

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 18467/S13

CORRESPONDENCE

NDA 18-467/S-013, S-014

16.
SEP - 1 1993

The DuPont Merck Pharmaceutical Company
331 Treble Cove Road
North Billerica, Massachusetts 01862

Attention: Laura A. Lee
Senior Regulatory Affairs Assistant

Dear Ms. Lee:

Please refer to your supplemental new drug application dated July 26, 1991 (S-013), and April 8, 1992 (S-014), submitted under section 505 of the Federal Food, Drug, and Cosmetic Act for Hepatolite, Kit for the Preparation of Technetium Disofenin.

We also acknowledge receipt on August 10, 1993, of your amendment dated August 6, 1993.

We consider this a major amendment under 21 CFR 314.60 of the regulations and we have determined that 45 additional days will be required for its review. The review clock will be extended accordingly. The new due date is September 24, 1993.

If you have any questions, please contact:

Ms. Susan Lange
Consumer Safety Officer
(301) 443-5818

Sincerely yours,

[Signature] 9/1/93
for Patricia Y. Love, M.D., M.B.A.
Acting Director
Division of Medical Imaging,
Surgical and Dental Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

MAR 24 1994

NDA 18-467/S-013 and S-014

The Du Pont Merck Pharmaceutical Company
Radiopharmaceutical Division
331 Treble Cove Road
North Billerica, Massachusetts 01862

Attention: Laura A. Lee
Senior Regulatory Affairs Associate

Dear Ms. Lee:

Reference is made to your approved supplemental new drug applications dated July 26, 1991, (S-013) and April 4, 1992, (S-014) for Hepatolite, Kit for the Preparation of Technetium Tc 99m Disofenin.

Supplement 013 provided for revisions to the package insert to include radiation dosimetry tables for jaundiced patients with malignant obstructive disease. Supplement 014 provided a new indication for the diagnosis and evaluation of acute cholecystitis when performed with morphine sulfate augmentation.

We acknowledge your submission dated February 25, 1994, providing final printed labeling (FPL).

We have reviewed the FPL that you have submitted in accordance with our approval letter dated December 29, 1993, and we find it acceptable.

Should additional information relating to the safety and effectiveness of this drug product become available, further revision of the labeling may be required.

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

Sincerely yours.

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Patricia Y. Love, M.D., M.B.A.
Acting Director
Division of Medical Imaging,
Surgical and Dental Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research