DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-626/S-007

Heyl Chemisch-pharmazeutische Fabrik GmbH & Co. KG
c/ Heyltex Corporation
Attention: B. Simons-Wirth, Ph.D
Head of Quality Assurance
925 South Mason Road
Katy, TX 77450

Dear Dr. Simons-Wirth:

Please refer to your supplemental new drug application dated April 21, 2008, received April 25, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Radiogardase® (Prussian blue insoluble) Capsules.

We acknowledge receipt of your correspondence dated August 21, 2008.

This supplemental new drug application provides for a new 36 capsule-count packaging configuration that utilizes an HDPE bottle with a child-proof closure and a tamper-evident seal.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on April 21, 2008.

## CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels, except with the revisions noted below, as soon as they are available, but no more than 30 days after they are printed. These changes may also be reported in the annual report.

1. Modify "gm" to "g" to denote "gram" as per the commitment submitted via correspondence on August 21, 2008.
2. The NDC number should be moved to the top of the label and be more prominent to meet the intent of the regulation 21 CFR 207.35 (b)(3) and be consistent to most drug labels.

Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 21-626/S-007**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Althea Cuff, Regulatory Project Manager, at (301) 796-4061.

Sincerely,

*{See appended electronic signature page}*

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch 8, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Hasmukh Patel

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