areas that other classes do not have, but we do not believe that any undue burden is placed upon any particular class of carriers under the rules as they now stand. In those instances where the carrier can make a reasonable demonstration that our rules as written cause undue burden or are not relevant to the rate schedule submitted, we will, of course, grant a waiver upon specific application therefor as provided for in the rules. If experience shows in the future that changes are necessary to accommodate the needs of different classes of carriers, we will entertain specific proposed amendments with respect thereto.

19. Although we have concluded that no changes should be made at this time in the rules under review, we currently have under consideration further possible changes therein. These prospective changes relate to the notice requirements for tariffs offering new or revised classes and subclasses of service.[3] At the time of any such proposed rulemaking, we expect to give consideration to any additional changes that interested parties may wish to propose in the light of further experience under the rules. However, there is one procedural rule change that we believe should be effectuated at this time.

20. The 14-day time period now permitted by § 1.773(b) for filing petitions to suspend tariffs may be appropriate for tariffs that are filed on approximately 30 days' notice and we propose no change therein. However, our rules now require carriers to file tariffs which constitute rate increases on at least 60 days', rather than 30 days' notice (§ 6158). As to such 60-day notice filings, we believe that petitions to suspend should be filed with the Commission and served upon the publishing carrier and the Chief, Common Carrier Bureau, substantially earlier than is now permitted under the 14-day rule. At present, interested parties have approximately 16 days after a 30-day tariff is filed within which to prepare and submit any petitions to suspend. We believe that for tariffs that are filed on 60 days' notice we should modify the filing requirements so as to afford the

[3] See report and order adopted Jan. 31, 1973, in Docket No. 19117, FCC 73-132; 39 FCC 2d 131.

Commission adequate time to consider protests without imposing undue time constraints on potential protesters. It appears to us that in these instances, it is reasonable to require any petitions to suspend to be filed within approximately 25 days after the tariff is filed. This would afford interested parties 9 days more than they now have to file objections to 30-day tariffs and would allow us adequate time to consider objections and timely filed responses. Accordingly, we shall require such petitions to be filed at least 35 days prior to the effective date of any 60-day tariff filing. This amendment to our rules is set forth below. Authority for this amendment is contained in sections 4(i), 4(j), and 203(b) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), and 203(b). Because this amendment relates to procedure and practice, the prior notice and effective date provisions of 5 U.S.C. 553 are inapplicable.

21. *Accordingly, it is ordered,* That the petitions for reconsideration are denied, and that § 1.773(b) of our rules is amended, effective April 3, 1973, as set forth below. *It is further ordered,* That this proceeding is terminated.

(Secs. 4, 203, 48 Stat., as amended 1066, 1070; 47 U.S.C. 154, 203)

Adopted: March 21, 1973.

Released: March 27, 1973.

FEDERAL COMMUNICATIONS COMMISSION,[1]

[SEAL] BEN F. WAPLE, *Secretary.*

In Part 1 of Chapter 1 of Title 47 of the Code of Federal Regulations, § 1.773 (b) is revised to read as follows:

§ 1.773 Petitions for suspension of tariff schedules.

* * * * *

(b) *When filed.* Any petition for suspension shall be filed with the Commission and served upon the publishing carrier and the Chief, Common Carrier Bureau, and the Chief of the appropriate Division of that Bureau at least 14 days before the effective date of the tariff schedule, except in those cases in which the tariff schedule in question is filed on 60, or more, days' notice to the public prior to the effective date thereof. In the latter cases, a petition for suspension shall be filed with the Commission and served upon the publishing carrier, the Chief, Common Carrier Bureau, and the Chief of the appropriate Division of that Bureau at least 35 days before the effective date of the tariff schedule. In case of emergency and within the time limits provided herein, a telegraphic request for suspension may be sent to the Commission setting forth succinctly the substance of the matters required by paragraph (a) of this section. A copy of any such telegraphic request shall be sent simultaneously to the publishing carrier and the Chief, Common Carrier Bureau, and the Chief of the appropriate Division of that Bureau and forthwith confirmed by petition filed and served in accordance with this section. (Sec. 1.4 does not apply to this § 1.773(b).)

* * * * *

[FR Doc.73-6138 Filed 3-29-73;8:45 am]

[1] Commissioners Burch, Chairman; Reid and Wiley concurring in the result; Commissioner Johnson dissenting.

[Docket No. 19617; FCC 73-324]

PART 73—RADIO BROADCAST SERVICES

Television Stations in Nashville, Tenn.

Report and order. In the matter of amendment of § 73.606(b), *table of assignments,* Television Broadcast Stations (Nashville, Tenn.), Docket No. 19617, RM-1944.

1. We here consider the rulemaking to amend the Television Table of Assignments (§ 73.606(b) of the Commission's rules and regulations) to change the educational noncommercial reservation from Channel 2 to Channel 8 at Nashville, Tenn., and to simultaneously modify the licenses of WSIX-TV (now Channel 8) and WDCN-TV (now Channel *2). This proceeding was instituted by a joint petition of the General Electric Broadcasting Co., Inc. (General Electric), and the Metropolitan Board of Education (the "Board"), the respective licensees of these stations. A notice of proposed rulemaking was adopted October 18, 1972 (FCC 72-945). (See 37 FR 22991.) Timely comments were filed separately by the two petitioners supporting the rulemaking proposal. South Central Broadcasting Corp., licensee of television Station WTVK, Channel 26 at Knoxville, Tenn., and Mr. Ben Lewis, TAVC Co., Inc., Nashville, Tenn., submitted comments by letter. WDXR-TV, Inc. (WDXR), licensee of UHF television Station WDXR-TV, Channel 29, Paducah, Ky., filed its opposition to the notice of proposed rulemaking. Reply comments were filed by General Electric and the Board directed to the WDXR opposition. WDXR also filed reply comments directed to comments of both General Electric and the Board.

2. The notice was adopted by the Commission so that it might explore the proposal of the petitioners, particularly the claim that its adoption would bring significant improvement and enlargement of the educational television service in the Nashville metropolitan area; immediate financial assistance for the improvement of educational telecasting including the establishment of color television and continuing support for an educational operation which has been "chronically underfinanced." General Electric also claimed that the requested changes would enlarge the service area of WSIX-TV and make the operation of that station and the ABC Television Network, with which it is affiliated, fully competitive with the low band VHF operations of the competing NBC and CBS affiliates.

3. The engineering aspects of the proposed substitution of channels has been addressed by all parties of interest. The Board submits that the Grade A service they would obtain by moving to Channel 8 would be greatly improved and that the Grade B service would be improved but to a lesser degree. Operating on Channel 2 the area within the proposed Grade A service for General Electric would be somewhat reduced but there would be a gain in the area encompassed by the Grade B contour. One engineering report included with the petition provides area figures for both grades of service on both channels based upon the standards set forth in Report R-6602 (a joint FCC/Industry method not yet incorporated in our rules.) Although these figures show a lessened coverage area, they parallel the current rules in showing the relative potential for channels. The proponents assert that the shadowing effect on Channel 8 is greater than that on Channel 2 so if General Electric operated on Channel 2 it could only render more effective service in hilly areas surrounding Nashville. The population and area figures for both the present and proposed services are not significantly different than they would be if new facilities were to be installed and the licensees remained on their present channels.

4. The terms of the agreement between the Board and General Electric provide that the present WSIX-TV transmitter and associated equipment required for transmission on Channel 8 would be installed by and at the expense of General Electric. A new antenna and transmission line would be supplied by General Electric and installed on a heavy duty tower on which General Electric would also install its new antenna. Alternatively the Board would be given $107,000 in cash. General Electric also agrees to provide antenna terminal equipment or $18,000, microwave links or $25,000, transmitter terminal equipment or $15,000, two color cameras, film chain and projector, multiplexer, one color video tape recorder and all terminal equipment or $410,000, for a total cash consideration equivalent of $575,000.

5. In addition to the foregoing equipment or cash offered to the Board, General Electric would construct a heavy duty tower upon which to mount the Channel 2 and Channel 8 antenna and all other equipment necessary to the operation of WDCN-TV. Tower space and space for a main and auxiliary transmitter would be leased to the Board for 99 years at $1 per year. General Electric also agrees to operate and maintain the transmitting and other equipment for a period of 99 years at no cost to the Board and within 5 years from the date of the Commission's final orders to install a new transmitter for Channel 8 or at the Board's option pay the Board $180,000 cash. In turn, the Board agrees to assign its present transmitter and associated equipment plus antenna and transmission line to General Electric which would absorb the expenses involved in moving the equipment. The agreement contains a host of other details relating to items such as warranties, guarantees, indemnity, closing, etc., none of which are pertinent here.

6. The proponents submitted a report on the estimated financial gain to WSIX-TV resulting from its proposed move to

Channel 2. This report (dated November 1970) provided estimates based on three assumed heights above average terrain, but no change in height is involved in the channel exchange here proposed. Consequently, we do not need to consider this matter further.

7. Upon invitation by the Board, WLAC–TV, Inc., Channel 5, Nashville submitted comments on the proposed channel exchange. WLAC suggests that consideration be given to a study with regard to the Channel 8 site location of WDCN so to permit it to provide a greater degree of service as part of the statewide system of educational stations. WLAC also discusses the economic considerations of the channel exchange, pointing out that the offer of equipment, (the) location on a tall tower and transmitter operation for a period of years in itself recognizes that there is considerable value to be gained on Channel 2 as opposed to operating on Channel 8. In the total scheme of things, states WLAC, this is a relatively small, temporary one-time funding, affecting only the plant and equipment and which in no way solves the real heart of the problem, adequate, permanent funding of the station's operation so as to bring maximum educational service to the public. WLAC feels there would be a material loss to the educational effort by the proposed exchange of channels.

8. WDXR–TV, Inc., licensee of independent UHF Station WDXR–TV, Channel 29, Paducah, Ky., opposed the proposed channel exchange. The thrust of WDXR–TV's opposition is directed to the overlap of its Grade B contour by the Grade B contour of WSIX–TV operating on Channel 2 at 1,349 feet HAAT as proposed, at 1,850 feet HAAT as discussed in the estimated financial gain of WSIX–TV and at 2,000 feet HAAT the maximum height permitted by FCC rules. As mentioned in paragraph 6, these matters would warrant consideration only when such a proposal were before us. Overlap of 192 square miles, 555 square miles, and 735 square miles with 3,140, 14,848, and 23,437 persons respectively it is said, would result. WDXR–TV further states that overlap would occur with Grade B contours of six other commercial UHF stations.[1] WDXR–TV also provides a map showing the overlap of WDCN–TV's Grade B contour by nine educational stations, five of which are in Kentucky, three in Tennessee, and two in Alabama. The Grade B contours of six of the nine stations overlap the present Grade B contour of WDCN–TV. WDXR–TV avers that these educational stations essentially surround the existing WDCN–TV coverage area and leave no significant area which will be filled by improved coverage from WDCN–TV. WDXR–TV asserts that the Commission has refused to exchange high-band and low-band VHF channels in circumstances where there were demonstrable advantages such as the improvement of service and coverage, and it cites the comments of WDCN–TV's consulting engineers to the effect that each channel has an advantage but on balance are equivalent.

9. Reply comments by General Electric concede the equivalence of the two channels and acknowledges that the competitive advantage conceived for the operation of WSIX–TV is slight, long range and debatable. When balanced against the financial undertakings of General Electric to improve the operation of WDCN–TV it contends that the advantage altogether disappears for some very considerable period of time, if not forever. General Electric asserts that WDCN–TV now operates a significantly substandard station; that its signal is poor and restricted; that its origination capacity is limited and its service suffers accordingly. General Electric submits that its proposed offer would solve each of these problems immediately, giving the public an excellent service and placing WDCN–TV in a far better position to find additional long range solutions to its funding problems. Thus, it is said, would enable WDCN–TV to improve its service to the public undistracted by at least some of the financial and technical limitations now characterizing its operation. Engineering data is provided by General Electric in an effort to show that WDXR–TV's overlap figures are not correct, and to show that taking into account cochannel interference to the WSIX–TV Grade B contour, the interference-free overlap area contains only 157 persons. This is based on the proposed height above average terrain of 1,349 feet and used the method specified in the present FCC rules.

10. Reply comments by the Board contend that an overlap involving 157 persons is de minimis and that WDXR–TV has failed to come forward with the barest prima facie case of economic impact. In answer to WDXR–TV's statement that there is no need for improved educational coverage, the Board states that the channel exchange will provide a first Tennessee educational service to an in-State area of 1,950 square miles with an approximate population of 85,000. The exchange would not only enlarge WDCN–TV's Grade B coverage but also its Grade A coverage from 2,855 square miles containing 608,103 persons to 7,716 square miles with 880,391 persons. According to a survey submitted by the Board, WDCN–TV's, signal quality was noticeably inferior to WSIX–TV's signal. The Board expects the exchange and the improvement in WDCN–TV's facilities which would result to correct this problem.

11. In its reply comments, WDXR–TV states that approval of the proposed channel exchange would create a bad precedent and disputes WDCN–TV's claims of "unique facts" since there are numerous television markets with a low band educational allocation and a high band commercial allocation each of which is a candidate for a similar proposal for exchange.

12. One of the two letters received in comment contains an objection to the exchange proposal if there is a reduction in the service of the ETV station. The other letter from Station WTVK Channel 26, Knoxville, Tenn., outlines that station's history as a pioneer UHF station, supports the exchange of channels and gives notice of its intention to again apply for the use of Channel 8 in Knoxville with the expressed hope that the Commission will be prepared to demonstrate the same reasonableness and flexibility with respect to their request for help.[2]

Conclusions

13. The situation here presented is in many respects similar to that found in the exchange of channels in New Orleans, La., where the Commission authorized the ETV reservation on Channel 8 to be changed to Channel 12. In other respects the conditions differ. The ETV station in New Orleans on Channel 8 was underfinanced, poorly located, did not have color equipment and was experiencing delays in expansion. The exchange in channels provided immediate financial relief and an improved broadcasting facility serving a greater area and population with the capability to broadcast in color. Technically the exchange of channels in New Orleans involved two channels in the VHF high band whereas the exchange of channels in Nashville involves one channel in the low VHF band and one in the high VHF band. With equal antenna-power facilities the high-band exchange would have no effect on coverage as determined by the methods contained in the Commission's rules. In low band/high band exchange assuming equivalent antenna height and power a form of trade off would result. To compensate for the advantages inherent in signal propagation on the lower channels, the Commission permits higher channel operations to utilize power more than three times that permitted on the lower channels. The intention was to make the channels, high and low, essentially equivalent. Each, however, has its advantages and disadvantages. The low band user gains in the Grade B service which is slightly extended and the high band user because of higher power, in Grade A service area. In the Nashville case, the educational operation would benefit by a considerable improvement in picture quality in the densely populated area within the Grade A service area. In this instance it would considerably increase Grade B service operating on Channel 8 simply because of the increased height of the antenna. An increase in Grade B service area could also be accomplished on Channel 2 through the same means if it had funds available for the purpose. It has not been our policy to sanction exchanges between high band and low band television channels. Thus,

[1] WRIP–TV, Channel 61, Chattanooga, Tenn.; WOWL–TV, Channel 15, Florence, Ala.; WHNT–TV, Huntsville, Ala.; WAAY–TV, Channel 31, Huntsville, Ala.; WMSL–TV, Channel 48, Huntsville, Ala., and WEHT, Channel 25, Evansville, Ind.

[2] We express no view in this regard since no such proposal is before us.

in the matter of amending § 73.606 to substitute Channel 2 for Channel 11 in Fort Worth, Tex., the Commission held that its general allocation policy of not changing individual assignments on the basis of claims of superior performance of one VHF channel over another would not be departed from except on a showing of exceptional circumstances. The Commission continues in its adherence to this policy. However, in this particular instance we are of the view that such exceptional circumstances do exist. In part these circumstances relate to the benefits which would flow to the Metropolitan Board of Education of Nashville and to the public it serves. WDCN–TV's service area would be enlarged (on Channel 8) by virtue of an increase in antenna height. While this same enlargement in service area could be achieved on Channel 2, funds for this purpose have not become available. At essentially no cost to it the Board would be able to improve its signal and correct current reception problems as well as reach a sizable additional in-State audience. WDCN–TV's ability to provide better and more flexible local programing would be greatly enhanced by the addition of improved studio equipment which will include new color cameras and a video tape recorder. WDCN–TV's picture quality will be measurably improved and its operating costs will be substantially reduced. It is reasonable to expect that these benefits would give immediate financial relief to WDCN–TV, thereby enabling it to concentrate its efforts toward a better educational and instructional service to the public not only of Nashville but to the midsection of Tennessee as a part of the State educational system. While it could be argued that these benefits are only short term, the fact remains that without these benefits WDCN–TV could continue for years as an underfinanced operation incapable of attracting financial assistance because of an inferior service.

14. Although General Electric has agreed to pay a substantial amount to the Board, this does not establish that in nonmonetary terms the Board or the public has lost. General Electric's advantage (and hence its willingness to compensate the Board) flows from the gain in Grade B coverage on Channel 2. State boundaries are of no moment to General Electric but the area servable by Channel 2 but not 8 lies in good measure outside Tennessee. Thus the Board has little need for this extension of coverage, for which it has no funds of its own in any event. Because of the coverage gain made possible by the exchange, the Board would much extend its coverage where it is needed, instate, as part of the statewide system. While high and low band VHF channels are equivalent, there are differences between them and the most effective utilization of them both is furthered by this proposal. In the Texas case cited earlier, such was not the case and the petitioner there simply preferred the low band channel because of the slightly larger Grade B coverage it would have provided. To accept this would have brought endless channel changes wherever the situation arose but our action here will have no such effect.

15. Concern about UHF impact has been expressed but the showings do not suggest that a real problem exists on this score. Using the present curves,[3] the overlap by General Electric's of WDXR–TV's Grade B contour would affect only 3,140 persons in the interference-free areas of both stations. The impact of such overlap, occurring at the periphery of WDXR–TV's Grade B contour, is clearly minimal. As such it poses no impediment to favorable action on this proposal.[4] Slight increases in overlap to five other stations has not caused them great concern nor does it us. The effects, if not miniscule, appear minor. In terms of increase in coverage by the educational station, contrary to one of the arguments, it comes in significant part in just those areas where it is needed. A first Tennessee educational service would be extended greatly and the presence of out-of-State educational signals is of highly limited importance. In sum, we find that the proposal before us is meritorious and it shall be ordered into effect.

16. In view of the foregoing, *It is ordered*, That, effective May 3, 1973, pursuant to authority contained in sections 4(i), 303, and 307(b) of the Communications Act of 1934, as amended, the Television Table of Assignments (§ 73.606 (b) of the Commission's rules and regulations) is amended to read as follows for the community indicated:

City	*Channel No.*
Nashville, Tenn.	2−, 4+, 5, *8+, 17, 30, *42

17. *It is further ordered*, That, effective May 3, 1973, and pursuant to section 316 (a) of the Communications Act of 1934, as amended, the outstanding license held by the Metropolitan Board of Education for Station WDCN–TV, Nashville, Tenn., is modified to specify operation on Channel *8 in lieu of Channel *2 subject to the following conditions:

(a) The licensee shall inform the Commission in writing no later than April 19, 1973, of its acceptance of this modification.

(b) The licensee shall submit to the Commission by June 4, 1973, all necessary information complying with the applicable technical rules for modification of authorization to cover the operation of Station WDCN–TV on Channel *8 at Nashville, Tenn., with the facilities specified in its "Petition for Rulemaking and the Issuance of Modified Authorization," filed jointly with the General Electric Broadcasting Co., Inc., in this proceeding.

(c) The licensee may continue to operate on Channel 2 under its outstanding authorization until it is ready to operate on the new frequency. Ten days prior to commencing operation on Channel *8, the licensee shall submit the same measurement data normally required in an application for a television broadcast station license.

