DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-626/SCP-001

Heyl Chemisch-pharmazeutiche Fabrik GmbH & Co. KG
c/o Heyltex Corporation
Attention: Robert Martin, Vice President of Operations
925 South Mason Road
PMB# 242
Katy, TX 77450

Dear Mr. Martin:

Please refer to your supplemental new drug application dated February 6, 2004, received February 10, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Radiogardase™ (insoluble Prussian blue) 0.5gm capsules.

We acknowledge receipt of your submission dated February 23, 2004.

This "Changes Being Effected" supplemental new drug application provides for rebottling and relabeling of the (b)(4)packages to be purchas ed by the CDC with English-language labels and in compliance with the conditions approved by the FDA under the Radiogardase™ NDA.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 23, 2004.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Patricia A. Stewart, Regulatory Project Manager, at (301) 827-7510.

Sincerely,

{See appended electronic signature page}

Eldon E. Leutzinger, Ph.D.
Chemistry Team Leader
Division of Medical Imaging and
Radiopharmaceutical Drug Products
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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

/s/

Eldon Leutzinger
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