DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 10-040/SLR-168

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

Dear Mrs. Benson:

Please refer to your supplemental new drug application dated March 20, 2002, received, March 21, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Renografin-60 - (Diatrizoate Meglumine and Diatrizoate Sodium Injection USP).

This "Changes Being Effected" supplemental new drug application, provided for the strengthening of the Warnings section of the labeling.

The **WARNINGS** section, under **Severe Adverse Events-In Advertent Intrathecal Administration** was revised to add the following statement:

> "The possibility exists for inadvertent administration into the intrathecal space during epidural administrations. Therefore, epidural administrative procedures, such as pain management catheter placement, should not be performed with use of this product."

The following changes were also noted and approved under the **How Supplied** section:

1. The NDC numbers were added for each package.
2. The sentence (b)----------(b)----------was removed.
3. The (b)---------- have been deleted.

We completed our review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted March 20, 2002). This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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, HF-2
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 Tyson, 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 this page is the manifestation of the electronic signature.

/s/

Patricia Love

10/23/02 02:17:57 PM