(d) The Metropolitan Board of Education shall not commence operation on Channel *8 until the Commission specifically authorizes it to do so.

18. *It is further ordered*, That, effective May 3, 1973, and pursuant to section 316(a) of the Communications Act of 1934, as amended, the outstanding license held by the General Electric Broadcasting Co., Inc., for Station WSIX–TV, Nashville, Tenn., is modified to specify operation on Channel 2 in lieu of Channel 8 subject to the following conditions:

(a) The licensee shall inform the Commission in writing no later than April 19, 1973, of its acceptance of this modification.

(b) The licensee shall submit to the Commission by June 4, 1973, all necessary information complying with the applicable technical rules for modification of authorization to cover the operation of Station WSIX–TV on Channel 2 at Nashville, Tenn., with the facilities specified in its "Petition for Rulemaking and the Issuance of Modified Authorization," filed jointly with the Metropolitan Board of Education, in this proceeding.

(c) The licensee may continue to operate on Channel 8 under its outstanding authorization until it is ready to operate on the new frequency. Ten days prior to commencing operation on Channel 2, the licensee shall submit the same measurement data normally required in an application for a television broadcast station license.

(d) The General Electric Broadcasting Co., Inc., shall not commence operation on Channel 2 until the Commission specifically authorizes it to do so.

19. *It is further ordered*, That, the change to operation on Channel 8 by Station WDCN–TV, and to operation on Channel 2 by Station WSIX–TV, with the facilities specified in the aforementioned petition, shall be effected simultaneously, or, if not effected simultaneously, shall be effected by one station only if the other station has gone off the air for a period prior to changing frequency pursuant to Commission authorization.

20. *It is further ordered*, That, the opposition pleading filed herein is denied.

21. *It is further ordered*, That, this proceeding is terminated.

(Secs. 4, 303, 307, 48 Stat., as amended, 1066, 1082, 1083; 47 U.S.C. 154, 303, 307)

Adopted: March 21, 1973.

Released: March 27, 1973.

FEDERAL COMMUNICATIONS COMMISSION,[5]

[SEAL] BEN F. WAPLE, *Secretary.*

[FR Doc.73–6137 Filed 3–29–73;8:45 am]

[3] Using those curves in R–6603, there would be no overlap with WDXR–TV at all.

[4] It has not been our practice to utilize the concept of an interference-free contour in resolving cases of alleged UHF impact. We therefor have not based our decision on the figure of 157 mentioned by General Electric, nor, as indicated above, need we.

[5] Commissioner Robert E. Lee dissenting and issuing a statement, which is filed as part of the original copy; Commissioner Johnson dissenting; Commissioner H. Rex Lee concurring in the result.

Title 50—Wildlife and Fisheries

CHAPTER II—NATIONAL MARINE FISHERIES SERVICE, NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION, DEPARTMENT OF COMMERCE

PART 262—U.S. STANDARDS FOR GRADES OF FROZEN RAW BREADED SHRIMP

Miscellaneous Amendments

MARCH 26, 1973.

In the September 7, 1972, issue of the FEDERAL REGISTER, a notice was published by the National Marine Fisheries Service to amend Title 50, CFR, Part 262—U.S. Standards for Grades of Frozen Raw Breaded Shrimp, pursuant to the authority vested in the Secretary of Commerce by Reorganization Plan No. 4 effective October 3, 1970 (35 FR 15627), and under the authority of Title II of the Agriculture Marketing Act of 1946, as amended (7 U.S.C. 1622 and 1624), transferred from the Department of the Interior to the Department of Commerce.

The purposes of the proposed amendments are: (1) To extend the standard to cover an additional style and sizes; (2) to include an optional alternate method for determining shrimp material; and (3) to allow for compliance to be determined during processing.

Interested persons were provided an opportunity to submit written comments in regard to the proposed amendments and three comments were received and considered.

One comment indicated that a proposed new style, designated as "Breaded Split Shrimp", would require amendment of the standard of identity for raw breaded shrimp, 21 CFR 36.0 and 21 CFR 36.1, to accommodate the product identity and designation for the new style. Accordingly, that product style and designation has been recognized but reserved.

Other comments questioned the limitation of loose breading and frost in the package on the basis of "Good Manufacturing Practice", and inclusion of such loose breading and frost as a part of the quantity of contents of the package. Examination of test results over the past several months revealed that no significant amount of loose breading and frost has been found in commercial samples of the packaged product. Thus no change has been made in the standard in respect to loose breading and frost.

Another comment dealt with a proposed change in the product description requiring that the shrimp be "deveined only where applicable", and defining "where applicable" as all shrimp larger than 70 count per pound in the raw headless state. The product description section of the standard requires that the shrimp be cleaned and peeled. Since the commercial process of peeling very small shrimp also results in a thorough cleaning and deveining of the shrimp, no change has been made in respect to deveining small shrimp, i.e., over 70 count per pound.

No changes, other than deletion of the text of § 262.2(c), have been made in the amendments to the standard as given below in respect to the proposed amendments.

The amendments to Part 262—U.S. Standards for Grades of Frozen Raw Breaded Shrimp follow:

Section 262.1 is amended as follows:

§ 262.1 Product description.

Frozen raw breaded shrimp are whole, clean, wholesome, headless, peeled shrimp which have been deveined where applicable of the regular commercial species, coated with a wholesome, suitable batter and/or breading. Whole shrimp consist of five or more segments of unmutilated shrimp flesh. They are prepared and frozen in accordance with good manufacturing practice and are maintained at temperatures necessary for the preservation of the product. Individual shrimp and/or pieces consolidated into larger units and covered with breading are not considered for grading under this standard.

A new § 262.2 *Composition of the product* is added as follows:

§ 262.2 Composition of the product.

(a) Frozen raw breaded shrimp shall contain not less than 50 percent by weight of shrimp material when the weight of the shrimp material is determined by the end product method as set forth in § 262.21(u).

(b) Shrimp material content of raw breaded shrimp may be determined by the on-line method as set forth in § 261.21(v): *Provided*, That the results are at least in compliance with the shrimp material content requirement of 50 percent by weight when verified by the official end product method.

(c) Production methods employed in official establishments shall be kept relatively constant for each product lot so as to minimize variations in any factor which may affect the relative shrimp material content.

Section 262.2 is redesignated as follows:

§ 262.3 Styles of frozen raw breaded shrimp.

Section 262.3 is redesignated and paragraph (c) is amended as follows:

§ 262.4 Types of frozen raw breaded shrimp.

* * * * *

(c) *Type III—Breaded split shrimp.* [Reserved]

Section 262.4 is redesignated as follows:

§ 262.5 Grades of frozen raw breaded shrimp.

Section 262.12 is amended as follows:

§ 262.12 Factors evaluated on the product in the breaded state.

(a) Factors affecting qualities that are measured on the product in the breaded state are uniformly of size, condition of coating, extraneous material, and damaged breaded shrimp. For the purpose of rating the factors that are scored in the breaded state, the schedule of point deduction in table 1 applies. This schedule of point deductions is based on the examination of one complete individual package or intended package (sample unit) regardless of the net weight of the contents of the package.

(b) The factor—ease of separation in the frozen state—shall be rated in addition to all other factors when frozen raw breaded shrimp is lot inspected on a lot basis.

Section 262.13 is amended as follows:

§ 262.13 Factors evaluated on unbreaded or thawed debreaded product.

Factors affecting qualities that are measured on the product in the unbreaded or thawed debreaded state are degree of deterioration, dehydrations, sand veins, black spot, extra shell, extraneous material, and swimmerets. For the purpose of rating the factors that are scored in the unbreaded or thawed debreaded state, the schedule of point deductions in table 2 applies. This schedule of point deductions is based on the examination of 20 whole shrimp selected from the processing line or from one or more packages. Examination of this sample of 20 whole shrimp is continued under § 262.21(u).

A new § 262.14 is added as follows:

§ 262.14 Hygienic processing.

Frozen raw breaded shrimp shall be processed and maintained in accordance with the applicable requirements of the Good Manufacturing Practice Regulations contained in Part 128 of Title 21, CFR, and the applicable requirements contained in Part 260 of this chapter.

§ 262.21 [Amended]

Section 262.21 is amended as follows:

a. Paragraph (s) is changed as follows:

(s) Net weight: Net weight is determined by use of a balance and by following steps given below:

b. Delete Step 7 and the paragraph following it and replace with a new Step 7.

7. Net weight of the shrimp is the weight of the shrimp and of any loose breading and frost, exclusive of packaging material. The amount of loose breading and frost shall not exceed the limits of good manufacturing practices.

c. Paragraphs (u) and (u)(2)(ii) are changed as follows:

(u) Percent shrimp material—official end product method:

(2) * * *

(ii) Calculate percent shrimp material.

$$\text{Percent shrimp material} = \frac{\text{Weight of debreaded sample (20 shrimp)}}{\text{Weight of sample (20 shrimp)}} \times 100 \div 2$$

(d) Paragraph (v) is redesignated as § 262.21(w) and a new paragraph (v) is added as follows:

(v) Percent shrimp material—on-line method: Percent shrimp material determined by the on-line method refers to the percent by weight of shrimp material in a sample as described below:

(1) Equipment needed:

(i) Water bath (a container with a 3- to 4-liter capacity).

(ii) Balance accurate to 0.1 gram or 0.01 ounce.

(iii) Stop-watch or regular watch readable to a second.

(iv) U.S. Standard sieve—½-inch sieve opening; 12-inch diameter.

(v) U.S. Standard sieve ASTM No. 20, 12-inch diameter.

(vi) Thermometer (immersion type accurate to ±2° F.).

(vii) Forceps, with blunt points.

(viii) Shallow pan.

(ix) Rubber policeman to remove bits of breading from shrimp.

(2) Procedure:

(i) Select in a random manner, a composite sample of 20 unfrozen raw breaded shrimp from production line(s). Weigh the composite sample on a scale, determining the weight of the sample to the nearest 0.1 gram or 0.01 ounce. Place the sample in a water bath filled to three-fourths capacity and in a container maintained at 60° F.–85° F. After shrimp are submerged in water and breading becomes soft, a "gentle" swirling action with hands may be applied to the shrimp to speed up the removal of the breading. Stack the sieves, the ½-inch mesh over the No. 20 and pour contents of container into them. Remove top sieve and drain on 45-degree angle for 2 minutes then transfer shrimp to balance. Rinse contents of No. 20 sieve onto a shallow pan and collect any particles of shrimp material (flesh, tail fin, etc.), and add to the shrimp on the balance and then weigh.

(ii) Calculate percent shrimp material:

$$\text{Percent shrimp material} = \frac{\text{Weight of debreaded sample}}{\text{Weight of sample}} \times 100$$

(iii) Frequency of on-line shrimp material content determination. A minimum of three determinations of shrimp material content shall be carried out for small production runs or lots of the same style product, i.e., 3 x (20 unfrozen raw breaded shrimp). For larger production runs or lots of the same style product, a minimum of one determination, i.e., 1 x (20 unfrozen raw breaded shrimp) shall be carried out for every hour of production of product of the same style.

A new § 262.22 is added as follows:

§ 262.22 Use of alternate methods of shrimp material determination.

(a) The official end product method in § 262.21(u) for determining shrimp material content shall be used for lot inspection, appeal inspection, and inspection for verification in official establishments when the on-line method is used.

(b) The on-line method in § 262.21(u)(2) for determining shrimp material content may be used during processing operations.

TABLE 1.—SCHEDULE OF POINT DEDUCTION FOR RATING IN FROZEN BREADED STATE

Delete the word "Frozen" from the title of Table 1.

Delete Factor 1. Loose breading or frost; and renumber remaining factors.

Add the words "in the frozen state" to renumbered Factor 1. Ease of separation.

TABLE 2.—SCHEDULE FOR POINT DEDUCTIONS FOR EXAMINATION IN THAWED, DEBREADED STATE DEDUCTIONS BASED ON 20 SHRIMP

Change the title of Table 2 to read as follows: Schedule for Point Deductions for Examination in Unbreaded or Thawed Debreaded State.

Change the designation of Factor 3 to read, "Sand veins where applicable." [1]

In the quality description of Factor 7. Extraneous material, change the footnote number from 1 to 2 and renumber footnote 1 to 2.

A new footnote 1 is added to Table 2 as follows:

[1] Deduction points for sand veins shall not be applied to shrimp smaller than 70 count per pound in the raw, headless state. The corresponding size in the breaded state is 40 count per pound and 80 count per pound in the peeled state.

The amendments to 50 CFR Part 262—U.S. Standards for Grades of Frozen Raw Breaded Shrimp shall become effective May 1, 1973, except that § 262.4(c) Type III—Breaded Split Shrimp, has been reserved and will be published and made effective after the Food and Drug Administration Standard of Identity for Raw Breaded Shrimp, 21 CFR 36.0 and 21 CFR 36.1 is amended to accommodate this product type and designation.

ROBERT M. WHITE,
Administrator.

[FR Doc.73-6060 Filed 3-29-73;8:45 am]

Title 32—National Defense

CHAPTER VII—DEPARTMENT OF THE AIR FORCE

SUBCHAPTER I—MILITARY PERSONNEL

PART 888b—ENLISTMENT IN THE AIR FORCE RESERVE

Correction

In FR Doc. 73-4484 appearing at page 6779 of the issue for Tuesday, March 13, 1973, the following changes should be made:

1. In the table in § 888b.16: (1) in Rule 1 the "×" under "Prior service" should be deleted; (2) in Rule 3 the footnote "2" under "Prior service" should be an "×"; and (3) in Rule 15, "or IV-For under orders" should read "IV-F or under orders".

2. In the table in § 888b.18, in Rule 3 under column B delete "(note 2)", which appears under "A U.S. citizen".

3. In § 888b.22, the paragraphs designated "aa", "bb", "cc", and "dd", should be designated "aa", "ab", "ac", and "ad" respectively.

PART 888f—SPECIFIED PERIOD OF TIME CONTRACT (SPTC)

Correction

In FR Doc. 73-4486 appearing at page 6793 of the issue for Tuesday, March 13, 1973, in the table in § 888f.6, in Rule 1 under column B, the material in parentheses, now reading "(information cycle to numbered AF or comparable level)", should read "(information copy to numbered AF or comparable level)".

SUBCHAPTER K—MILITARY TRAINING AND SCHOOLS

PART 901a—APPOINTMENT TO THE U.S. AIR FORCE ACADEMY

Correction

In FR Doc. 73-4487 appearing at page 6794 of the issue for Tuesday, March 13, 1973, § 901.9 *Regular (competitive)* and § 901.10 *Reserve (competitive)* should be designated §§ 901a.9 and 901a.10 respectively.

Title 21—Food and Drugs

CHAPTER II—BUREAU OF NARCOTICS AND DANGEROUS DRUGS, DEPARTMENT OF JUSTICE

PART 308—SCHEDULES OF CONTROLLED SUBSTANCES

On January 8, 1973, the Bureau republished the schedules of controlled substances in compliance with section 202(a) (21 U.S.C. 812(a)). (38 FR 953) This republication listed only those sections of Part 308 which actually enumerated substances which were controlled or excluded, exempted or excepted from some or all of the controls under the Act. The Bureau has been informed that the FEDERAL REGISTER construes this publication as a repeal of all of the portions of Part 308 not contained in the January 8, 1973, order. Since this was not the Bureau's intent and although the Bureau does not believe that the other sections were actually repealed, the Director has ordered the publication of the entire Part 308 of title 21 of the Code of Federal Regulations as in effect on March 31, 1973. The January 8 publication also omitted certain excepted

compounds in § 308.24 and this omission has been corrected in this publication.

Dated: March 23, 1973.

JOHN E. INGERSOLL,
Director, Bureau of Narcotics and Dangerous Drugs.

GENERAL INFORMATION

AUTHORITY: Secs. 201, 202, 501(b), 84 Stat. 1245, 1246, 1247, 1248, 1249, 1250, 1251, 1252, 1271, 21 U.S.C. 811, 812, 871(b).

GENERAL INFORMATION

§ 308.01 Scope of Part 308.

Schedules of controlled substances established by section 202 of the Act (21 U.S.C. 812), as they are changed, updated, and republished from time to time, are set forth in this part.

§ 308.02 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term "Act" means the Controlled Substance Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) The term "hearing" means any hearing held pursuant to this part for the issuance, amendment, or repeal of any rule issuable pursuant to section 201 of the Act.

(c) The term "isomer" means, except as used in § 308.11(d), the optical isomer. As issued in § 308.11(d), the term "isomer" means the optical, position or geometric isomer.

(d) The term "interested person" means any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act.

(e) The term "proceeding" means all actions taken for the issuance, amendment, or repeal of any rule issued pursuant to section 201 of the Act, commencing with the publication by the Director of the proposed rule, amended rule, or repeal in the FEDERAL REGISTER.

(f) Any term not defined in this section shall have the definition set forth in section 102 and 1001 of the Act (21 U.S.C. 802 and 951) and § 301.02 of this chapter.

§ 308.03 Bureau Controlled Substances Code Number.

(a) Each controlled substance, or basic class thereof, has been assigned a "Bureau Controlled Substances Code Number" for purposes of identification of the substances or class on certain Certificates of Registration issued by the Bureau pursuant to § 301.44 of this chapter and on certain order forms issued by the Bureau pursuant to § 305.05(d) of this chapter. Certain applicants for registration must include the appropriate numbers on the application as required in § 301.32(d) and applicants for procurement and/or individual manufacturing quotas must include the appropriate number on the application as required in §§ 303.12(b) and 303.22(a).

(b) Except as stated in paragraph (a) of this section, no applicant or registrant is required to use the Bureau Controlled Substances Code Number for any purpose.

§ 308.04 Submission of information by manufacturers.

(a) Each person who manufactures, packages, repackages, labels, relabels, or distributes under his own label any product (including any compound, mixture, or preparation, diagnostic, reagent, buffer, or biological) containing any quantity of any controlled substance (whether such product is itself controlled or is excepted, exempted, or excluded from some or all controls pursuant to § 308.21–24 or § 308.31–32) shall submit information required in paragraph (b) of this section for each such product being manufactured or sold on July 1, 1972. The information should be submitted by registered mail, return receipt requested, to the Assistant Director for Scientific Support. Attention: Label Project, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537, by August 31, 1972. In the case of new products manufactured after July 1, 1972, or new dosage forms or other unit forms manufactured after July 1, 1972, or changes in information submitted by August 31, 1972, the registrant shall submit the information regarding such item within 30 days after the date on which the manufacture commences or information change occurs. In the case of products, the manufacture of which is discontinued after July 1, 1972, the registrant shall submit notice of such discontinuance within 30 days after the date on which manufacture ceases. In the case of products the manufacture of which was discontinued before July 1, 1972, which are still being sold, the registrant shall submit a notice of such discontinuance with his initial submission.

(b) Two labels or other documents reflecting the following information shall be submitted with reference to each dosage form or other unit form of each item containing any quantity of any controlled substance:

(1) The trade name, brand name, or other commercial name of the product;

(2) The generic or chemical name and quantity of each active ingredient, including both controlled and noncontrolled substances (if any of this information is a proprietary trade secret, please indicate those portions);

(3) The National Drug Code Number assigned to the product, if any; and

(4) The weight (in metric measure) of each dosage unit or the weight (in metric measure) of the controlled substance per 100 grams of finished product for all items containing any quantity of any narcotic controlled substance in solid dosage forms.

SCHEDULES

§ 308.11 Schedule I.

(a) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Bureau Controlled Substances Code Number set forth opposite it.

