



NDA 17-836/SCS-008
ISO-TEX DIAGNOSTICS
Attention: Thomas J. Maloney, President
P.O. Box 909
Friendswood, Texas 77546

Dear Mr. Maloney:

Please refer to your supplemental new drug application dated February 12, 2003, received February 13, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for JEANATOPE (Iodinated I 125 Albumin Injection, USP).

We acknowledge receipt of your submissions dated March 1, April 13 and April 14, 2004.

This supplemental new drug application provides for adding the multiple dose vial strength of 3.7 megabecquerels (MBq) or 100 microcuries (μCi) with a radioactive concentration 10 $\mu\text{Ci/ml}$ (10 ml per vial) to the drug product.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below:

1. Under **Blood Volume Determination** section the sub headers should read:
B. Administration of Dose and; **C. Calculation of Blood**
2. Under **Radiation Dosimetry** section, in the last paragraph the word **doses** was replaced with **dosed**, this appears to be a clerical error if so please revise.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert submitted February 12, 2004, and immediate container and carton labels submitted February 12, 2004. These revisions are terms of the approval of this application(s).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-836/SCS-008." Approval of this submission by FDA is not required before the labeling is used.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Renee C. Tyson, Regulatory Project Manager, at (301) 827-1503.

Sincerely,

{See appended electronic signature page}

Eldon E. Leutzinger, Ph.D.
Chemistry Team Leader
Division of Medical Imaging and
Radiopharmaceutical Drug Products
HFD-160
DNDC II, Office of New Drug Chemistry

**This is a representation of an electronic record that was signed electronically and
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/s/

Eldon Leutzinger
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