



NDA 17-697/S-017

Bracco Diagnostics Inc.
Attention: Melanie Benson,
Director, U.S. Regulatory Affairs
PO Box 5225
Princeton, NJ 08540

Dear Ms. Benson:

Please refer to your supplemental new drug application dated October 27, 2004, received October 28, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kinevac® (sincalide for injection).

This “Changes Being Effected” supplemental new drug application provides for revisions to the *Indications and Usage* section to more accurately reflect today’s practice and use of the drug.

We completed our review of this application, as amended, and it is approved, effective on the date of this letter.

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 Ryan Barraco, Consumer Safety Officer, at (301) 443-8017.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Acting Division Director
Division of Gastrointestinal & Coagulation Drug
Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Joyce Korvick
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