(b) *Opiates.* Unless specifically excepted or unless listed in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol	9601
(2) Allylprodine	9602
(3) Alphacetylmethadol	9603
(4) Alphameprodine	9604
(5) Alphamethadol	9605
(6) Benzethidine	9606
(7) Betacetylmethadol	9607
(8) Betameprodine	9608
(9) Betamethadol	9609
(10) Betaprodine	9611
(11) Clonitazene	9612
(12) Dextromoramide	9613
(13) Dextrorphan	9614
(14) Diampromide	9615
(15) Diethylthiambutene	9616
(16) Dimenoxadol	9617
(17) Dimepheptanol	9618
(18) Dimethylthiambutene	9619
(19) Dioxaphetyl butyrate	9621
(20) Dipipanone	9622
(21) Ethylmethylthiambutene	9623
(22) Etonitazene	9624
(23) Etoxeridine	9625
(24) Furethidine	9626
(25) Hydroxypethidine	9627
(26) Ketobemidone	9628

(27) Levomoramide 9629
(28) Levophenacylmorphan 9631
(29) Morpheridine 9632
(30) Noracymethadol 9633
(31) Norlevorphanol 9634
(32) Normethadone 9635
(33) Norpipanone 9636
(34) Phenadoxone 9637
(35) Phenampromide 9638
(36) Phenomorphan 9647
(37) Phenoperidine 9641
(38) Piritramide 9642
(39) Proheptazine 9643
(40) Properidine 9644
(41) Propiram 9649
(42) Racemoramide 9645
(43) Trimeperidine 9646

(c) *Opium derivatives.* Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine 9319
(2) Acetyldihydrocodeine 9051
(3) Benzylmorphine 9052
(4) Codeine methylbromide 9070
(5) Codeine-N-Oxide 9053
(6) Cyprenorphine 9054
(7) Desomorphine 9055
(8) Dihydromorphine 9145
(9) Etorphine 9056
(10) Heroin 9200
(11) Hydromorphinol 9301
(12) Methyldesorphine 9302
(13) Methyldihydromorphine 9304
(14) Morphine methylbromide 9305
(15) Morphine methylsulfonate 9306
(16) Morphine-N-Oxide 9307
(17) Myrophine 9308
(18) Nicocodeine 9309
(19) Nicomorphine 9312
(20) Normorphine 9313
(21) Pholcodine 9314
(22) Thebacon 9315

(d) *Hallucinogenic substances.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this paragraph only, the term "isomer" includes the optical, position, and geometric isomers):

(1) 3,4-methylenedioxy amphetamine 7400
(2) 5 - methoxy - 3,4-methylenedioxy amphetamine 7401
(3) 3,4,5-trimethoxy amphetamine 7390
(4) Bufotanine 7433
Some trade and other names: 3 - (β-Dimethylaminoethyl) - 5 - hydroxyindole; 3 - (2 - dimethylaminoethyl) - 5-indolol; *N,N* - dimethylserotonin; 5-hydroxy - *N*-dimethyltryptamine; mappine.
(5) Diethyltryptamine 7434
Some trade and other names: *N,N*-Diethyltryptamine; DET.
(6) Dimethyltryptamine 7435
Some trade or other names: DMT.
(7) 4 - methyl-2,5-dimethoxyamphetamine 7395
Some trade and other names: 4 - methyl - 2,5 - dimethoxy-α - methylphenethylamine; "DOM"; and "STP".
(8) Ibogaine 7260
Some trade and other names: 7 - Ethyl - 6,6α,7,8,9,10,12,13-octahydro - 2 - methoxy-6,9-methano-5H-pyrido (1',2':1,2 azepino 4,5-b) indole; tabernanthe iboga.
(9) Lysergic acid diethylamide 7315
(10) Marihuana 7360
(11) Mescaline 7381
(12) Peyote 7415
(13) N-ethyl-3-piperidyl benzilate 7482
(14) N-methyl-3-piperidyl benzilate 7484
(15) Psilocybin 7437
(16) Psilocyn 7438
(17) Tetrahydrocannabinols 7370
Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:
Δ^1 cis or trans tetrahydrocannabinol, and their optical isomers.
Δ^6 cis or trans tetrahydrocannabinol, and their optical isomers.
$\Delta^{3,4}$ cis or trans tetrahydrocannabinol, and its optical isomers.
(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions are covered.)

§ 308.12 Schedule II.

(a) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the controlled substances code number set forth opposite it.

(b) *Substances, vegetable origin or chemical synthesis.* Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding naloxone hydrochloride, but including the following:

(i) Raw opium 9600
(ii) Opium extracts 9610
(iii) Opium fluid extracts 9620
(iv) Powdered opium 9639
(v) Granulated opium 9640
(vi) Tincture of opium 9630
(vii) Apomorphine 9035
(viii) Codeine 9050
(ix) Ethylmorphine 9190
(x) Hydrocodone 9193
(xi) Hydromorphone 9194
(xii) Metopon 9260
(xiii) Morphine 9300
(xiv) Oxycodone 9143
(xv) Oxymorphone 9652
(xvi) Thebaine 9333

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subparagraph (1) of this paragraph, except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw, 9650.

(4) Coca leaves (9040) and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine (9041) or ecgonine (9180).

(c) *Opiates.* Unless specifically excepted or unless in another sechedule any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine 9010
(2) Anileridine 9020
(3) Benzitramide 9800
(4) Dihydrocodeine 9120
(5) Diphenoxylate 9170
(6) Fentanyl 9801
(7) Isomethadone 9226
(8) Levomethorphan 9210
(9) Levorphanol 9220
(10) Metazocine 9240
(11) Methadone 9250
(12) Methadone-Intermediate, 4-cy-
(13) Moramide-Intermediate, 2-methano-2-dimethylamino - 4,4 - diphenyl butane 9254
(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid 9802
(14) Pethidine 9230
(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4 - phenylpiperidine 9232
(16) Pethidine-Intermediate-B, ethyl-4 - phenylpiperidine-4-carboxylate 9233
(17) Pethidine - Intermediate - C, 1-methyl-4-phenylpiperidine - 4-carboxylic acid 9234
(18) Phenazocine 9715
(19) Piminodine 9730
(20) Racemethorphan 9732
(21) Racemorphan 9733

(d) *Stimulants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers 1100
(2) Methamphetamine, its salts, isomers, and salts of its isomers 1105
(3) Phenmetrazine and its salts 1630
(4) Methylphenidate 1726

§ 308.13 Schedule III.

(a) Schedule III shall consist of the drugs and other substances, by whatever

official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Bureau controlled substances code number set forth opposite it.

(b) *Stimulants.* Unless specifically excepted or unless listed in another schedule any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under § 308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances, 1405.

(c) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid	2100
(2) Chlorhexadol	2510
(3) Glutethimide	2550
(4) Lysergic acid	7300
(5) Lysergic acid amide	7310
(6) Methyprylon	2575
(7) Phencyclidine	7471
(8) Sulfondiethylmethane	2600
(9) Sulfonethylmethane	2605
(10) Sulfonmethane	2610

(d) *Nalorphine* (a narcotic drug) 9400.

(e) *Narcotics drugs.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium	9803
(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts	9804
(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium	9805
(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts	9806
(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts	9807
(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts	9808
(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts	9809
(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts	9810

§ 308.14 Schedule IV.

(a) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Bureau controlled substances code number set forth opposite it.

(b) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Barbital	2145
(2) Chloral betaine	2460
(3) Chloral hydrate	2465
(4) Ethchlorvynol	2540
(5) Ethinamate	2545
(6) Methohexital	2264
(7) Meprobamate	2820
(8) Methylphenobarbital	2250
(9) Paraldehyde	2585
(10) Petrichloral	2591
(11) Phenobarbital	2285

§ 308.15 Schedule V.

(a) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) *Narcotic drugs containing nonnarcotic active medicinal ingredients.* Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs or salts thereof, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Nor more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

EXCLUDED NONNARCOTIC SUBSTANCES

§ 308.21 Application for exclusion of a nonnarcotic substance.

(a) Any person seeking to have any nonnarcotic substance which may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301), be lawfully sold over the counter without a prescription, excluded from any schedule, pursuant to section 201(g)(1) of the Act (21 U.S.C. 811(g)(1)), may apply to the Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537.

(b) An application for an exclusion under this section shall contain the following information:

(1) The name and address of the applicant;

(2) The name of the substance for which exclusion is sought; and

(3) The complete quantitative composition of the substance.

(c) Within a reasonable period of time after the receipt of an application for an exclusion under this section, the Director shall notify the applicant of his acceptance or nonacceptance of his application, and if not accepted, the reason therefor. The Director need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraph (b) of this section. If the application is accepted for filing, the Director shall issue and publish in the FEDERAL REGISTER his order on the application, which shall include a reference to the legal authority under which the order is issued and the findings of fact and conclusions of law upon which the order is based. This order shall specify the date on which it shall take effect. The Director shall permit any interested person to file written comments on or objections to the order within 60 days of the date of publication of his order in the FEDERAL REGISTER. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Director shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Director shall reinstate, revoke, or amend his original order as he determines appropriate.

(d) The Director may at any time revoke any exclusion granted pursuant to section 201(g) of the Act (21 U.S.C. 811(g)) by following the procedures set forth in paragraph (c) of this section for handling an application for an exclusion which has been accepted for filing.

§ 308.22 Excluded substances.

The following nonnarcotic substances which may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301), be lawfully sold over the counter without a prescription, are excluded from all schedules pursuant to section 201(g)(1) of the Act (21 U.S.C. 811(g)(1)):

EXCLUDED OVER-THE-COUNTER DRUGS

Trade name or other designation	Composition	Manufacturer or supplier
Amodrine	Tablet: Phenobarbital, 8 mg.; aminophylline, 100 mg.; racephedrine hydrochloride, 25 mg.	G. D. Searle & Co.
Bronkaid	Tablet: Phenobarbital, 8 mg.; ephedrine sulfate, 24 mg.; glyceryl guaiacolate, 100 mg.; theophylline, 100 mg.; thenyldiamine, 10 mg.	Drew Pharmacal Co., Inc.
Bronkolixir	Elixir (5 cc): Phenobarbital, 4 mg.; ephedrine sulfate, 12 mg.; glyceryl guaiacolate, 50 mg.; theophylline, 15 mg.; chlorpheniramine maleate, 1 mg.	Breon Laboratories Inc.
Bronkotabs	Tablet: Phenobarbital, 8 mg.; ephedrine sulfate, 24 mg.; glyceryl guaiacolate, 100 mg.; theophylline, 100 mg.; thenyldiamine, 10 mg.	Do.
Primatene	Tablet: Phenobarbital, ¼ gr.; ephedrine, ¾ gr.	Whitehall Laboratories.
Rynal	Solution for Spray; dl-Desoxyephedrine HCL 0.22%; antipyrine 0.28%; pyrilamine maleate 0.01%; methyl dodecylbenzyltrimethyl ammonium chloride 0.02%; glycerine dehydrate 1.50%.	Blaine Co.
Tedral	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Warner-Chilcott Laboratories.
Tedral anti-H	Tablet: Phenobarbital, 8 mg.; chlorpheniramine maleate, 2 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Do.
Tedral one-half strength	Tablet: Phenobarbital, 4 mg.; theophylline, 65 mg.; ephedrine hydrochloride, 12 mg.	Do.
Tedral pediatric suspension	Suspension (5 cc): Phenobarbital, 4 mg.; ephedrine hydrochloride, 12 mg.; theophylline, 65 mg.	Do.
Tedral suppositories double strength.	Suppository: Phenobarbital, 16 mg.; theophylline, 260 mg.; ephedrine hydrochloride, 48 mg.	Do.
Tedral suppositories regular strength.	Suppository: Phenobarbital, 8 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Do.
Vereqnad	Tablet: Phenobarbital, 8 mg.; theophylline calcium salicylate, 130 mg.; ephedrine hydrochloride, 24 mg.; glyceryl guaiacolate, 100 mg.	Knoll Pharmaceutical Co.
Do	Suspension (5 cc): Phenobarbital, 4 mg.; theophylline calcium salicylate, 65 mg.; ephedrine hydrochloride, 12 mg.; glyceryl guaiacolate, 50 mg.	Do.

EXEMPT CHEMICAL PREPARATIONS

§ 308.23 Exemption of certain chemical preparations; application.

(a) The Director may, by regulation, exempt from the application of all or any part of the Act any chemical preparation or mixture containing one or more controlled substances listed in any schedule, which preparation or mixture is intended for laboratory, industrial, educational, or special research purposes and not for general administration to a human being or other animal, if the preparation or mixture either:

(1) Contains no narcotic controlled substance and is packaged in such a form or concentration that the packaged quantity does not present any significant potential for abuse (the type of packaging and the history of abuse of the same or similar preparations may be considered in determining the potential for abuse of the preparation or mixture); or

(2) Contains either a narcotic or nonnarcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion, or concentration, that the preparation or mixture does not present any potential for abuse. If the preparation or mixture contains a narcotic controlled substance, the preparation or mixture must be formulated in such a manner that it incorporates methods of denaturing or other means so that the preparation or mixture is not liable to be abused or have ill effects, if abused, and so that the narcotic substance cannot in practice be removed.

(b) Any person seeking to have any preparation or mixture containing a controlled substance and one or more noncontrolled substances exempted from the application of all or any part of the Act, pursuant to paragraph (a) of this section, may apply to the Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537.

(c) An application for an exemption under this section shall contain the following information:

(1) The name, address, and registration number, if any, of the applicant;

(2) The name, address, and registration number, if any, of the manufacturer or importer of the preparation or mixture, if not the applicant;

(3) The exact trade name or other designation of the preparation or mixture;

(4) The complete qualitative and quantitative composition of the preparation or mixture (including all active and inactive ingredients and all controlled and noncontrolled substances);

(5) The form of the immediate container in which the preparation or mixture will be distributed with sufficient descriptive detail to identify the preparation or mixture (e.g., bottle, packet, vial, soft plastic pillow, agar gel plate, etc.);

(6) The dimensions or capacity of the immediate container of the preparation or mixture;

(7) The label and labeling, as defined in § 302.01 of this chapter, of the immediate container and the commercial containers, if any, of the preparation or mixture;

(8) A brief statement of the facts which the applicant believes justify the granting of an exemption under this paragraph, including information on the use to which the preparation or mixture will be put;

(9) The date of the application; and

(10) Which of the information submitted on the application, if any, is deemed by the applicant to be a trade secret or otherwise confidential and entitled to protection under subsection 402(a)(8) of the Act (21 U.S.C. 842(a)(8)) or any other law restricting public disclosure of information.

(d) The Director may require the applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted.

(e) Within a reasonable period of time after the receipt of an application for an exemption under this section, the Director shall notify the applicant of his acceptance or nonacceptance of his application, and if not accepted, the reason therefor. The Director need not accept an application for filing if any of the requirements prescribed in paragraph (c) or requested pursuant to paragraph (d) is lacking or is not set forth as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraph (c) and (d) of this section. If the application is accepted for filing, the Director shall issue and publish in the FEDERAL REGISTER his order on the application, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Director shall permit any interested person to file written comments on or objections to the order within 60 days of the date of publication of his order in the FEDERAL REGISTER. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Director shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Director shall reinstate, revoke, or amend his original order as he determines appropriate.

(f) The Director may at any time revoke or modify any exemption granted pursuant to this section by following the procedures set forth in paragraph (e) of this section for handling an application for an exemption which has been accepted for filing. The Director may also modify or revoke the criteria

by which exemptions are granted (and thereby modify or revoke all preparations and mixtures granted under the old criteria) and modify the scope of exemptions at any time.

§ 308.24 **Exempt chemical preparations.**

(a) The chemical preparations and mixtures set forth in paragraph (i) of this section have been exempted by the Director from application of sections 302, 303, 305, 306, 307, 308, 309, 1002, 1003, and 1004 of the Act (21 U.S.C. 822–3, 825–9, 952–4) and § 301.74 of this chapter, to the extent described in paragraphs (b) to (h) of this section.

(b) Registration and security: Any person who manufactures an exempt chemical preparation or mixture must be registered under the Act and comply with all relevant security requirements regarding controlled substances being used in the manufacturing process until the preparation or mixture is in the form described in paragraph (i) of this section. Any other person who handles an exempt chemical preparation after it is in the form described in paragraph (i) of this section is not required to be registered under the Act to handle that preparation, and the preparation is not required to be stored in accordance with security requirements regarding controlled substances.

(c) Labeling: In lieu of the requirements set forth in Part 302 of this chapter, the label and the labeling of an exempt chemical preparation must be prominently marked with its full trade name or other description and the name of the manufacturer or supplier as set forth in paragraph (i) of this section, in such a way that the product can be readily identified as an exempt chemical preparation. The label and labeling must also include in a prominent manner the statement "For industrial use only" or "For chemical use only" or "For in vitro use only—not for human or animal use" or "Diagnostic reagent—for professional use only" or a comparable statement warning the person reading it that human or animal use is not intended. The symbol designating the schdeule of the controlled substance is not required on either the label or the labeling of the exempt chemical preparation, nor is it necessary to list all ingredients of the preparation.

(d) Records and reports: Any person who manufactures an exempt chemical preparation or mixture must keep complete and accurate records and file all reports required under Part 304 of this chapter regarding all controlled substances being used in the manufacturing process until the preparation or mixture is in the form described in paragraph (i) of this section. In lieu of records and reports required under Part 304 of this chapter regarding exempt chemical preparations, the manufacturer need only record the name, address, and registration number, if any, of each person to whom the manufacturer distributes any exempt chemical preparation. Each importer or exporter of an exempt narcotic chemical preparation must submit a semiannual report of the total quantity of each substance imported or exported in each calendar half-year within 30 days of the close of the period to the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537. Any other person who handles an exempt chemical preparation after it is in the form described in paragraph (i) of this section is not required to maintain records or file reports.

(e) Quotas, order forms, prescriptions, import, export, and transshipment requirements: Once an export chemical preparation is in the form described in paragraph (i) of this section, the requirements regarding quotas, order forms, prescriptions, import permits and declarations, export permit and declarations, and transshipment and intransit permits and declarations do not apply. These requirements do apply, however, to any controlled substances used in manufacturing the exempt chemical preparation before it is in the form described in paragraph (i) of this section.

(f) Criminal penalties: No exemption granted pursuant to § 308.23 affects the criminal liability for illegal manufacture, distribution, or possession of controlled substances contained in the exempt chemical preparation. Distribution, possession, and use of an exempt chemical preparation are lawful for registrants and nonregistrants only as long as such distribution, possession, or use is intended for laboratory, industrial, or educational purposes and not for immediate or subsequent administration to a human being or other animal.

(g) Bulk materials: For materials exempted in bulk quantities, the Director may prescribe requirements other than those set forth in paragraphs (b) through (e) of this section on a case-by-case basis.

(h) Changes in chemical preparations: Any change in the quantitative or qualitative composition of the preparation or mixture after the date of application, or change in the trade name or other designation of the preparation or mixture, set forth in paragraph (i) of this section, requires a new application for exemption.

