DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food and Drug Administration
Rockville MD 20857

NDA 11-324/S-028

Bracco Diagnostics
Attention: Edward Kowzun
Associate Director, Drug Safety
P.O. Box 5225
Princeton, New Jersey 08543-5225

Dear Mr. Kowzun:

Please refer to your supplemental new drug application dated September 24, 1993, received October 1, 1993, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Sinografin (diatrizoate meglumine and iodipimide meglumine injection).

This supplemental new drug application provides for a revision of the ADVERSE REACTIONS and HOW SUPPLIED sections of the label.

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 labeling dated September 24, 1993. 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.

If you have any questions, call Tia Harper-Velazquez, Pharm.D., 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

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/s/

Patricia Love

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