



NDA 18-735/SLR-043

Bracco Diagnostics Inc.
Attention: Melanie Benson
Director, US Regulatory Affairs
P.O.Box 5225
Princeton, NJ 08543-5225

Dear Ms. Benson:

Please refer to your supplemental new drug application dated February 14, 1997, received February 20, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ISOVUE-M (Iopamidol Injection).

This "Changes Being Effected" supplemental new drug application proposes to add the following statement to the WARNINGS section of the package insert:

“Contrast media may promote sickling in individuals who are homozygous for sickle cell disease when injected intravenously or intra-arterially. Although Isovue-M is not injected intravascularly, measurable plasma levels are attained after intrathecal administration of iopamidol.”

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted February 14, 1997). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
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.

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

Sincerely,

{See appended electronic signature page}

Patricia Y. Love, M.D., M.B.A.

Director

Division of Medical Imaging and Radiopharmaceutical

Drug Products

Office of Drug Evaluation III

Center for Drug Evaluation and Research

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

Patricia Love

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