(i) The following preparations and mixtures, in the form and quantity listed in the application submitted (indicated as the "date of application") are designated as exempt chemical preparations for the purposes set forth in this section:

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Abbott Laboratories	CEP agarose plates, No. 9023-01 and 9023-02.	Foil pouch: 4⅛" x 4" and 6⅛" x 5¼".	Aug. 21, 1972
Do	CEP agarose plates (for research studies only), No. 9023-03 and 9023-04.	Foil pouch: 4⅛" x 4" and 6⅛" x 5¼".	Do.
Do	DILU-tainer CEP barbital acetate buffer, No. 9025-03.	Plastic bag: 6" x 13"	Do.
Do	Tetrasorb-125 T-4 diagnostic kit, No. 7775.	Vial: 11 ml	Do.
Do	Irosorb-59 diagnostic kit, No. 6764	Vial: 10 ml	Do.
Do	T-7 I-125 diagnostic kit No. 7734	Vial: 11 ml	Nov. 15, 1972
Do	Quantisorb T-4N diagnostic kit No. 6719.	Vial: 11 ml	Do.
American Hospital Supply Corp. (Dade Division).	Adsorbed plasma reagent No. B4233-1 and No. B4233-2.	Bottle: 1 ml	Aug. 16, 1971
Do	Owren's veronal buffer No. B4234-25	Bottle: 15 ml	Do.
Do	Phosphatase substrate No. B5312-1 and No. B5312-5.	Bottle: 73 mg. dry powder.	Do.
Do	Serum reagent No. B4233-1 and No. B4233-2.	Bottle: 2 ml	Do.
Do	Thrombin reagent (bovine) No. B4233-15.	Bottle: 1 ml	Do.
Do	Thyroxine buffer No. B5630-1	Bottle: 5 ml	Do.
American Hospital Supply Corp. (Harleco Division).	Barbital buffer B-1 No. 96772	Vial: 12.12 grams per 7 dram vial.	Sept. 15, 1971
Do	Barbiturate standards set. No. 64808	Vial: 9 x 3 ml. of 8 single and 1 mixed at 15 mg per dl.	Oct. 22, 1971
Do	Barringer & Woodard buffered substrate No. 23695.	Vial: 0.73 gram per 15 x 45 mm. vial.	Sept. 15, 1971
Do	Buchler instrument buffer B-2 double strength, pH 8.6, 0.075 m No. 93834.	Vial: 36.36 grams	Do.
Do	Buffer barbital, pH 8.6, No. 96804	Vial: 1.51 grams per 15 x 45 mm. vial.	Do.
Do	Buffer barbital, pH 8.8, No. 7691	Vial: 11.76 grams per 10 dram vial.	Do.
Do	Barbital-sodium buffer salt, No. 11731	Bottle: 250 ml	June 6, 1972
Do	Barbital-acid buffer salt, No. 1173	Bottle: 250 ml	Do.
Do	Buffer salt-barbital acetate mixture, pH 8.6, No. 3787.	Vial: 14.7 grams per 29.5 × 80 mm. vial.	Sept. 15, 1971
Do	Buffer salt mixture, pH 8.8, No. 7644	Vial: 17.85 grams per 29.5 × 80 mm. vial.	Do.
Do	Buffer salt mixture Spinco B-1, pH 8.6, 0.05 ionic strength, No. 3047.	Vial: 12.12 grams per 29.5 × 80 mm. vial.	Do.
Do	Buffer salt mixture Spinco B-2, pH 8.6, 0.075 ionic strength, No. 3048.	Vial: 18.18 grams per 29.5 × 80 mm. vial.	Do.
Do	Buffered barbital sodium chloride, pH 7.5, No. 64647.	Vial: 14.7 grams per vial.	Do.
Do	Buffered substrate glycerophosphate Bodansky, No. 23881.	Vial: 0.924 grams per 15 × 45 mm. vial.	Do.
Do	Buffered veronal, pH 7.5, No. 64322	Vial: 16.48 grams per vial.	Do.
Do	Gilleress & Davis buffered substrate, No. 23701.	Vial: 1.228 grams per 15 × 45 mm. vial.	Do.
Do	Hematoxylin, acid-alum solution No. 64720.	Bottle: 15 and 32 oz., and 2.5 gal.	Dec. 29, 1972
Do	King & Armstrong buffered substrate, No. 23721.	Vial: 1.14 grams per 15 × 45 mm. vial.	Sept. 15, 1971
Do	Roe & Whitmore buffered substrate, No. 23686.	Vial: 0.854 grams per 15 × 45 mm. vial.	Do.
Do	Shinowara, Jones & Reinhart buffered substrate, No. 23738.	Vial: 0.945 grams per 15 × 45 mm. vial.	Do.

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Do	Thymol barbital buffer, MacLagan Modified, pH 7.8, No. 29944.	Vial: 1.256 grams per 15 × 45 mm. vial.	Do.
Do	Thymol buffer 100 ml., 100 mg., Huerga & Popper, No. 29929.	Vial: 0.964 grams per 15 × 45 mm. vial.	Do.
Do	Thymol buffer, pH 7.8, MacLagan, No. 29949.	Vial: 1.02 grams per vial.	Do.
Do	Thymol buffer, pH 7.55 Mateer, No. 29951.	Vial: 0.96 grams per 15 × 45 mm. vial.	Do.
Do	Zinc sulfate, pH 7.5 (Kunkel), No. 64050.	Vial: 0.514 grams per vial.	Do.
Amersham/Searle	Amobarbital-2-C14, No. CFA-401	Ampule: 110 mm. x 13 mm. or Vial: 38.40 mm. x 11 ml.	Sept. 19, 1972
Do	Morphine (N-methyl-C14) Hydrochloride No. CFA-363.	do	Mar. 27, 1972
Do	Pentothal—S35 sodium salt, No. SJ-77.	Ampule: 110 mm. x 13 mm. or Vial: 38.40 mm. x 11 mm.	Sept. 19, 1972
Do	Codeine (N-methyl-C14) Hydrochloride No. CFA-421.	Ampule: 10 cc	Mar. 27, 1972
Applied Sciences Laboratories, Inc.	Mixture 1—opiates	Vial: 1 ml	Oct. 6, 1972
Do	Mixture 2—stimulants	do	Do.
Do	Mixture 3—depressants	do	Do.
Do	Mixture 4—barbiturates	do	Do.
Do	Mixture 5—kit of representatives	do	Do.
Becton, Dickinson and Co. (Spectra Biologicals Division).	HepaScreen CEP barbital buffer, No. K-751.	Envelope: 3.5" x 5.5"	Aug. 11, 1972
Do	HepaScreen CEP plates, Nos. K-742 and K-743.	Plate: 3.5" x 3.5"	Do.
Beckman Instruments, Inc. (Spinco Division).	Beckman buffer B-1	Packet: 12.14 gm	Apr. 24, 1971
Do	Beckman buffer B-2	Packet: 18.16 gm	Do.
Bio-Rad Laboratories, Inc	Bio-Rad electrophoresis buffer	Bottle: 500 ml	Dec. 14, 1972
Do	Electrophoresis buffer, dry-pack	Package: 6.15 gm	Do.
Do	Reagent No. 3	Bottle: 165 cc	Do.
Buchler Instruments	Buffer salt-type I, barbital-sodium, barbital mixture pH 8.6 No. 3-1035.	Vial: 36.36 gm	Dec. 6, 1972
Do	Buchler instrument buffer B-2 double strength, pH 8.6, 0.075 m No. 93834.	Vial: 36.36 grams	Sept. 15, 1971
Burroughs Wellcome Co	Lanoxitest beta digoxin radioimmunoassay kit with tritiated digoxin No. KT07.	Bottle: 125 ml	Nov. 16, 1972
Chemed Corp. (Dearborn Chemical Division).	Zinc reagent No. 2, No. 704	Pillow: 10 mg. each	June 23, 1971
Collaborative Research, Inc	Kit to include: LSD antiserum No. Z-20; I-125-LSD-Polymer No. Z-11; LSD standard.	Bottle: 1 and 2 dram	Nov. 14, 1972
Clarkson Laboratory and Supply, Inc.	Hematoxylin stain, Mayer's No. S-1302.	Gallon	Dec. 12, 1972
Cordis Laboratories	Barbital-acetate buffer, powder 709-317.	Package: 20 envelopes—10.65 grams per envelope.	July 27, 1972
Do	Counterelectrophoresis, plates CEP I 709-304.	Package: 5 plates—18 ml. per plate.	Do.
Do	Counterelectrophoresis, plates CEP II 709-305.	do	Do.
Do	Counterelectrophoresis, plates CEP III 709-306.	do	Do.
Do	Counterelectrophoresis, plates CEP IV 709-307.	do	Do.
Do	Counterelectrophoresis, plates CEP I 709-324.	Package: 10 plates—8.5 ml. per plate.	Do.
Do	Counterelectrophoresis, plates CEP II 709-325.	do	Do.
Do	Counterelectrophoresis, plates CEP III 709-326.	do	Do.
Do	Counterelectrophoresis, plates CEP IV 709-327.	do	Do.
Do	GVB^{2+} buffer, 753-037	Bottle: 50 ml	Do.
Do	Glucose—GVB^{2+} buffer, 753-038	do	Do.
Do	EDTA (0.014AM)—GVB buffer, 753-034	Bottle: 5 ml	Do.
Do	EDTA (0.01M)—GVB buffer, 753-031	do	Do.
Do	5X Isotonic veronal buffer	Bottle: 1,000 ml	Do.

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Fisher Scientific Co	Electrophoretic buffer No. 1, pH 8.60, ionic strength 0.05, catalog No. E-1.	Packet: 12.14 grams	Oct. 27, 1972
Do	Electrophoretic buffer No. 2, pH 8.80, ionic strength 0.075, catalog No. E-2.	Packet: 18.16 grams	Do.
Gebman Instruments Co	Drug standard set No. 51910	Set: 3 vials of 2 ml. each	Apr. 5, 1972
Do	Drug control set No. 51911	Set: 3 vials of 50 ml. each	Do.
Do	High resolution, buffer-Tris Barbital buffer No. 51104.	Vial: 10 dram	Dec. 22, 1971
Do	Beprachrom drug system, No. 51920	Chambers: 6 cm. x 9 cm	Sept. 6, 1972
General Diagnostics	fas T^3, No. 36903	Vial: 10.5 cm x 1.2 cm	Aug. 25, 1972
Gugol Science Corp	Gugol concentrate No. 10109	Vials: 20 ml., 90 ml., and 450 ml.	Mar. 28, 1972
Hach Chemical Co	pH 8.5 buffer powder pillows, No. 920-68.	Pillow: 0.5 gm. each	Nov. 30, 1971
Do	pH 8.3 buffer powder pillows, No. 898-68.	Pillow: 1 gram each	Do.
Do	Zincover II powder pillows, No. 2917	do	Do.
Do	Buffered substrate, glycerophosphate, Roe & Whitmore, pH 9.6, No. 20060.	Vial: 0.855 gram per 100 ml.	Do.
Do	Buffered substrate, glycerophosphate, Shinowara, Jones & Reinhart, pH 10.9, No. 20063.	Vial: 0.925 gram per 100 ml.	Do.
Do	Buffered substrate, glycerophosphate, Shinowara, Jones & Reinhart—Stock, No. 20061.	Vial: 1.85 gram per 100 ml.	Do.
Do	Buffered substrate, glycerophosphate, Shinowara, Jones & Reinhart, pH 5.0, No. 20062.	Vial: 0.925 gram per 100 ml.	Do.
Hoffman-La Roche Inc	Abuscreen radio-immunoassay for morphine (I125), No. 43021.	Vial: 30 ml	Sept. 27, 1972
Do	Abuscreen radio-immunoassay for morphine (^{3}H), No. 43016.	Vial: 60 ml	Do.
Hyland Division Travenol Laboratories, Inc.	Agar gel plates No. 3003	Package: 8 plates—25 ml. per plate.	Aug. 31, 1971
Do	Agar gel plates No. 3016	Package: 10 plates—25 ml. per plate.	Do.
Do	Agar gel plates No. 3058	do	Do.
Do	Buffer No. 3017	Vial: 250 ml	Do.
Do	Buffer No. 3059	do	Do.
Do	Diluting fluid No. 3400	Vial: 10 ml	Do.
Do	Partial thromboplastin liquid, No. 3481.	Vial: 0.1 ml	Do.
Do	PTC reagent dried, No. 3497	Vial: 1 ml	Do.
Do	Supplemental urine clinical chemistry control, dried, No. 0402 and No. 0621.	Vial: 25 ml	Do.
Do	Partial thromboplastin, dried, No. 3491.	Vial: 1 ml. and 5 ml	Do.
Do	Agar gel plates, No. 8794	Plate: 25 ml	Aug. 1, 1972
Do	Buffer, No. 8793	Vial: 250 ml	Do.
Do	T-3	Vial: 10 ml	Dec. 19, 1972
Do	T-4	Vial: 10 ml	Do.
Do	Toxicology serum control, dried, No. 6541.	Vial: 10 ml	Oct. 26, 1972
Do	Toxicology urine control, dried, No. 6562.	do	Do.
Industrial Biological Laboratories, Inc.	DGV solution	Vial: 100 cc	Dec. 28, 1971
Lederle Laboratories Division of American Cyanamid Co.	DGV buffer, 5x No. 2606-37	Vial: 20 ml	Nov. 19, 1971
Do	Serum toxicology control drugs A, No. 2949-69.	Vial: 10 ml	Do.
Do	Abnormal urine control, No. 2971-80	Vial: 25 ml	Do.
Do	Urine toxicology control drugs I, No. 2950-61.	do	Do.
Do	Urine toxicology drugs I screening proficiency, No. 2951-61.	do	Mar. 13, 1972
Do	Urine toxicology control drugs 2—barbiturates, No. 2952-61.	do	Do.
Do	Urine toxicology control drugs 2—barbiturates, proficiency No. 2953-61.	do	Do.

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Lederle Laboratory Division of American Cyanamid Co.	Urine toxicology control drugs 3— amphetamines No. 2954-61.	do	Dec
Do	Urine toxicology control drugs 3— amphetamines, proficiency No. 2955-61.	do	Dec
Do	Urine toxicology control, drugs 4— alkaloid No. 2956-61.	do	Dec
Do	Urine toxicology control, drugs 4— alkaloid, proficiency No. 2957-61.	do	Dec
Mallard, Inc	High resolution buffer-tris barbital buffer No. 51104.	Vial: 1½ dram	Dec. 22, 1971
Mallinckrodt Chemical Works	Res-O-Mat ETR solution	Vial: 1½ dram	Feb. 17, 1972
Do	Res-O-Mat T4 solution	do	Do.
MCI Biomedical	IEP buffer; pH 8.2, 0.04 ionic strength.	Package: 6.510 grams	Aug. 28, 1972
MEAD Diagnostics	T-3 test fas T , No. L6902	Vial: ½" x 1¹³⁄₁₆"	May 31, 1972
Do	T-4 test fas T4, No. L6905	Vial: ½" x 1¹³⁄₁₆"	Do.
Meloy Laboratories	Agar gel plate kit No. F-101, F-211, F-212, F-213, G-202, G-303, and G-304.	Package: 6 plates and 2 vials (30 x 70 mm) per kit.	Nov. 30, 1971
Do	Barbital buffer (or electrophoresis buffer).	Vial: 12.12 grams per 29.5 x 80 mm. vial.	Sept. 15, 1971
Miles Laboratories, Inc	Tetralute	Bottle: 4.9 gram	July 29, 1970
Nalco Chemical Co	Zn-1P No. 723	Pillow: 10 mg. each	Nov. 30, 1971
Do	Zn-2P No. 723	do	Do.
Purex Laboratories, Inc	Cannabis sativa, allergenic extract, 1,000 pnu/cc.	Vial: 2 cc	Sept. 29, 1971
Do	Cannabis sativa, allergenic extract, 20,000 pnu/cc.	Vial: 50 cc	Do.
Ortho Diagnostics	Activated Thromobo FAX No. 720000	Bottle: 3.2 ml	Sept. 21, 1971
Do	Hapindex, agar gel plate, No. 740000	Plate: 43 ml. per plate	Do.
Do	Ortho abnormal plasma coagulation control.	Packet: 96.5 mg	Do.
Do	Ortho HAA positive control No: 740900.	Vial: 1 mg	Mar. 27, 1972
Schering Corp	Hepaquik	Vial: 9 dram and plate	July 16, 1972
Schwarz/Mann Division, Becton Dickson and Co.	DL-amphetamine sulfate C14 sterile aqueous solution.	Flask: 0.05 mc, 0.1 mc, 0.5 mc, 1.0 mc.	Sept. 14, 1972
Do	D-amphetamine sulfate C14 sterile aqueous solution.	do	Do.
Do	L-amphetamine sulfate C14 sterile aqueous solution.	do	Do.
Do	Secobarbital 5 C14	do	Do.
Do	Secobarbital 2 C14	do	Do.
Do	Barbital buffer salt mixture, No. 0752-04 and No. 0752-07.	Vial: 50 cc	Nov. 4, 1971
SGA Scientific Corp	Barbital-acid buffer salt, No. 1173	Bottle: 4 oz	Do.
Do	Barbital-sodium buffer salt, No. 11731	do	Do.
Do	Barringer & Woodard buffered substrate No. 29665.	Vial: 0.73 gram per 15 x 45 mm. vial.	Sept. 15, 1971
Do	Buchler instrument buffer B-2 double strength, pH 8.6, 0.075 m No. 33834.	Vial: 36.36 grams	Do.
Do	Buffer barbital, pH8.8, No. 7691	Vial: 11.76 grams per 10 dram vial.	Do.
Do	Buffer salt—barbital acetate, mixture pH 8.6, No. 3787.	Vial: 14.7 grams per 29.5 x 80 mm. vial.	Do.
Do	Buffer salt mixture pH 8.8, No. 7644	Vial: 17.85 grams per 29.5 x 80 mm. vial.	Do.
Do	Buffer salt mixture Spinco B-1, pH 8.6, 0.05 ionic strength, No. 3947.	Vial: 12.12 grams per 29.5 x 80 mm. vial.	Do.
Do	Buffer salt mixture Spinco B-2, pH 8.6, 0.075 ionic strength, No. 3948.	Vial: 18.18 grams per 29.5 x 80 mm. vial.	Do.
Do	Buffered barbital, sodium chloride, pH 7.5, No. 646-7.	Vial: 14.7 grams per vial.	Do.
Do	Buffered substrate glycerophosphate Bodansky No. 23681.	Vial: 0.924 gram per 15 x mm. vial.	Do.
Do	Buffered veronal, pH 7.5, No. 64322	Vial: 16.48 grams per vial.	Do.
Do	Gifferes & Davis buffered substrate, No. 2370L.	Vial 1.228 grams per 15 x mm. vial.	Do.
Do	King & Armstrong buffered substrate, No. 23725.	Vial: 1.14 grams per 15 x 45 mm. vial.	Do.
Do	Roe & Whitmore buffered substrate, No. 23686.	Vial: 0.854 gram per 15 x 45 mm. vial.	Do.
Do	Scientific products buffer salt mixture B-2, No. 93953.	Vial: 18.18 grams per 10 dram vial.	Do.
Do	Shinowara, Jones & Reinhart buffered substrate, No. 23738.	Vial: 0.945 gram per 15 x 45 mm. vial.	Do.
Do	Thymol barbital buffer McLagan Modified pH 7.8, No. 29044.	Vial: 1.256 grams per 15 x 45 mm. vial.	Do.
Do	Thymol buffer 100 ml=100 mg., Huergs & Pepper, No. 29059.	Vial: 0.564 gram per 15 x 45 mm. vial.	Do.
Do	Thymol buffer pH 7.8, MacLagan, No. 29049.	Vial: 1.02 grams per vial.	Do.
Do	Thymol buffer pH 7.55 Mateer, No. 29051.	Vial: 0.96 gram per 15 x 45 mm. vial.	Do.
Do	Thymol turbidity test set, No. 3105	Packet: 1 gram	Nov. 4, 1971
Do	Zinc sulfate pH 7.5 (Kunkel), No. 64050.	Vial: 0.534 gram per vial.	Sept. 15, 1971
E.R. Squibb & Sons, Inc	AuSure barbital buffer powder, No. B79209.	Vial: 1.51 grams	July 28, 1971
Do	AuSure CEP plate, No. B78309	Plate: 40c. per plate	Sept. 16, 1971
Do	Barbital buffer mixture No. 09501	Vial: 6.055 gm	Dec. 21, 1972
Do	Barbital buffer for use with gastrin immutope kit, No. 09510.	Vial: 20 cc	Nov. 21, 1972
Supelco, Inc	Amobarbital No. 04-9170	Ampule: 1 ml	Dec. 22, 1972
Do	Amphetamine No. 04-9165	do	Do.
Do	Aprobarbital No. 04-9171	do	Do.
Do	Barbital No. 04-9169	do	Do.
Do	Butetehal No. 04-9172	do	Do.
Do	Codeine No. 04-9161	do	Do.
Do	Cyclobarbital No. 04-9175	do	Do.
Do	Glutethimide No. 04-9173	do	Do.
Do	Heptabarbital No. 04-9176	do	Do.
Do	Heroin No. 04-9162	do	Do.
Do	Hexobarbital No. 04-9177	do	Do.
Do	Methadone No. 04-9163	do	Do,
Do	Methamphetamine No. 04-9168	do	Do.
Do	Mephobarbital No. 04-9178	do	Do.
Do	Morphine No. 04-9160	do	Do.
Do	Pentobarbital No. 04-9179	do	Do.
Do	Phenobarbital No. 04-9181	do	Do.
Do	Phenylmethylbarbituric acid No. 04-9182.	do	Do.
Do	Secobarbital No. 04-9180	do	Do.
SYVA Co	Frat benzoyl ecgonine calibrator	Vial: 1 ml	Sept. 13, 1972
Do	Frat methadone calibrator	do	Do.
Do	Frat opiate calibrator	do	Do.
Do	Frat amphetamine calibrator	do	Do.
Do	Frat barbiturate calibrator	do	Do.
TLC Corp	Chromat/o/screen kit for amphetamines, No. JJ-175.	Vial: 1.9 cm. X1.6 cm	July 6, 1972
Do	Chromat/o/screen kit for alkaloids, No. JJ-176.	do	Do.
Do	Chromat/o/screen kit for barbiturates, No. JJ-177.	do	Do.
Warner-Lambert Co. (General Diagnostics Division).	Platelin	Vial: 7.3 ml	Mar. 13, 1792
Do	Platelin plus activator	do	Do.
Do	Simplastin	Vials: 4.7 ml., 7.3 ml. and 16.5 ml.	Do.
Do	Simplastin-A	Vial: 7.3 ml	Do.
Do	TGTR set	Package: 4 tests per set	Do.
Wien Laboratories, Inc	Buffer reagent pH 8.6 No. T-5065	Bottle: 4 oz	Dec. 22, 1972
Do	Coated charcoal suspension No. T-5077.	do	Do.
Do	P.E.G. solution No. T-5080	do	Do.

