DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA18-107/S-011

SUPPLEMENT APPROVAL

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

Dear Ms. Benson:

Please refer to your supplemental new drug application dated May 22, 2008, received May 27, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MDP-Bracco™ (Kit for the Preparation of Technetium Tc 99m Medronate).

This "Changes Being Effected in 30 days" supplemental new drug application provides for an alternate drug product manufacturing site (b) (4) .

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed upon labeling text submitted in your May 22, 2008 submission.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the submitted labeling (package insert submitted May 22, 2008). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 18-107."

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 Althea Cuff, Regulatory Project Manager, at (301) 796-4061.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch 8, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Hasmukh Patel

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