DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 10-040/SPD-163

Bracco Diagnostics, Inc.
Attention: Melanie Benson
Director, US Regulatory Affairs
107 College Road
Princeton, NJ 08540

Dear Ms. Benson:

Please refer to your supplemental new drug application dated September 17, 1990, received, September 19, 1990, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cystographin Dilute (Diatrizoate Meglumine Injection USP, 18%).

We acknowledge receipt of your submission dated November 25, 2002 and March 21, 2003.

Your submission of March 21, 2003 constituted a complete response to our December 24, 2003 action letter.

This supplemental new drug application provides for a revised draft package insert for Cystographin Dilute (Diatrizoate Meglumine Injection USP, 18%).

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text dated September 16, 2003 with the minor editorial revisions listed below:

(b)(4)

However, the Divisions request the addition of the statement "Not intended for pediatric use." Under the **Pediatric Use** section.

3. **DRUG PREPARATION**-The Division proposes the last sentence of this paragraph referencing the use of product if frozen or if crystallization occurs, read as follows: " If the product is frozen or solids are seen, do not use the container, discard."

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert submitted March 21, 2003). These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 10-040/SPD-163." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
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 C. Tyson, Regulatory Project Manager, at (301) 827- 1503.

Sincerely,

{See appended electronic signature page}

Sally Loewke, M.D.
Acting 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/

Sally Loewke

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