EXCEPTED STIMULANT OR DEPRESSANT COMPOUNDS

§ 308.31 Application for exception of a stimulant or depressant compound.

(a) Any person seeking to have any compound, mixture, or preparation containing any depressant or stimulant substance listed in § 308.13 (b) or (c), or in § 308.14, or in § 308.15, excepted from the application of all or any part of the Act, pursuant to section 202(d) of the Act (21 U.S.C. 812(d)), may apply to the Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537, for such exception.

(b) An application for an exception under this section shall contain the following information:

(1) The complete quantitative composition of the dosage form.

(2) Description of the unit dosage form together with complete labeling.

(3) A summary of the pharmacology of the product including animal investigations and clinical evaluations and studies, with emphasis on the psychic and/or physiological dependence liability (this must be done for each of the active ingredients separately and for the combination product).

(4) Details of synergisms and antagonisms among ingredients.

(5) Deterrent effects of the noncontrolled ingredients.

(6) Complete copies of all literature in support of claims.

(7) Reported instances of abuse.

(8) Reported and anticipated adverse effects.

(9) Number of dosage units produced for the past 2 years.

(c) Within a reasonable period of time after the receipt of an application for an exception under this section, the Director shall notify the applicant of his acceptance or nonacceptance of the application, and if not accepted, the reason therefor. The Director need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth so as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraph (b) of this section. If accepted for filing, the Director shall publish in the FEDERAL REGISTER general notice of his proposed rulemaking in granting or denying the application. Such notice shall include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule granting or denying an exception, and, in the discretion of the Director, a summary of the subjects and issues involved. The Director shall permit any interested person to file written comments on or objections to the proposal and shall designate in the notice of proposed rule making the time during which such filings may be made. After consideration of the application and any comments on or objections to his proposed rulemaking, the Director shall issue and publish in the FEDERAL REGISTER his final order on the application, which shall set forth the findings of fact and conclusions of law upon which the order is based. This order shall specify the date on which it shall take effect, which shall not be less than 30 days from the date of publication in the FEDERAL REGISTER unless the Director finds that conditions of public health or safety necessitate an earlier effective date, in which event the Director shall specify in the order his findings as to such conditions.

(d) The Director may at any time revoke any exception granted pursuant to section 202(d) of the Act (21 U.S.C. 812(d)) by following the procedures set forth in paragraph (c) of this section for handling an application for an exception which has been accepted for filing.

§ 308.32 Excepted compounds.

(a) Until criteria are adopted by the Bureau by which the Director may determine whether to except any compound, mixture, or preparation containing any depressant or stimulant substance listed in § 308.13 (b) or (c), or in § 308.14, or in § 308.15, from the application of all or any part of the Act pursuant to section 202(d) of the Act (21 U.S.C. 812(d)), the drugs set forth in paragraph (b) of this section have been excepted by the Director from application of the sections 305, 307, 308, 309, 1002, 1003, and 1004 of the Act (21 U.S.C. 825, 827–9, 952–4) and of § 301.74(d) of this chapter for administrative purposes only. The excepting of these drugs by the Director should not be construed as an adoption or rejection of the criteria by which these drugs were originally excepted. Any deviation from the quantitative composition of any of the listed drugs shall require a petition for exception in order for that drug to be excepted.

(b) The following drugs in dosage unit form, and any other drug of the quantitative composition shown below for one of the following drugs or which is the same except that it contains a lesser quantity of controlled substances or other substances which do not have a stimulant, depressant, or hallucinogenic effect, and which are restricted by law to dispensing on prescription, are excepted from the application of sections 305, 307, 308, 309, 1002, 1003, and 1004 of the Act (21 U.S.C. 825, 827–9, 952–4) and of § 301.74(d) of this chapter:

EXCEPTED PRESCRIPTION DRUGS

Trade name or other designation	Composition	Manufacturer or supplier
A.E.A.	Tablet: Amobarbital, 25 mg.; aminophylline, 120 mg.; ephedrine hydrochloride, 25 mg.	Haack Laboratories, Inc.
Alased	Tablet: Phenobarbital, 16.2 mg.; homatropine methylbromide, 3.6 mg.; aluminum hydroxide gel, dried, 7½ gr.; magnesium trisilicate, 2½ gr.	Norgine Laboratories, Inc.
Alcitex	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/200 gr.; calcium carbonate, 3½ gr.; magnesium carbonate, 2½ gr.; cerium oxalate, ½ gr.	Paul B. Elder Co., Inc.
Algoson	Tablet: Butabarbital sodium, 7.5 mg.; acetaminophen, 300 mg.	McNeil Laboratories Inc.
Alhydrox	Tablet: Phenobarbital, ½ gr.; aluminum hydroxide, 5 gr.; atropine sulfate, — gr.	Physicians Supply.
Alkasans	Tablet: Phenobarbital, 8.0 mg.; atropine sulfate, 0.06 mg.; kaolin-alumina gel, 500 mg.	P. J. Noyes Co.
Alsical	Powder (60 gr.): Phenobarbital, ¾ gr.; belladonna extract, ¼ gr.; calcium carbonate, 24 gr.; magnesium trisilicate, 15 gr.; magnesium oxide, 10 gr.; aluminum hydroxide gel, dried, 10 gr.	Dorsey Laboratories.
Alubelap	Tablet: Phenobarbital, 8 mg.; aluminum hydroxide gel, dried, 2300 mg.; belladonna extract, 4 mg.	Haack Laboratories, Inc.
Aludrox SA suspension	Suspension (5 cc.): Butabarbital, 3 mg.; ambutonium bromide, 2.5 mg.	Wyeth Laboratories.
Aludrox SA tablets	Tablet: Butabarbital, 8 mg.; ambutonium bromide, 2.5 mg.	Wyeth Laboratories.
Alu-Mag	Tablet: Phenobarbital, ¼ gr.; aluminum hydroxide gel, dried, 2½ gr.; magnesium trisilicate, 2½ gr.; belladonna leaf extract, ¼ gr.	Norsal Laboratories, Inc.
Alumazen	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.; magnesium trisilicate, 500 mg.; aluminum hydroxide gel, dried, 250 mg.; saccharin sodium, 0.12 mg.	The Zemmer Co.
Aluminum hydroxide, magnesium trisilicate, and kaolin with phenobarbital and atropine sulfate.	Tablet: Phenobarbital, ¼ gr.; aluminum hydroxide, 2 gr.; magnesium trisilicate, 4 gr.; kaolin, colloidal, 2 gr.; atropine sulfate, 1/200 gr.	Buffalo Pharmaceutical Supply Corp.
Aminodrox with phenobarbital	Tablet: Phenobarbital, 15 mg.; aminophylline, 0.1 gm.; aluminum hydroxide gel, dried, 0.12 gm.	The S. E. Massengill Co.
Aminodrox-forte with phenobarbital	Tablet: Phenobarbital, 15 mg.; aminophylline, 200 mg.; aluminum hydroxide gel, dried, 250 mg.	Do.
Aminophylline and amytal	Capsule: Amobarbital, 32 mg.; aminophylline, 0.1 gm.	Eli Lilly Co.
Aminophylline with pentobarbital	Suppository: Pentobarbital sodium, 100 mg.; aminophylline, 500 mg.	G. D. Searle & Co.
Aminophylline and phenobarbital	Tablet: Phenobarbital, 15 mg.; aminophylline, 100 mg.	The Zemmer Co.
Do	Tablet: Phenobarbital, ¼ gr.; aminophylline, 100 mg.	The Blue Line Chemical Co.
Aminophylline with phenobarbital	Tablet: Phenobarbital, 16 mg.; aminophylline, 100 mg.	H. E. Dubin Laboratories, Inc.
Do	Tablet: Phenobarbital, 15 mg.; aminophylline, 100 mg.	G. D. Searle & Co.
Do	Tablet: Phenobarbital, 15 mg.; aminophylline, 200 mg.	Do.
Do	Tablet: Phenobarbital, 30 mg.; aminophylline, 200 mg.	Do.
Amobarbital and PETN	Capsule: Amobarbital, 50 mg.; pentaerythritol tetranitrate, 30 mg.	Meyer Laboratories, Inc.
Ampyrox with butabarbital sodium (AMPYROX).	Tablet: Butabarbital sodium, 15 mg.; scopolamine methylnitrate, 2 mg.	Paul B. Elder Co., Inc.

Trade name or other designation	Composition	Manufacturer or supplier
Ampyrox with butabarbital sodium, elixir.	Elixir (5 cc.): Butabarbital sodium, 10 mg.; scopolamine methylnitrate, 1 mg.	Do.
Amsed (NAP-37)	Tablet: Phenobarbital, ¼ gr.; hyoscine hydrobromide, 0.0072 mg.; atropine sulfate, 0.024 mg.; hyoscyamine hydrobromide, 0.128 mg.	North American Pharmacal, Inc.
Amsodyne	Tablet: Phenobarbital, ¼ gr.; extract belladonna leaves, ¼ gr.; aspirin, 5 gr.; caffeine, ¼ gr.	Paul B. Elder Co., Inc.
Antacia No. 3 with phenobarbital and atropine.	Tablet: Phenobarbital, ⅓ gr.; atropine sulfate, 1/200 gr.; calcium carbonate, 5 gr.; magnesium hydroxide, 5 gr.	Meyers and Co.
Antispasmodic	Tablet (purple): Phenobarbital, 16.2 mg.; hyoscyamine sulfate, 0.1037 mg.; homatropine methylbromide, 0.567 mg.; hyoscine hydrobromide, 0.0065 mg.	Hydrex Co., Inc.
Antispasmodic-enzyme	Tablet: Phenobarbital, 8.1 mg.; hyoscyamine sulfate, 0.0519 mg.; homatropine methylbromide, 0.2885 mg.; hyoscine hydrobromide, 0.0033 mg.; pancreatin, 100 mg.; pepsin, 150 mg.	Do.
Antrocol	Tablet or capsule: Phenobarbital, 16 mg.; atropine sulfate, 0.324 mg.; colloidal sulfur, 22 mg.	Wm. P. Poythress & Co., Inc.
Aqualin-plus, children	Suppository: Pentobarbital sodium, ½ gr.; theophylline, 1½ gr.	The Wm. A. Webster Co.
Aqualin-plus No. 1	Suppository: Pentobarbital sodium, ¾ gr.; theophylline, 3½ gr.	Do.
Aqualin-plus No. 2	Suppository: Pentobarbital sodium, 1½ gr.; theophylline, 7½ gr.	Do.
Aqualin-plus No. 2A	Suppository: Pentobarbital sodium, ¾ gr.; theophylline, 7½ gr.	Do.
Asmahar	Tablet: Butabarbital, 30 mg.; ephedrine sulfate, 25 mg.; theophylline hydroxide, 130 mg.	The Blue Line Chemical Co.
Astracol	Tablet: Butabarbital, 15 mg.; aminophylline, 180 mg.; phenylpropanolamine hydrochloride, 25 mg.; chlorpheniramine maleate, 2 mg.; aluminum hydroxide gel, dried, 60 mg.; magnesium trisilicate, 60 mg.	The Vale Chemical Co., Inc.
Asperase, modified with phenobarbital.	Tablet: Phenobarbital, 0.008 gm.; acetylsalicylic acid, 0.5 gm.	P. J. Noyes Co.
Atropal	Tablet: Phenobarbital, ⅓ gr.; atropine sulfate, 1/200 gr.; magnesium trisilicate, 2½ gr.; aluminum hydroxide gel, dried, 2½ gr.	Mallinckrodt Chemical Works.
Atrosilital	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.; magnesium trisilicate, 0.5 gm.; saccharin sodium, 0.12 mg.	The Zemmer Co.
Banthine with phenobarbital	Tablet: Phenobarbital, 15 mg.; methantheline bromide, 50 mg.	G. D. Searle & Co.
Barbatro No. 1	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.	The S. E. Massengill Co.
Barbatro No. 2	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.25 mg.	Do.
Barbeloid	Tablet: Amobarbital sodium, 20 mg.; hyoscyamine sulfate, 0.125 mg.; hyoscine hydrobromide, 0.007 mg.; homatropine methylbromide, 0.5 mg.	The Vale Chemical Co., Inc.
Barbidonna elixir	Elixir (5 cc.): Phenobarbital, 16 mg.; hyoscyamine sulfate, 0.1286 mg.; atropine sulfate, 0.0250 mg.; scopolamine hydrobromide, 0.0074 mg.	Mallinckrodt Chemical Works.
Barbidonna tablets	Tablet: Phenobarbital, 16 mg.; hyoscyamine sulfate, 0.1286 mg.; atropine sulfate, 0.0250 mg.; scopolamine hydrobromide, 0.0074 mg.	Do.
Barboma elixir	Elixir (1/30 cc.): Phenobarbital, 0.4 gm.; homatropine methylbromide, 33.8 mg.	The Blue Line Chemical Co.
Barboma tablets	Tablet: Phenobarbital, ¼ gr.; homatropine methylbromide, 1/33 gr.	Do.
Bardase	Tablet or elixir (4 cc.): Phenobarbital, 16.2 mg.; hyoscyamine sulfate, 0.1 mg.; hyoscine hydrobromide, 0.007 mg.; atropine, 0.020 mg.; Taka-Diastase, 162.0 mg.	Parke, Davis & Co.
Bar-Don elixir	Elixir (30 cc.): Phenobarbital, 100 mg.; hyoscyamine hydrobromide, 0.60 mg.; hyoscine hydrobromide, 0.042 mg.; atropine sulfate, 0.12 mg.	Warren-Teed Pharmaceuticals Inc.
Bar-Don tablets	Tablet: Phenobarbital, 16.670 mg.; hyoscyamine hydrobromide, 0.10 mg.; hyoscine hydrobromide, 0.007 mg.; atropine sulfate 0.020 mg.	Do.

Trade name or other designation	Composition	Manufacturer or supplier
Belap No. 0	Tablet: Phenobarbital, 8 mg.; belladonna extract, 8 mg.	Hasek Laboratories, Inc.
Belap No. 1	Tablet: Phenobarbital, 15 mg.; belladonna extract, 8 mg.	Do.
Belap Ty-Med	Tablet: Amobarbital, 30 mg.; homatropine methylbromide, 7.5 mg.	Do.
Belladenal	Tablet: Phenobarbital, 30 mg.; bellafoline, 0.25 mg.	Sandoz Pharmaceuticals.
Do	Elixir (15 cc.): Phenobarbital, 15.6 mg.; bellafoline, 0.078 mg.	Do.
Bellatol elixir	Elixir (5 cc.): Butabarbital sodium, 20 mg.; tincture belladonna, 0.83 cc.	The Zemmer Co.
Bellergal	Tablet: Phenobarbital, 20 mg.; ergotamine tartrate, 0.3 mg.; levorotatory alkaloids of belladonna, 0.1 mg.	Sandoz Pharmaceuticals.
Do	Tablet: Phenobarbital, 40 mg.; ergotamine tartrate, 0.6 mg.; levorotatory alkaloids of belladonna, 0.2 mg.	Do.
Beplete with belladonna elixir	Elixir (4 cc): Phenobarbital, 15 mg.; vitamin B_1, 1.5 mg.; vitamin B_2, 1 mg.; vitamin B_6, 0.33 mg.; vitamin B_{12}, 1.66 mg.; niacinamide, 10 mg.; pantothenol, 0.2 mg.; belladonna alkaloids, 0.2 mg.	Wyeth Laboratories.
Bexadonna	Tablet: Phenobarbital, 16 mg.; homatropine methylbromide, 10 mg.; hyoscine hydrobromide, 0.0065 mg.; hyoscyamine sulfate, 0.1 mg.	Bexar Pharmaceuticals.
Bilamide	Tablet: Phenobarbital, ¼ gr.; dried ox bile, 2 gr.; dehydrocholic acid, 2 gr.; homatropine methylbromide, 1/48 gr.	Norgine Laboratories, Inc.
Binitrin	Tablet: Butabarbital sodium, 15.0 mg.; nitroglycerin, 0.3 mg.; pentaerythritol tetranitrate, 10.1 mg.	The Vale Chemical Co., Inc.
Biosatphen	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.; bismuth subnitrate, 120 mg.; cerium oxalate, 120 mg.	The Zemmer Co.
Bismuth, belladonna, and phenobarbital.	Capsule: Phenobarbital, ¼ gr.; bismuth subgallate, 5 gr.; extract belladonna leaf, ½ gr.	The Bernard Co.
Buffadyne A-S	Tablet: Amobarbital, 15 mg.; aspirin, 300 mg.; phenacetin, 150 mg.; caffeine, 30 mg.; homatropine methylbromide, 2.5 mg.; aluminum hydroxide gel, 75 mg.; magnesium hydroxide, 45 mg.	Lemmon Pharmacal Co.
Buffadyne with barbiturates	Tablet: Secobarbital sodium, 8 mg.; amobarbital, 8 mg.; aspirin, 300 mg.; phenacetin, 150 mg.; caffeine, 30 mg.; aluminum hydroxide gel, 75 mg.; magnesium hydroxide, 45 mg.	Do.
Bunesia	Tablet: Butabarbital sodium, 10 mg.; homatropine methylbromide, 2.5 mg.; magnesium hydroxide, 300 mg.	McNeil Laboratories, Inc.
Buren	Tablet: Butabarbital, 15 mg.; phenazopyridine hydrochloride, 150 mg.; scopolamine hydrobromide, 0.0065 mg.; atropine sulfate, 0.0194 mg.; hyoscyamine sulfate, 0.1037 mg.	B. F. Ascher & Co., Inc.
Burrinem	Tablet: Butabarbital sodium, 15 mg.; reserpine, 0.1 mg.; rutin, 20 mg.; mannitol hexanitrate, 30 mg.	The Zemmer Co.
Butabarbital and hyoscyamine sulfate.	Tablet of elixir (5 cc.): Butabarbital, 15 mg.; hyoscyamine sulfate, 0.125 mg.	McNeil Laboratories, Inc.
Do	Capsule: Butabarbital, 45 mg.; hyoscyamine sulfate, 0.375 mg.	Do.
Butibel	Tablet or elixir (5 cc.): Butabarbital sodium, 15 mg.; belladonna extract, 15 mg. (hyoscyamine sulfate, 0.138 mg.; hyoscine hydrobromide, 0.027 mg.; atropine sulfate, 0.067 mg.).	McNeil Laboratories, Inc.
Butibel R-A	Tablet: Butabarbital sodium, 30 mg.; belladonna extract, 30 mg.	Do.
Butibel-gel suspension	Suspension (15 cc.): Butabarbital sodium, 7.5 mg.; belladonna extract, 7.5 mg. (total alkaloids 0.187 mg.); activated attapulgite, 1.5 mg.; pectin, 75 mg.	Do.
Butibel-gel tablets	Tablet: Butabarbital sodium, 7.5 mg.; belladonna extract, 7.5 mg. (total alkaloids 0.0935 mg.); activated attapulgite, 300 mg.; pectin, 45 mg.	Do.

