



NDA 18-124/SCS-013

CIS-US, Inc.
Attention: Jeanne A. Fiore
Director, Regulatory Affairs/Quality Assurance
10 De Angelo Drive
Bedford, MA 01730

Dear Ms. Fiore:

Please refer to your supplemental new drug application dated August 20, 2003, received August 22, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AN-MDP (Kit for the Preparation of Technetium Tc99m Medronate for Injection).

We acknowledge receipt of your submissions dated October 31, November 6, December 29, 2003, July 2 and 16, November 8 and 15, December 3, 2004, and April 14 and 18, 2005.

Your submission of December 3, 2004 constituted a complete response to our November 5, 2004 action letter.

This supplemental new drug application provided for the following changes:

1. The manufacturer of the drug substance, Medronic Acid (MDP), (b)(4)
(b)(4)
2. The final product manufacturing site to the CIS facility in Bedford, MA
3. The final product formulation and composition to duplicate that of an existing, active NDA, commercial product
4. The (b)(4)
5. The -----n
6. The (b)(4) cycle
7. Add qualified raw material facility for raw material and final product testing
8. The MDP raw material and final test methods and specifications for the reformulated product
9. The final product name to CIS-MDP™.
10. Extend expiration date to 18 months, after execution of (b)(4) stability programs
11. Package insert and finished product labeling to correspond to the proposed kit changes

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels) and/or submitted labeling (package insert submitted April 18, 2005, immediate container and carton labels submitted December 12, 2004).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 18-124SCS-013.**" 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 Patricia A. Stewart, Regulatory Project Manager, at (301) 827-7496.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

Eldon Leutzinger
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