DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-131/S-009/S-016

Bracco Diagnostics, Inc.
Attention: Ms. Melanie Benson
Director, U.S. Regulatory Affairs
P.O. Box 5225
Princeton, New Jersey 08543-5225

Dear Ms. Benson:

Please refer to your supplemental new drug applications dated May 4, 1995, received May 5, 1995, and dated June 8, 1999, received June 9, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ProHance®, (gadoteridol) Injection.

These "Changes Being Effected" supplemental new drug applications provide for changes to the clinical trials section and the addition of adverse drug reactions to the adverse drug reaction section of the labeling. Please refer to our fax of September 10, 2002, and the teleconference of September 13, 2002, in which you agreed to the labeling language provided by the Division. Please also refer to your fax of September 30, 2002, in which you confirmed your agreement with the labeling language proposed by the Division.

We have completed the review of these supplemental applications 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 agreed upon labeling text. Accordingly, the supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling contained in this letter and in the fax of September 10, 2002.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplements NDA 20-131/S-009/S-016." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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

Please submit one market package of the drug product when it is available.

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 CAPT James Moore, 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

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