Trade name or other designation	Composition	Manufacturer or supplier
Butibel-Zyme	Tablet: Butabarbital sodium, 15 mg.; belladonna extract, 15 mg. (total alkaloids 0.187 mg.); proteolytic enzyme standardized, 10 mg.; amylolytic enzyme standardized, 20 mg.; cellulolytic enzyme standardized, 5 mg.; lipolytic enzyme standardized, 100 mg.; iron ox bile (45% cholic acid), 30 mg.	Do.
Butigetic	Tablet: Butabarbital sodium, 15 mg.; acetaminophen, 200 mg.; phenacetin, 150 mg.; caffeine, 30 mg.	Do.
Cafergot P-B	Tablet: Phenobarbital sodium, 30 mg.; ergotamine tartrate, 1 mg.; caffeine, 100 mg.; levorotatory alkaloids of belladonna, 0.125 mg.	Sandoz Pharmaceuticals.
Do	Suppository: Pentobarbital, 60 mg.; ergotamine tartrate, 2 mg.; caffeine, 100 mg.; levorotatory alkaloids of belladonna, 0.25 mg.	Do.
Cal-Ma-Phen	Tablet: Phenobarbital, ¼ gr.; calcium-carbonate, 5 gr.; magnesium hydroxide, 5 gr.; atropine sulfate, 1/150 gr.	Physicians Supply Co.
Cantil with phenobarbital	Tablet: Phenobarbital, 16 mg.; mepenzolate bromide, 25 mg.	Lakeside Laboratories, Inc.
Carbonates No. 3 with phenobarbital and atropine.	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.11 mg.; calcium carbonate, 224 mg.; magnesium carbonate, 160 mg.; bismuth subcarbonate, 32 mg.	P. J. Noyes Co.
Cardalin-Phen	Tablet: Phenobarbital, ¼ gr.; aminophylline, 5 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Mallinckrodt Chemical Works.
Cardilate-P	Tablet: Phenobarbital, 15 mg.; erythrityl tetranitrate, 10 mg.	Burroughs Wellcome & Co. (U.S.A.) Inc.
Cholarsee	Tablet: Pentobarbital, 27.5 mg.; oxtriphylline, 200 mg.; racephedrine, 20 mg.	Warner-Chilcott Laboratories.
Co-Elorine 25	Capsule: Amobarbital, 8mg.; tricyclamol chloride, 25 mg.	Eli Lilly and Co.
Co-Elorine 100	Capsule: Amobarbital, 16 mg.; tricyclamol chloride, 100 mg.	Do.
Cold Preparation, special	Tablet: Phenobarbital, 8.1 mg.; chlorpheniramine maleate, 2 mg.; pseudoephedrine hydrochloride, 60 mg.; salicylamide, powder, 300 mg.	Knight Pharmacal Co.
Covadil	Tablet: Butabarbital sodium, 30 mg.; pentaerythritol tetranitrate, 15 mg.	The Blue Line Chemical Co.
Dactil with phenobarbital	Tablet: Phenobarbital, 16 mg.; piperidolate hydrochloride, 50 mg.	Lakeside Laboratories, Inc.
Dalnite	Tablet: Pentobarbital sodium, ¼ gr. aminophylline, 3 gr.; ephedrine hydrochloride, ¼ gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Mallinckrodt Chemical Works.
Dalnite-KI	Tablet: Phenobarbital, ¼ gr.; aminophylline, 3 gr.; ephedrine hydrochloride, ¼ gr.; potassium iodide, 5 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Do.
Dalnite Night	Tablet: Phenobarbital, ½ gr.; pentobarbital sodium, ½ gr.; aminophylline, 4 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Do.
Darleon PB	Tablet: Phenobarbital, 15 mg.; oxyphencyclimine hydrochloride, 6 mg.	Pfizer Laboratories.
Distraegus	Tablet: Diallylbarbituric acid, ¼ gr.; nitroglycerin, 1/150 gr.; sodium nitrite, 1 gr.; tincture crataegus, 2 minims.	Buffington's, Inc.
Dis-Tropine	Tablet: Diallylbarbituric acid, ¼ gr.; atropine sulfate, 1/200 gr.; magnesium carbonate, 2½ gr.; calcium carbonate, 3½ gr.; bismuth subcarbonate, 1 gr.	Do.
Dilantin with phenobarbital	Capsule: Phenobarbital, ¼ gr.; diphenylhydantoin sodium, 0.1 gm.	Parke, Davis & Co.
Do	Capsule: Phenobarbital, ½ gr.; diphenylhydantoin sodium, 0.1 gm.	Do.
Dolonil	Tablet: Butabarbital, 15 mg.; phenazopyridine hydrochloride, 150 mg.; hyoscyamine hydrobromide, 0.3 mg.	Warner-Chilcott Laboratories.
Donabarb	Tablet: Phenobarbital, ¼ gr.; powder extract belladonna, ¼ gr.	Paul B. Elder Co., Inc.
Donaphen, new special donaphen	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.024 mg.; scopolamine hydrobromide, 0.0072 mg.; hyoscyamine hydrobromide, 0.128 mg.	Burt Krotz Co.
Donna-Sed elixir	Elixir (5 cc.): Phenobarbital, 16.2 mg.; hyoscyamine hydrobromide, 0.1037 mg.; atropine sulfate, 0.0194 mg.; hyoscine hydrobromide, 0.0065 mg.	North American Pharmacal, Inc.
Donnasep	Tablet: Phenobarbital, 8.1 mg.; phenazopyridine hydrochloride, 50.0 mg.; methenamine mandelate, 500 mg.; hyoscyamine sulfate, 0.0519 mg.; atropine sulfate, 0.0097 mg.; hyoscine hydrobromide, 0.0033 mg.	A. H. Robins Co., Inc.
Donphen	Tablet: Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1 mg.; atropine sulfate, 0.02 mg.; scopolamine hydrobromide, 8 µg.	Lemmon Pharmacal Co.
Dormital-HM	Tablet: Phenobarbital, ¼ gr.; homatropine methylbromide, 1/144 gr.; strontium bromide, 1 gr.	Buffington's Inc.
Dynapin with phenobarbital	Tablet: Phenobarbital, 15 mg.; nitroglycerin, 0.5 mg.; pentaerythritol tetranitrate, 15 mg.	Key Pharmacal Co.
Ehnaloin with phenobarbital	Capsule: Phenobarbital, 15 mg.; diphenylhydantoin, 1½ gr.	Paul B. Elder Co., Inc.
Ephedrine and sodium phenobarbital.	Tablet: Sodium phenobarbital, ¼ gr.; ephedrine sulfate, 1/24 gr.	The Vale Chemical Co., Inc.
Ephedrine sulfate and phenobarbital.	Tablet: Phenobarbital, 15 mg.; ephedrine sulfate, 25 mg.	The Zemmer Co.
Ephedrine with phenobarbital	Tablet: Phenobarbital, ¼ gr.; ephedrine sulfate, 1/24 gr.	P. J. Noyes Co.
Ercafital	Tablet: Phenobarbital, 7.5 mg.; ergotamine tartrate, 0.5 mg.; caffeine, 60 mg.	The Blue Line Chemical Co.
Ethrava-trate	Tablet: Mephobarbital, 16 mg.; pentaerythrityl tetranitrate, 20 mg.; ethaverine hydrochloride, 30 mg.	North American Pharmacal, Inc.
En-Phed-Amin	Tablet: Phenobarbital, 30 mg.; aminophylline, 0.1 gm.; ephedrine sulfate, 30 mg.; extract euphorbia, 0.1 gm.	Warren-Teed Pharmaceuticals Inc.
En-Phed-Ital	Tablet: Phenobarbital sodium, 30 mg.; ephedrine sulfate, 30 mg.; extract euphorbia, 0.12 gm.	Do.
Fensobel	Tablet: Phenobarbital, 8.1 mg.; belladonna extract, 2.95 mg.; aluminum hydrochloride gel, dried, 63 mg.; magnesium trisilicate, 63 mg.; bismuth subcarbonate, 32.5 mg.; magnesium carbonate, 252 mg.; precipitated calcium carbonate, 303.5 mg.; malt diastase, 12.5 mg.; peppermint oil, 3 mg.	United States Vitamin & Pharmaceutical Corp.
Franol	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine hydrochloride, 32 mg.	Winthrop Laboratories.
Homechol	Tablet: Pentobarbital sodium, 8.0 mg.; homatropine methylbromide, 2.5 mg.; dehydrocholic acid, 60.0 mg.; ox bile extract, 150.0 mg.	Lemmon Pharmacal Co.
Homopent	Tablet: Pentobarbital sodium, 15 mg.; homatropine methylbromide, 2.5 mg.; magnesium trisilicate, 300 mg.	Lemmon Pharmacal Co.
H-P-A (modified)	Tablet: Phenobarbital, ½ gr.; aspirin, 5 gr.; extract hyoscyamus, ½ gr.	Paine Drug Co.
Hybephen	Tablet: Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1277 mg.; atropine sulfate, 0.0233 mg.; hyoscine hydrobromide, 0.0094 mg.	The S. E. Massengill Co.
Hybephen elixir	Elixir (5 cc.): Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1277 mg.; atropine sulfate, 0.0233 mg.; hyoscine hydrobromide, 0.0094 mg.	Do.
Hydrochol plus	Tablet: Amobarbital, 15 mg.; dehydrocholic acid, 200 mg.; scopolamine methylnitrate, 0.5 mg.; ox bile desiccated, 50 mg.	Paul B. Elder Co., Inc.
Hytrona antispasmodic elixir	Elixir (5 cc.): Phenobarbital, 16 mg.; belladonna alkaloids, 0.2 mg.	Pitman-Moore.
Hytrona antispasmodic tablets	Tablet: Phenobarbital, 16 mg.; belladonna alkaloids, 0.2 mg.	Do.
Hocalm	Tablet: Methobarbital, 30 mg.; methscopolamine nitrate, 2.5 mg.; d-calcium pantothenate, 25 mg.	Warren-Teed Pharmaceuticals Inc.
Isordil with phenobarbital	Tablet: Phenobarbital, 15 mg.; isosorbide dinitrate, 10 mg.	Ives Laboratories Inc.
Isuprenol	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine, 32 mg.; isoproterenol hydrochloride, 10 mg.	Winthrop Laboratories.
Isuprenol, mild	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine, 32 mg.; isoproterenol hydrochloride, 5 mg.	Do.

Trade name or other designation	Composition	Manufacturer or supplier
Isuprel compound elixir	Elixir (15 cc.); Phenobarbital, 6 mg.; isoproterenol hydrochloride, 2.5 mg.; ephedrine sulfate, 12 mg.; theophylline, 48 mg.; potassium iodide, 150 mg.	Do.
Kaphebel	Tablet: Phenobarbital, 1/3 gr.; belladonna root, 1/4 gr.; kaolin colloidal, 7 1/2 gr.	Paul B. Elder Co., Inc.
Kaumodic	Tablet: Pentobarbital, 8 mg.; methscopolamine nitrate, 2 mg.; cellulase, 9 mg.; pancrestin, 500 mg.; glutamic acid hydrochloride, 200 mg.; ox bile extract, 100 mg.; pepsin, 150 mg.	Dorsey Laboratories.
Kavatrate	Tablet: Phenobarbital sodium, 1/4 gr.; veratrum veride, 1/4 gr.; mistletoe, 1/6 gr.; hawthorn tincture, 30 minims; sodium nitrite, 1 gr.	Key Pharmacal Co.
Kie with phenobarbital	Tablet: Phenobarbital, 16 mg.; potassium iodide 400 mg.; ephedrine sulfate, 24 mg.	Laser Inc.
Klophyllin	Tablet: Phenobarbital, 15 mg.; aminophyllin, 130 mg.; potassium iodide, 125 mg.	G. D. Searle & Co.
Luftodil suspension	Suspension (5 cc.): Phenobarbital, 8 mg.; theophylline, 50 mg.; ephedrine hydrochloride, 12 mg.; glyceryl guaiacolate, 100 mg.	Mallinckrodt Chemical Works.
Luftodil tablets	Tablet: Phenobarbital, 16 mg.; theophylline, 100 mg.; ephedrine hydrochloride, 24 mg.; glyceryl guaiacolate, 200 mg.	Do.
Lufyllin-EP	Tablet: Phenobarbital, 16 mg.; lufyllin (dyphylline), 100 mg.; ephedrine hydrochloride; 16 mg.	Do.
Magnesium hydroxide-phenobarbital compound.	Tablet: Phenobarbital sodium, 15 mg.; magnesium hydroxide, 300 mg.; atropine sulfate with aromatics, 0.12 mg.	McNeil Laboratories, Inc.
Malgiyn compound	Tablet or suspension (5 cc.): Phenobarbital, 16.2 mg.; belladonna alkaloids, 0.162 mg.; dihydroxy aluminum aminoacetate, 0.5 gm.	Brayten Pharmaceutical Co.
Mannaphen	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.	The Vale Chemical Co., Inc.
Mannaphen with rutin	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.; rutin, 20 mg.	Do.
Mannitol hexanitrate with phenobarbital.	Tablet: Phenobarbital, 1/4 gr.; mannitol hexanitrate, 1/6 gr.	P. J. Noyes Co.
Do	Tablet: Phenobarbital, 1/4 gr.; mannitol hexanitrate, 1/6 gr.	The Blue Line Chemical Co.
Maxitol	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 15 mg.; rutin, 15 mg.; ascorbic acid, 15 mg.	Burt Krone Co.
Meprane phenobarbital	Tablet: Phenobarbital, 16 mg.; promethestrol dipropionate, 1 mg.	Reed & Carnrick.
Mesopin-PB	Tablet or elixir (5 cc.): Phenobarbital, 15 mg.; homatropine methylbromide, 5 mg.	Endo Laboratories Inc.
Metamine with butabarbital	Tablet: Butabarbital, 16.2 mg.; trolnitrate phosphate, 2 mg.	Pfizer Laboratories.
Do	Tablet: Butabarbital, 48.6 mg.; trolnitrate phosphate, 10 mg.	Do.
Mezal	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.	The S. E. Massengill Co.
Milprem-200	Tablet: Meprobamate 200 mg. conjugated estrogens—equine 0.4 mg.	Wallace Pharmaceuticals.
Milprem-100	Tablet: Meprobamate 400 mg. conjugated estrogens—equine 0.4 mg.	Do.
Milpath-200	Tablet: Meprobamate 200 mg. tridihexethyl chloride, 25 mg.	Do.
Milpath-100	Tablet: Meprobamate 400 mg. tridihexethyl chloride, 25 mg.	Do.
Miltrate-10	Tablet: Meprobamate 200 mg. pentaerythritol tetranitrate, 10 mg.	Do.
Miltrate-20	Tablet: Meprobamate 200 mg. pentaerythritol tetranitrate, 20 mg.	Do.
Monomeb	Tablet: Mephobarbital, 32 mg.; penthienate bromide, 5 mg.	Winthrop Laboratories.
Mudrane	Tablet: Phenobarbital, 21 mg.; potassium iodide, 195 mg.; aminophylline, 130 mg.; ephedrine hydrochloride, 16 mg.	Wm. P. Poythress & Co., Inc.
Mudrane G G elixir	Elixir (5 cc.): Phenobarbital, 5.4 mg.; theophylline 20 mg.; ephedrine hydrochloride, 4 mg.; glyceryl guaiacolate, 26 mg.	Do.
Nactisol	Tablet: Butabarbital sodium, 15 mg.; poldine methylsulfate, 4 mg.	McNeil Laboratories, Inc.

Trade name or other designation	Composition	Manufacturer or supplier
Natrona compound	Tablet: Phenobarbital, 15 mg.; extract hawthorn berries, 30 mg.; extract mistletoe, 15 mg.; sodium nitrite, 60 mg.; sodium bicarbonate, 0.2 gm.	The Zemmer Co.
Neocholan	Tablet: Phenobarbital, 8 mg.; dehydrocholic acid, 250 mg.; bile extract, 15 mg.; homatropine methylbromide, 1.2 mg.	Pitman-Moore.
Nergestic	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.10 mg.; magnesium trisilicate, 0.5 gm.	The S. E. Massengill Co.
Nitrased	Tablet: Secobarbital, 15 mg.; nitroglycerin, 0.4 mg.; pentaerythrityl tetranitrate, 15 mg.	Lemmon Pharmacal Co.
Nophesan tablets	Tablet: Phenobarbital, 8 mg.; acetylsalicylic acid, 300 mg.	P. J. Noyes Co.
Novalene	Tablet: Phenobarbital, 16 mg.; ephedrine sulfate, 24 mg.; potassium iodide, 162 mg.; calcium lactate, 162 mg.	Lemmon Pharmacal Co.
Ozsorbil-PB	Capsule: Phenobarbital, 7.5 mg.; belladonna extract, 7.5 mg.; dehydrocholic acid, 32 mg.; desoxycholic acid, 32 mg.; ox bile extract, 65 mg.; sorbitan mono-oleate, 180 mg.; oleic acid, 180 mg.	Ives Laboratories, Inc.
Paminal elixir	Elixir (5 cc.): Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	The Upjohn Co.
Pamine PB elixir	Elixir (5 cc.): Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	Do.
Pamine PB, half strength	Tablet: Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	Do.
Pediatric piptal antipyretic	Solution (0.6 cc.): Phenobarbital, 3 mg.; pipenzolate bromide, 5 mg.; acetaminophen, 60 mg.	Lakeside Laboratories, Inc.
Pedatric piptal with phenobarbital	Solution (0.5 cc.): Phenobarbital, 3 mg.; pipenzolate bromide, 2 mg.	Do.
Penocetylon	Tablet: Phenobarbital, 1/4 gr.; acetylsalicylic acid, 5 gr.	Paul B. Elder Co., Inc.
Pentaerythrityl tetranitrate with phenobarbital.	Tablet: Phenobarbital, 16 mg.; pentaerythrityl tetranitrate, 10 mg.	P. J. Noyes Co.
Do	Tablet: Phenobarbital, 16 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Pentratrol with phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	North American Pharmacal Co.
Pentraline	Tablet: Butabarbital sodium, 10 mg.; reserpine, 0.05 mg.; pentaerythrityl tetranitrate, 10 mg.	McNeil Laboratories, Inc.
Perbuzem	Tablet: Butabarbital sodium, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	The Zemmer Co.
Peribar L-A No. 1	Tablet: Phenobarbital, 48.6 mg.; pentaerythrityl tetranitrate, 30 mg.	Whittier Laboratories, Inc.
Peritrate with phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	Warner-Chilcott.
Do	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Peritrate with phenobarbital SA	Tablet: Phenobarbital, 45 mg.; pentaerythrityl tetranitrate, 80 mg.	Do.
Phedorine	Tablet: Diallylbarbituric acid, 16 mg.; extract stramonium, 8 mg. (alkaloids 0.0015 gr.); ephedrine, 8 mg.; theophyline, 100 mg.	Buffington's, Inc.
Phenaphen plus	Tablet: Phenobarbital, 16.2 mg.; phenacetin, 194 mg.; aspirin, 162 mg.; hyoscyamine sulfate, 0.031 mg.; phenyramine maleate, 12.5 mg.; phenylephrine hydrochlorida, 10 mg.	A. H. Robins Co., Inc.
Phenobarbital and atropine	Tablet: Phenobarbital, 1/4 gr.; atropine sulfate, 1/100 gr.	The Blue Line Chemical Co.
Do	do	Meyers & Co.
Do	do	Paine Drug Co.
Do	Tablet: Phenobarbital, 1/4 gr.; atropine sulfate, 1/100 gr.	The Vale Chemical Co., Inc.
Phenobarbital with atropine sulfate.	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.	The Zemmer Co.
Phenobarbital with atropine sulfate No. 2.	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.	Do.
Phenobarbital and atropine sulfate.	Tablet: Phenobarbital, 1/4 gr.; atropine sulfate, 1/100 gr.	Buffington's Inc.
Phenobarbital and atropine No. 1	Tablet: Phenobarbital, 16 mg.; atropine sulfate, 0.13 mg.	Pitman-Moore.
Phenobarbital and atropine No. 2	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.65 mg.	Do.

