DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-245/S-032

Bracco Diagnostics, Inc.
Attention: Melanie Benson
Director, U.S. Regulatory Affairs
107 College Road East
Princeton, New Jersey 08540

Dear Ms. Benson:

Please refer to your supplemental new drug application dated March 3, 2005, received March 8, 2005, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Gastrografin (Diatrizoate Meglumine) Solution USP.

This "Changes Being Effected" supplemental new drug application provides for the marketing of the unit dose 30mL fill size.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL for the immediate container and the carton) submitted on March 3, 2005.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call James Moore, Regulatory Project Manager, at (301) 827-6254.

Sincerely,

{See appended electronic signature page}

Eldon Leutzinger, Ph.D.
Chemistry Team Leader for the
Division of Medical Imaging and Hematologic
Drug Products
(HFD-160)
DNDCII, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Eldon Leutzinger

8/29/2005 03:18:36 PM