Inspections, Compliance, Enforcement, and Criminal Investigations

Gambro Dialysatoren, GmbH 9/4/09

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

SEP 4 2009

WARNING LETTER

VIA FEDERAL EXPRESS {AND FACSIMILE}

Heiko Zimmermann, Ph.D.
Sr. VP & Site Executive Manager

Gambro Dialysatoren, GmbH

Holger-Crafoord-Strasse 26

Hechingen, D-72379 Germany

Dear Dr. Zimmermann:

During an inspection of your firm located in Hechingen, Germany on May 4, 2009, through May 7, 2009, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures dialyzers for hemodialysis. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

Our inspection revealed that your devices are misbranded under section 502(t)(2) of the Act 21 U.S.C. 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. 360i, and 21 CFR Part 803 - Medical Device Reporting (MDR) regulation. Significant deviations include, but are not limited to, the following:

1. Failure to submit an MDR report within 30 days of receiving or otherwise becoming 803.50(a)(1).

For example, complaint #**(b)(6)** involves a device identified as the Polyflux 170 H, product code 103579, lot 6-4691-H-01. It was reported that the patient experienced dyspnea, nausea, cephalea, hypotension and paresthesias. As a result of these medical conditions, the patient was treated with hydrocortisone and a 0.9% saline solution. This sequence of events has been determined to meet the definition of a serious injury as that term is defined in 21 CFR 803.3 of Title 21 of the Code of Federal Regulations, because the injury or illness necessitated medical intervention to preclude permanent impairment of a body function or permanent damage

to a body structure.

The information in the complaint file indicates that your firm was in possession of information that reasonably suggests that one of your marketed devices may have caused or contributed to a serious injury. Your firm failed to submit an MDR report for this event to the within the 30-day timeframe as required by 21 CFR 803.50(a)(1). In fact, no MDR was filed.

2. Failure to submit an MDR report within 30 days of receiving or otherwise becoming aware of information, from any source, that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, as required by 21 CFR 803.50(a)(2).

For example:

a. Complaint # **(b)(6)** involves a device identified as the Polyflux 17 L, product code 102058, Lot 7-4075-H-01. It was reported that this device leaked at the upper arterial inlet, right below the lid.

Because the device is considered to be a life-sustaining device, this malfunction would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

The information in the complaint file indicates that your firm was in possession of information that reasonably suggests that one of your marketed devices may have malfunctioned and would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur. Your firm failed to submit an MDR report for this event to the FDA within the 30-day timeframe as required by 21 803.50(a)(2). In fact, no was filed.

b. Complaint #**(b)(6)** involves a device identified as the Polyflux 24 R, product code 104324, lot 7-3928-H-01. It was reported that this device experienced a blood leak and that a corrective action was taken to prevent the leaking. Because the device is considered to be a life-sustaining device, this malfunction would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

The information in the complaint file indicates that your firm was in possession of information that reasonably suggests that one of your marketed devices may have malfunctioned and would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur. Your firm failed to submit an MDR report for this event to the FDA within the 30-day timeframe as required by 21 CFR 803.50(a)(2). In fact, no MDR was filed.

c. Complaint #**(b)(6)** involves a device identified as the Polyflux 21 R, product code 100691, lot 8-3722-H-01. It was reported that this device blew up while the patient was being treated which resulted in the dialyzer leaking blood into the drain box and into the Hansen connectors. Because the device is considered to be a life-sustaining device, this malfunction would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

The information in the complaint file indicates that your firm was in possession of information that reasonably suggests that one of your marketed devices may have malfunctioned and would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur. Your firm failed to submit an MDR report for this event to the FDA within the 30-day timeframe as required by 21 CFR 803.50(a)(2). In fact no MDR was filed.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct

these violations may result in regulatory action, which may include detaining your devices without physical examination upon entry into the United Stales until the corrections are completed. Section 801(a) of the Act (21 U.S.C. 381(a)). Also, U.S. federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to: Paul F. Tilton, Branch Chief, Ob/Gyn, Gastroenterology, and Urologic Devices Branch, Division of Enforcement A, Office of Compliance, 10903 New Hampshire Avenue, WO66-3540, Silver Spring MO 20993. If you have any questions about the content of this letter please contact Mr. Tilton at (301) 796-5770.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter may be symptomatic of serious problems in your firm's manufacturing firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,

/S/

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health