Trade name or other designation	Composition	Manufacturer or supplier
Phenobarbital and atropine tablets	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 1/4000 gr.	P.J. Noyes Co.
Do	Tablet: Phenobarbital, 16 mg.; atropine sulfate, 1/200 gr.	Do.
Phenobarbital and atropine tablets No. 2.	Tablet: Phenobarbital, 1/4 gr.; atropine sulfate, 1/200 gr.	Do.
Phenobarbital and atropine tablets No. 3.	Tablet: Phenobarbital, 1/2 gr.; atropine sulfate, 1/200 gr.	Do.
Phenobarbital and belladonna	Tablet: Phenobarbital, 1/4 gr.; belladonna leaves 1/2 gr. (total alkaloids 0.0015 gr.).	The Vale Chemical Co., Inc.
Do	Tablet: Phenobarbital, 1/4 gr.; belladonna extract, 1/4 gr.	Paine Drug Co.
Do	Tablet: Phenobarbital, 16 mg.; belladonna extract, 8 mg.	Eli Lilly and Co.
Phenobarbital and belladonna No. 2.	Tablet: Phenobarbital, 1/4 gr.; belladonna extract, 1/4 gr. (alkaloids 0.00156 gr.)	The Upjohn Co.
Phenobarbital with mannitol hexanitrate.	Tablet: Phenobarbital, 7.5 mg., mannitol hexanitrate 15 mg.; ascorbic acid powder, 25 mg.; rutin, 25 mg.	Paul B. Elder Co., Inc. (Harold M. Harter, D.V.M.)
Phenobarbital and mannitol hexanitrate.	Tablet: Phenobarbital, 1/4 gr.; mannitol hexanitrate, 1/2 gr.	Meyer Drug & Surgical Supply Co.
Phenobarbital sodium atropine No. 1.	Tablet: Phenobarbital sodium, 8 mg.; atropine sulfate, 60 µg.	McNeil Laboratories, Inc.
Phenobarbital sodium atropine No. 2.	Tablet: Phenobarbital sodium, 15 mg.; atropine sulfate, 120 µg.	Do.
Phenobarbital sodium atropine No. 3.	Tablet: Phenobarbital sodium, 30 mg.; atropine sulfate, 200 µg.	Do.
Phenobarbital and sodium nitrite.	Tablet: Phenobarbital, 1/4 gr.; sodium nitrite, 1 gr.	P.J. Noyes Co.
Phenobarbital theocalcin	Tablet: Phenobarbital, 15 mg.; theobromine calcium salicylate, 0.5 gm.	Knoll Pharmaceutical Co.
Phenodonna tablets	Tablet: Phenobarbital, 1/4 gr.; tincture belladonna, 6 minims.	Flint Medical & Surgical Supply Co.
Phenodrox	Tablet: Phenobarbital, 1/4 gr.; atropine sulfate, 1/200 gr.; magnesium trisilicate, 4 gr.; aluminum hydroxide gel, dried, 4 gr.	North American Pharmacal Inc.
Phyldros	Tablet: Phenobarbital, 15 mg.; neothylline, 100 mg.; ephedrine sulfate, 25 mg.	Lemmon Pharmacal Co.
Piptal PHB elixir	Elixir (5cc.): Phenobarbital, 16 mg.; pipenzolate bromide 5 mg.	Lakeside Laboratories, Inc.
Piptal PHB tablets	Tablet: Phenobarbital, 16 mg.; pipenzolate bromide, 5 mg.	Do.
Prantal with phenobarbital	Tablet: Phenobarbital, 16 mg.; diphemanil methylsulfate, 100 mg.	Schering Corp.
Premarin with phenobarbital	Tablet: Phenobarbital 32 mg.; conjugated estrogense-equin, 6.626 mg.	Ayerst Laboratories.
Probanthine with phenobarbital	Tablet: Phenobarbital, 15 mg.; probanthine, 15 mg.	G. D. Searle & Co.
Probital	Tablet: Phenobarbital, 15 mg.; probanthine, 7.5 mg.	Do.
Propenite	Tablet: Phenobarbital sodium, 12 mg.; sodium nitrite, 60 mg.; hawthorn berries extract, 120 mg.; mistletoe extract, 60 mg.	The Zemmer Co.
Prydonnal Spansule	Capsule: Phenobarbital, 65 mg.; belladonna alkaloids, 0.4 mg. (hyoscyamine sulfate, 0.305 mg.; atropine sulfate, 0.06 mg.; scopolamine hydrobromide, 0.035 mg.).	Smith Kline & French Laboratories.
Quadrinal	Tablet: Phenobarbital, 24 mg.; ephedrine hydrochloride 24 mg.; theophylline calcium salicylate, 130 mg.; potassium iodide, 300 mg.	Knoll Pharmaceutical Co.
Do	Suspension (5 cc.): Phenobarbital, 12 mg.; ephedrine hydrochloride, 12 mg.; theophylline calcium salicylate, 65 mg.; potassium iodide 160 mg.	Do.
Quintrate with nitroglycerin and phenobarbital.	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.; nitroglycerin, 0.4 mg.	Paul B. Elder Co., Inc. (Glynn A. Beard).
Quintrate with phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	Do.
Do	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Robinul-PH	Tablet: Phenobarbital, 16.2 mg.; glycopyrrolate, 1.0 mg.	A. H. Robins Co., Inc.
Robinul-PH forte	Tablet: Phenobarbital, 16.2 mg.; glycopyrrolate, 2.0 mg.	Do.
Rubexatal	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 30 mg.; ascorbic acid, 10 mg.; rutin, 20 mg.	Lemmon Pharmacal Co.
Rutol	Tablet: Phenobarbital, 8.0 mg.; mannitol hexanitrate, 16 mg.; rutin, 16 mg.	Pitman-Moore.
Salisil with phenobarbital	Tablet: Phenobarbital, 1/4 gr.; acetylsalicylic acid, 5 gr.; magnesium trisilicate, 2 gr.	Paul B. Elder Co., Inc.
Selbella	Tablet: Phenobarbital, 1/3 gr.; aluminum hydroxide, 5 gr.; belladonna extract, 1/3 gr.	Wyeth Laboratories
Sed-Tens	Tablet (12 hr.): Amobarbital, 50 mg.; homatropine methylbromide, 7.5 mg.	Lemmon Pharmacal Co.
Sibena	Tablet: Butabarbital sodium, 16 mg.; simethicone, 25 mg.; belladonna extract, 16 mg. (total alkaloids 0.20 mg.).	Plough Laboratories, Inc.
Sodium nitrite with phenobarbital.	Tablet: Phenobarbital sodium, 1/3 gr.; sodium nitrite, 1 gr.; sodium bicarbonate, 2 gr.; hawthorn berries, fluid extract, 1/4 minim.	Paine Drug Co.
Do	Tablet: Phenobarbital, 1/2 gr.; sodium nitrite, 1 gr.	Buffalo Pharmaceutical Supply Corp.
Spasticol PB	Tablet: Phenobarbital, 15 mg.; homatropine methylbromide, 2.5 mg.	Key Pharmaceuticals, Inc.
Spastosed	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.13 mg.; calcium carbonate, 227 mg.; magnesium hydroxide, 162 mg.	North American Pharmacal, Inc.
Synirin	Tablet: Pentobarbital, 8 mg.; aspirin, 324 mg.	Wm. P. Poythress & Co., Inc.
TCS	Tablet: Phenobarbital, 16 mg.; theobromine salicylate, 0.4 gm., calcium salicylate, 0.06 gm.	Do.
Tedral-25	Tablet: Butabarbital 25 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Warner-Chilcott Laboratories.
Tedral S.A	Tablet: Phenobarbital, 25 mg.; theophylline, 180 mg.; ephedrine hydrochloride, 48 mg.	Do.
Tensodin	Tablet: Phenobarbital, 15 mg.; ethaverine hydrochloride, 30 mg.; theophylline calcium salicylate, 260 mg.	Knoll Pharmaceutical Co.
Tensophen	Tablet: Phenobarbital, 16 mg.; nitroglycerin, 0.26 mg.; sodium nitrite, 32 mg.; podophyllin, 1 mg.; extract beef bile, 16 mg.	P. J. Noyes Co.
Thedritem	Tablet: Phenobarbital, 8 mg.; theophylline, hydrous, 100 mg.; ephedrine hydrocloride, 25 mg.	The Zemmer Co.
Theobarb	Tablet: Phenobarbital, 32 mg.; theobromine, 325 mg.	Mallinckrodt Chemical Works.
Theobarb-R	Tablet: Phenobarbital, 10 mg.; reserpine, 0.1 mg.; theobromine, 324 mg.	Do.
Theobarb special	Tablet: Phenobarbital, 16 mg.; theobromine, 325 mg.	Do.
Theobromine and phenobarbital	Tablet: Phenobarbital, 16 mg.; theobromine, 0.3 gm.	P. J. Noyes Co.
Theobromine-phenobarbital	Tablet: Phenobarbital, 30 mg.; theobromine, 0.3 gm.	The S. E. Massengill Co.
Do	Tablet: Phenobarbital, 32 mg.; theobromine, 324 mg.	The Upjohn Co.
Theobromine-phenobarbital compound.	Tablet: Phenobarbital, 1/4 gr.; theobromine, 2 1/2 gr.; potassium iodide, 2 1/2 gr.; potassium bicarbonate, 2 gr.	Do.
Theobromine with phenobarbital No. 1.	Tablet: Phenobarbital, 15 mg.; theobromine, 324 mg.	Buffington's, Inc.
Theobromine and sodium acetate with phenobarbital.	Tablet: Phenobarbital, 1/4 gr.; theobromine and sodium acetate, 3 gr.	Paul B. Elder Co., Inc.
Theobromine sodium salicylate with phenobarbital.	Tablet: Phenobarbital, 15 mg.; theobromine sodium salicylate, 300 mg.	The Zemmer Co.
Theocardone No. 1	Tablet: Phenobarbital, 15 mg.; theobromine, 300 mg.	Haack Laborstories, Inc.
Theocardone No. 2	Tablet: Phenobarbital, 30 mg.; theobromine, 300 mg.	Do.
Theodide	Tablet: Phenobarbital, 1/4 gr.; potassium iodide, 2 1/2 gr.; theobromine sodium salicylate, 2 1/2 gr.	The Vale Chemical Co., Inc.
Theoglycinate with phenobarbital.	Tablet: Phenobarbital, 16 mg.; theophylline-sodium glycinate, 324 mg.	Brayten Pharmaceutical Co.
Theoglycinate with racephedrine and phenobarbital.	Tablet: Phenobarbital, 16 mg.; theophylline-sodium glycinate, 324 mg.; racephedrine hydrochloride, 24 mg.	Do.

Trade name or other designation	Composition	Manufacturer or supplier
Theoplaphen	Tablet: Phenobarbital, 15 mg.; theobromine sodium salicylate, 0.2 gm.; calcium lactate, 0.1 mg.	The S. E. Massengill Co.
Theominal	Tablet: Phenobarbital, 32 mg.; theobromine, 320 mg.	Winthrop Laboratories.
Theominal M	Tablet: Phenobarbital, 16 mg.; theobromine, 320 mg.	Do.
Theominal R S	Tablet: Phenobarbital, 16 mg.; theobromine, 320 mg.; alseroxylon, 1.5 mg.	Do.
Theophen	Tablet: Phenobarbital, ¾ gr.; theobromine sodium salicylate, 5 gr.; calcium carbonate, 2½ gr.	The Vale Chemical Co., Inc.
Theorate	Tablet: Phenobarbital, 16.2 mg.; theobromine, 324 mg.	Whittier Laboratories, Inc.
Thymodyne	Tablet: Phenobarbital, 32 mg.; theophylline anhydrous, 130 mg.; ephedrine sulfate, 24 mg.	P. J. Noyes Co.
Trocinate with phenobarbital	Tablet: Phenobarbital, 16 mg.; thiphenamil hydrochloride, 100 mg.	Wm. P. Poythress & Co., Inc.
Tricloid	Tablet: Phenobarbital, 16 mg.; tricyclamol chloride, 50 mg.	Burroughs Wellcome & Co.
Triophen	Tablet: Phenobarbital, ¼ gr.; astropinesulfate, 1/150 gr.; magnesium trisilicate, 7 gr.	The Vale Chemical Co., Inc.
Valpin-PB	Tablet or elixir (5 cc.): Phenobarbital, 8 mg.; anisotropine methylbromide, 10 mg.	Endo Laboratories Inc.
Vasorutin	Tablet: Diallylbarbituric acid, ¾ gr.; nitroglycerin, 1/250 gr.; sodium nitrite, 1 gr.; tincture crataegus, 2 minims; rutin, 20 mg.	Buffington's, Inc.
Veralzem	Tablet: Phenobarbital, 15 mg.; veratrum viride, 80 mg.; sodium nitrite, 60 mg.	The Zemmer Co.
Veratrite	Tablet: Phenobarbital, ¼ gr.; cryptenamine, 40 CSR (carotid sinus reflex) units; sodium nitrite, 1 gr.	Neisler Laboratories, Inc.
Veritag	Tablet: Phenobarbital, 16 mg.; veratrum viride, 40 mg.; sodium nitrite, 65 mg.	S. J. Tutag and Co.
Vertegus	Tablet: Phenobarbital, ¼ gr.; veratrum viride, ¼ gr.; sodium nitrite, 1 gr.; mistletoe, ½ gr.; hawthorn berries, ½ gr.	Burt Krone Co.
Veruphen	Tablet: Phenobarbital, 15 mg.; rutin, 20 mg.; veratrum viride, 15 mg.; sodium nitrite, 60 mg.	The Zemmer Co.
Viritin	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 30 mg.; veratrum viride alkaloids, 1.5 mg.; rutin, 20 mg.	Lemmon Pharmacal Co.
W-T	Powder (4 gm.): Phenobarbital, 15 mg.; belladonna extract, 10 mg. (0.12 mg. belladonna alkaloids); benzocaine, 15 mg.; calcium carbonate, 1.55 gm.; magnesium oxide, 0.5 gm.; aluminum hydroxide gel, dried, 60 mg.	Warren-Teed Pharmaceuticals Inc.
W-T	Tablet: Phenobarbital, 1/16 gr.; belladonna extract, 1/324 gr.; benzocaine, 1/16 gr.; calcium carbonate, 6 gr.; magnesium trisilicate, 3¾ gr.; aluminum hydroxide gel, dried, 2½ gr.; chlorophyll extract, 1%.	Do.
Xanlophen	Tablet: Phenobarbital, 16.2 mg.; theobromine, 162 mg.; ethylenediamine dihydriodide, 32.4 mg.	Pitman-Moore.
Zallegen compound	Tablet: Phenobarbital, 8 mg.; tocamphyl, 75 mg.; homatropine methylbromide, 2.5 mg.	The S. E. Massengill Co.
Zantrate	Tablet: Cyclopentenylallylbarbituric acid, ½ gr.; ephedrine sulfate, ¾ gr.; theophylline anhydrous, 2 gr.	The Upjohn Co.
Zem-Dab	Tablet: Butabarbital sodium, 16 mg.; dehydrocholic acid, 60 mg.; ox bile desiccated, 120 mg.; homatropine methylbromide, 2.5 mg.	The Zemmer Co.
No. 23	Tablet: Phenobarbital, ½ gr.; aminophylline, 3 gr.	Stayner Corp.
No. 35	Tablet: Phenobarbital, ½ gr.; aminophylline, 1.5 gr.; ephedrine sulfate, ¾ gr.	Do.
No. 36	Tablet: Pentabarbital sodium, ¾ gr.; ephedrine sulfate, ¾ gr.; aminophylline, 3 gr.	Do.
No. 65	Tablet: Phenobarbital, ¼ gr.; extract belladonna, ¼ gr.	Do.
No. 66	Tablet: Phenobarbital, ¼ gr.; extract belladonna, ¼ gr.	Do.
No. 75	Tablet: Phenobarbital, ¼ gr.; belladonna, ¼ gr.	Bariatric Corp.
No. 88	Tablet: Phenobarbital, ¼ gr.; aminophylline, 1.5 gr.	Stayner Corp.
No. 89	Tablet: Phenobarbital, ½ gr.; aminophylline, 1.5 gr.	Do.
No. 111	Tablet: Phenobarbital, ½ gr.; ephedrine sulfate, ¾ gr.	Do.
No. 136	Tablet: Phenobarbital, 30 mg.; homatropine methylbromide, 5 mg.	Do.
No. 643	Tablet: Phenobarbital, ¼ gr.; theophylline, 2 gr.; ephedrine hydrochloride, ¾ gr.	Do.
Rx. No. 4104	Tablet: Phenobarbital, ¼ gr.; calcium carbonate, 7½ gr.; magnesium oxide, 4 gr.; atropine sulfate, 1/200 gr.	The Zemmer Co.
Rx. No. 4105	Tablet: Phenobarbital, ¼ gr.; calcium carbonate, 10 gr.; atropine sulfate, 1/200 gr.	Do.
Rx. No. 4108	Capsule: Phenobarbital, ¼ gr.; atropine sulfate, 1/200 gr.; calcium carbonate, 6½ gr.; magnesium oxide, heavy, 2 gr.	Do.
Rx. No. 4123	Capsule: Phenobarbital, ¼ gr.; bismuth subgallate, 5 gr.; extract belladonna, ½ gr.	Do.
Rx. No. 4126	Capsule: Pentobarbital sodium, 15 mg.; extract belladonna, 10 mg.	Do.
Rx. No. 4143	Capsule: Phenobarbital, ¼ gr.; aminophylline, 1.5 gr.; potassium iodide, 1 gr.	Do.
Rx. No. 4152	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/200 gr.	Do.
Rx. No. 4155	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/1000 gr.; aluminum hydroxide gel, 3¾ gr.; kaolin, 3¾ gr.	Do.
Rx. No. 4170	Tablet: Phenobarbital, ½ gr.; atropine sulfate, 1/200 gr.; calcium carbonate, 10 gr.	Do.
Rx. No. 4184	Capsule: Sodium butabarbital, 15 mg.; belladonna extract, 15 mg.	Do.

HEARINGS

§ 308.41 Hearings generally.

In any case where the Director shall hold a hearing on the issuance, amendment, or repeal of rules pursuant to section 201 of the Act, the procedures for such hearing and accompanying proceedings shall be governed generally by the rulemaking procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by section 201 of the Act (21 U.S.C. 811), by §§ 308.42–308.51, and by §§ 316.41–316.67 of this chapter.

§ 308.42 Purpose of hearing.

