DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-773

OCT 29 1998

Bracco Diagnostics Inc.
Attention: Madhu Anant
Associate Director, Regulatory Affairs
P.O. Box 5225
Princeton, NJ 08543-5225

Dear Ms. Anant:

Please refer to your new drug application (NDA) dated April 29, 1998, received April 30, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SonoRx (simethicone coated cellulose suspension) aqueous suspension .

We acknowledge receipt of your submissions dated October 8, November 5, 1997, December 4 and 17, 1997, April 29, September 28, October 8, 26, 27 (via facsimile), and 28 (via facsimile) 1998 . Your submission of April 29, 1998 constituted a full response to our September 30, 1997, action letter. The user fee goal date for this application is October 31, 1998.

This new drug application provides for the use of SonoRx (simethicone coated cellulose suspension) an orally administered gas shadowing reduction agent that is indicated to enhance the delineation of upper abdominal anatomy in conjunction with ultrasound imaging.

We have completed the review of this application, as amended, 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 enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case 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 NDA 20-773." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitment specified in your fax dated October 28, 1998 . This commitment, along with any completion dates agreed upon, is listed below.

> "To file a labeling supplement containing the pediatric dosing recommendations within 12 months. This will be based on oral volume information contained in medical references and literature".

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

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-40
> Food and Drug Administration
> 5600 Fishers Lane
> Rockville, Maryland 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, contact Rubynell Jordan, Consumer Safety Officer, at (301) 443-1560.

Sincerely,

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

Enclosure