If requested by any interested person after proceedings are initiated pursuant to § 308.44, the Director shall hold a hearing for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issuable pursuant to section 201(a) of the Act (21 U.S.C. 811(a)). Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

§ 308.43 Waiver or modification of Rules.

The Director or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

§ 308.44 Initiation of proceedings for rulemaking.

(a) Any interested person may submit a petition to initiate proceedings for the issuance, amendment, or repeal of any rule or regulation issuable pursuant to the provisions of section 201 of the Act.

(b) Petitions shall be submitted in quintuplicate to the Director in the following form:

_____
(Date)

DIRECTOR, BUREAU OF NARCOTICS
AND DANGEROUS DRUGS
Department of Justice,
Washington, D.C. 20537.

DEAR SIR: The undersigned_____ hereby petitions the Director to initiate proceedings for the issuance (amendment or repeal) of a rule or regulation pursuant to section 201 of the Controlled Substances Act.

Attached hereto and constituting a part of this petition are the following:

(A) The proposed rule in the form proposed by the petitioner. (If the petitioner seeks the amendment or repeal of an existing rule, the existing rule, together with a reference to the section in the Code of Federal Regulations where it appears, should be included.)

(B) A statement of the grounds which the petitioner relies for the issuance (amendment or repeal) of the rule. (Such grounds shall include a reasonably concise statement of the facts relied upon by the petitioner,

including a summary of any relevant medical or scientific evidence known to the petitioner.)

All notices to be sent regarding this petition should be addressed to:

(Name)

(Street Address)

(City and State)

Respectfully yours,

(Signature of petitioner)

(c) Within a reasonable period of time after the receipt of a petition, the Director shall notify the petitioner of his acceptance or nonacceptance of the petition, and if not accepted, the reason therefor. The Director need not accept a petition for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth so as to be readily understood. If the petitioner desires, he may amend the petition to meet the requirements of paragraph (b) of this section. If accepted for filing, a petition may be denied by the Director within a reasonable period of time thereafter if he finds the grounds upon which the petitioner relies are not sufficient to justify the initiation of proceedings.

(d) The Director shall, before initiating proceedings for the issuance, amendment, or repeal of any rule either to control a drug or other substance, or to transfer a drug or other substance from one schedule to another, or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation and the Secretary's recommendations as to whether such drug or other substance should be so controlled, transferred, or removed as a controlled substance. The recommendations of the Secretary to the Director shall be binding on the Director as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Director shall not control that drug or other substance.

(e) If the Director determines that the scientific and medical evaluation and recommendations of the Secretary and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or additional control over the drug or other substance, or substantial evidence that the drug or other substances should be subjected to lesser control or removed entirely from the schedules, he shall initiate proceedings for control, transfer, or removal as the case may be.

(f) If and when the Director determines to initiate proceedings, he shall publish in the FEDERAL REGISTER general notice of any proposed rule making to issue, amend, or repeal any rule pursuant to section 201 of the Act. Such published notice shall include a statement of the time, place, and nature of any hearings on the proposal in the event a hearing is requested pursuant to § 308.45. Such hearings may not be commenced until after the expiration of at least 30 days from the date the general notice is published in the FEDERAL REGISTER. Such published notice shall also include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule, and, in the discretion of the Director, a summary of the subjects and issues involved.

(g) The Director may permit any interested persons to file written comments on or objections to the proposal and shall designate in the notice of proposed rule making the time during which such filings may be made.

§ 308.45 Request for hearing or appearance; waiver.

(a) Any interested person desiring a hearing on a proposed rulemaking, shall, within 30 days after the date of publication of notice of the proposed rulemaking in the FEDERAL REGISTER, file with the Director a written request for a hearing in the form prescribed in § 316.47 of this chapter.

(b) Any interested person desiring to participate in a hearing pursuant to § 308.41 shall, within 30 days after the date of publication of the notice of hearing in the FEDERAL REGISTER, file with the Director a written notice of his intention to participate in such hearing in the form prescribed in § 316.48 of this chapter. Any person filing a request for a hearing need not also file a notice of appearance; the request for a hearing shall be deemed to be a notice of appearance.

(c) Any interested person may, within the period permitted for filing a request for a hearing, file with the Director a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(d) If any interested person fails to file a request for a hearing; or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

(e) If all interested persons waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Director may cancel the hearing, if scheduled, and issue his final order pursuant to § 308.48 without a hearing.

§ 308.46 Burden of proof.

At any hearing, the proponent for the issuance, amendment, or repeal of any rule or regulation shall have the burden of proof.

§ 308.47 Time and place of hearing.

The hearing will commence at the place and time designated in the notice of proposed rulemaking published in the FEDERAL REGISTER but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

§ 308.48 Final order.

As soon as practicable after the presiding officer has certified the record to the Director, the Director shall cause to be published in the FEDERAL REGISTER his order in the proceeding, which shall set forth the final rule and the findings of fact and conclusions of law upon which the rule is based. This order shall specify the date on which it shall take effect, which shall not be less than 30 days from the date of publication in the FEDERAL REGISTER unless the Director finds that conditions of public health or safety necessitate an earlier effective date, in which event the Director shall specify in the order his findings as to such conditions.

§ 308.49 Control required under international treaty.

Pursuant to section 201(d) of the Act (21 U.S.C. 811(d)), where control of a substance is required by U.S. obligations under international treaties, conventions, or protocols in effect on May 1, 1971, the Director shall issue and publish in the FEDERAL REGISTER an order controlling such substance under the schedule he deems most appropriate to carry out obligations. Issuance of such an order shall be without regard to the findings required by subsections 201(a) or 202(b) of the Act (21 U.S.C. 811(a) or 812(b)) and without regard to the procedures prescribed by § 308.41 or subsections 201 (a) and (b) of the Act (21 U.S.C. 811 (a) and (b)). An order controlling a substance shall become effective 30 days from the date of publication in the FEDERAL REGISTER, unless the Director finds that conditions of public health or safety necessitate an earlier effective date, in which event the Director shall specify in the order his findings as to such conditions.

§ 308.50 Control of immediate precursors.

Pursuant to section 201(e) of the Act (21 U.S.C. 811(e)), the Director may, without regard to the findings required by subsection 201(a) or 202(b) of the Act (21 U.S.C. 811(a) or 812(b)) and without regard to the procedures prescribed by § 308.41 or subsections 201 (a) and (b) of the Act (21 U.S.C. 811 (a) and (b)), issue and publish in the FEDERAL REGISTER an order controlling an immediate precursor. The order shall designate the schedule in which the immediate precursor is to be placed, which shall be the same schedule in which the controlled substance of which it is an immediate

precursor is placed or any other schedule with a higher numerical designation. An order controlling an immediate precursor shall become effective 30 days from the date of publication in the FEDERAL REGISTER, unless the Director finds that conditions of public health or safety necessitate an earlier effective date, in which event the Director shall specify in the order his findings as to such conditions.

§ 308.51 Pending proceedings.

All administrative proceedings pending before the Bureau on the effective date of this part, including the matter of listing chlordiazepoxide and its salts and diazepam as drugs subject to control under the Drug Abuse Control Amendments of 1965, shall be continued and brought to final determination in accord with the laws and regulations in effect prior to such effective date.

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Title 24—Housing and Urban Development

CHAPTER X—FEDERAL INSURANCE ADMINISTRATION, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

SUBCHAPTER B—NATIONAL FLOOD INSURANCE PROGRAM

PART 1914—AREAS ELIGIBLE FOR THE SALE OF INSURANCE

Status of Participating Communities

Section 1914.4 of Part 1914 of Subchapter B of Chapter X of Title 24 of the Code of Federal Regulations is amended by adding in alphabetical sequence a new entry to the table. In this entry, a complete chronology of effective dates appears for each listed community. Each date appearing in the last column of the table is followed by a designation which indicates whether the date signifies: (1) The effective date of the authorization of the sale of flood insurance in the area under the emergency or under the regular flood insurance program; (2) the effective date on which the community became ineligible for the sale of flood insurance because of its failure to submit land use and control measures as required pursuant to § 1909.24(a); or (3) the effective date of a community's formal reinstatement in the program pursuant to § 1909.24(b). The entry reads as follows:

§ 1914.4 Status of participating communities.

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State	County	Location	Map No.	State map repository	Local map repository	Effective date of authorization of sale of flood insurance for area
* * *	* * *	* * *	* * *	* * *	* * *	* * *
Alabama	Lowndes	Benton, Town of.	I 01 085 0315 01	Alabama Development Office, Office of State Planning, State Office Bldg., 501 Dexter Ave., Montgomery, AL 36104. Alabama Insurance Department, Room 453, Administrative Bldg., Montgomery, Ala. 36104.	Staggers Clinic, 117 Market St., Benton, AL 36785.	Feb. 25, 1972. Emergency. Apr. 6, 1973. Regular.
Do	Jefferson	Birmingham, City of.	----------	----------	----------	Mar. 30, 1973. Emergency.
Colorado	El Paso	Colorado Springs, City of.	----------	----------	----------	Do.
Connecticut	Litchfield	Deep River, Town of.	----------	----------	----------	Do.
Delaware	Sussex	Bethany Beach, Town of.	I 10 005 0020 01 I 10 005 0020 02	Division of Soil and Water Conservation, Department of Natural Resources and Environmental Control, Tatnall Bldg., Capital Complex, Dover, Del. 19901. Delaware Insurance Department, 21 The Green, Dover, DE 19901.	President of the Board of Commissioners, Town of Bethany Beach, Bethany Beach, Del. 19930.	Nov. 12, 1972. Emergency. Mar. 30, 1973. Regular.
Florida	Manatee	Holmes Beach, City of.	----------	----------	----------	July 10, 1970. Emergency. June 11, 1971. Regular. Sept. 15, 1972. Suspension. Mar. 26, 1973. Reinstated.
Illinois	Cook	LaGrange, Village of.	----------	----------	----------	Mar. 30, 1973. Emergency.
Do	Lake	Mundelein, Village of.	----------	----------	----------	Do.
Do	St. Clair	Unincorporated areas.	----------	----------	----------	Do.
Indiana	Dearborn	Aurora, City of	I 18 029 0230 01 through I 18 029 0230 04.	Division of Water, Department of Natural Resources, 608 State Office Bldg., Indianapolis, Ind. 46204. Indiana Insurance Department, 509 State Office Bldg., Indianapolis, Ind. 46204.	Aurora Planning Commission, Third and Main Sts., P.O. Box 158, Aurora, IN 47001.	Jan. 19, 1973. Emergency. Apr. 6, 1973. Regular.
Do	Elkhart	Goshen, City of	----------	----------	----------	Mar. 30, 1973. Emergency.
Do	Marion	Speedway, Town of.	----------	----------	----------	Do.
Kentucky	Harlan	Loyall, City of	I 21 095 2100 01	Division of Water, Kentucky Department of Natural Resources, Capitol Plaza Office Tower, Frankfort, Ky. 40601. Kentucky Insurance Department, Old Capitol Annex, Frankfort, Ky. 40601.	City Clerk's Office, City of Loyall, Loyall, Ky. 40854.	Dec. 3, 1971. Emergency. Apr. 6, 1973. Regular.
Do	Woodford	Unincorporated areas.	----------	----------	----------	Mar. 30, 1973. Emergency.
Maine	York	Saco, City of	----------	----------	----------	Do.
Maryland	Charles	Unincorporated areas.	----------	----------	----------	Do.
Massachusetts	Plymouth	Marion, Town of	I 25 023 0677 01 through I 25 023 0677 07	Division of Water Resources, Water Resources Commission, State Office Bldg., 100 Cambridge St., Boston, MA 02202. Massachusetts Division of Insurance, 100 Cambridge St., Boston, MA 02202.	The Town Hall, 2 Spring St., Marion, MA 02738.	Oct. 8, 1971. Emergency. Apr. 6, 1973. Regular.

State	County	Location	Map No.	State map repository	Local map repository	Effective date of authorization of sale of flood insurance for area
* * *	* * *	* * *	* * *	* * *	* * *	* * *
Michigan	Bay	Unincorporated Townships of Fraser, Garfield, Gibson, Kawkawlin only.				Mar. 30, 1973.
Do	do	Bangor, Township of.				Do.
Do	do	Bay City, City of				Do.
Do	do	Essexville, City of				Do.
Do	do	Frankenlust, Township of.				Do.
Do	do	Hampton, Township of.				Do.
New York	Cattaraugus	Allegany, Town of.				Do.
Do	do	Allegany, Village of.				Do.
Do	Cortland	Dryden, Village of.				Do.
Do	Monroe	Wheatland, Town of.				Do.
Do	Niagara	Youngstown, Village of.				Do.
Do	Ontario	Geneva, Town of				Do.
Do	Orleans	Kendall, Town of				Do.
Do	Wayne	Palmyra, Town of				Do.
Do	do	Sodus, Town of				Do.
Ohio	Delaware	Westerville, City of.				Do.
Do	Erie	Huron, City of				Do.
Do	Cuyahoga	Lakewood, City of.				Do.
Do	do	Merritt, Township of.				Do.
Do	do	Pinecoming, Township of.				Do.
Do	Kent	Grandville, City of.				Do.
Do	do	Kentwood, City of.				Do.
Do	Monroe	Estral Beach, Village of.				Do.
Do	Oakland	Farmington, Township of.				Do.
Do	do	West Bloomfield, Township of.				Do.
Do	Wayne	Grosse Pointe Woods, City of.				Do.
Do	do	Trenton, City of				Do.
Minnesota	Hennepin	Champlin, Village of.				Do.
Oregon	Tillamook	Tillamook, City of.				Do.
Pennsylvania	Berks	Lower Alsace, Township of.				Do.
Do	Blair	Hollidaysburg, Borough of.				Do.
Do	Centre	Bellefonte, Borough of.				Do.
Do	do	Haines, Township of.				Do.
Do	Chester	East Bradford, Township of.				Do.
Do	Dauphin	Hummelstown, Borough of.				Do.
Do	do	Londonderry, Township of.				Do.
Do	do	South Hanover, Township of.				Do.
Do	Juniata	Port Royal, Borough of.				Do.
Do	Lycoming	Armstrong, Township of.				Do.
Do	do	Wolf, Township of.				Do.
Do	Montgomery	Lower Providence, Township of.				Do.
Do	Northampton	Freemansburg, Borough of.				Do.
Do	Schuylkill	Blythe, Township of.				Do.
Rhode Island	Kent	Warwick, City of	I 44 003 0230 07 I 44 003 0230 08	Rhode Island Statewide Planning Program, 265 Melrose St., Providence, RI 02907. Rhode Island Insurance Division, 169 Weybosset St., Providence, RI 02903.	Department of City Plan, City Hall, Warwick, R.I. 02886.	June 19, 1970. Emergency. Apr. 6, 1973. Regular.

State	County	Location	Map No.	State map repository	Local map repository	Effective date of authorization of sale of flood insurance for area
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Texas	Potter and Randall	Amarillo, City of				Mar. 30, 1973.
Virginia	Shenandoah	Unincorporated areas.				Do.
Wisconsin	Iron	Hurley, City of	I 55 051 2230 01	Department of Natural Resources, P.O. Box 450, Madison, WI 53701. Wisconsin Insurance Department, 212 North Bassett St., Madison, WI 53703.	City Clerk's Office, City Hall, City of Hurley, Hurley, Wis. 54534.	May 28, 1971, Emergency. Apr. 6, 1973, Regular.
Do.	Outagamie	Appleton, City of	I 55 087 0170 01 I 55 087 0170 02	do.	Department of Planning and Development, City Hall, City of Appleton, Appleton, Wis. 54911.	Apr. 23, 1971, Emergency. Apr. 6, 1973, Regular.
Do.	Pierce	River Falls, City of.				Mar. 30, 1973. Emergency.

(National Flood Insurance Act of 1968 (title XIII of the Housing and Urban Development Act of 1968), effective Jan. 28, 1969 (33 FR 17804, Nov. 28, 1968), as amended (secs. 408–410, Public Law 91–152, Dec. 24, 1969), 42 U.S.C. 4001–4127; and Secretary's delegation of authority to Federal Insurance Administrator, 34 FR 2680, Feb. 27, 1969)

Issued: March 23, 1973.

GEORGE K. BERNSTEIN,
Federal Insurance Administrator.

[FR Doc.73-5863 Filed 3-29-73;8:45 am]

PART 1915—IDENTIFICATION OF SPECIAL HAZARD AREAS

List of Communities With Special Hazard Areas

The Federal Insurance Administrator finds that comments and public procedure and the use of delayed effective dates in identifying the areas of communities which have special flood or mudslide hazards, in accordance with 24 CFR Part 1915, would be contrary to the public interest. The purpose of such identifications is to guide new development away from areas threatened by flooding, a purpose which is accomplished pursuant to statute by denying subsidized flood insurance to structures thereafter built within such areas. The practice of issuing proposed identifications for comment or of delaying effective dates would tend to frustrate this purpose by permitting imprudent or unscrupulous builders to start construction within such hazardous areas before the official identification became final, thus increasing the communities' aggregate exposure to loss of life and property and the agency's financial exposure to flood losses, both of which are contrary to the statutory purposes of the program. Accordingly, the Department is not providing for public comment in issuing this amendment and it will become effective March 29, 1973. Section 1915.3 is amended by adding in alphabetical sequence a new entry to the table, which entry reads as follows:

§ 1915.3 List of communities with special hazard areas.

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State	County	Location	Map No.	State map repository	Local map repository	Effective date of identification of areas which have special flood hazards
* * *	* * *	* * *	* * *	* * *	* * *	* * *
Alabama	Lowndes	Benton, Town of.	H 01 085 0315 01	Alabama Development Office, Office of State Planning, State Office Bldg., 501 Dexter Ave., Montgomery, AL 36104. Alabama Insurance Department, Room 453, Administrative Bldg., Montgomery, Ala. 36104.	Staggers Clinic, 117 Market St., Benton, AL 36785.	Apr. 6, 1973.
Delaware	Sussex	Bethany Beach, Town of.	H 10 005 0020 01 H 10 005 0020 02	Division of Soil and Water Conservation, Department of Natural Resources and Environmental Control, Tatnall Bldg., Capital Complex, Dover, Del. 19901. Delaware Insurance Department, 21 The Green, Dover, DE 19901.	President of the Board of Commissioners, Town of Bethany Beach, Bethany Beach, Del. 19930.	Do.
Florida	Broward	Pembroke Pines, City of.	H 12 011 2408 01 H 12 011 2408 02	Department of Community Affairs, 309 Office Plaza, Tallahassee, Fla. 32301. State of Florida Insurance Department, Treasurer's Office, The Capitol, Tallahassee, Fla. 32304.	Office of the City Engineer, City Hall, City of Pembroke Pines, Pembroke Pines, Fla. 33023.	Do.
Illinois	Cook	Flossmoor, Village of.	H 17 031 3080 01 through H 17 031 3080 03.	Department of Local Government Affairs, 309 West Washington St., Chicago, IL 60606. Illinois Insurance Department, 525 West Jefferson St., Springfield, IL 62702.	Village Manager's Office, Village of Flossmoor, Flossmoor, Ill. 60422.	Do.
Indiana	Dearborn	Aurora, City of	H 18 029 0230 01 through H 18 029 0230 04.	Division of Water, Department of Natural Resources, 608 State Office Bldg., Indianapolis, Ind. 46204. Indiana Insurance Department, 509 State Office Bldg., Indianapolis, 46204.	Aurora Planning Commission, Third and Main Sts., P.O. Box 158, Aurora, IN 47001.	Do.
Kentucky	Harlan	Loyall, City of	H 21 095 2100 01	Division of Water, Kentucky Department of Natural Resources, Capitol Plaza Office Tower, Frankfort, Ky. 40601. Kentucky Insurance Department, Old Capitol Annex, Frankfort, Ky. 40601.	City Clerk's Office, City of Loyall, Loyall, Ky. 40854.	Do.