



NDA 19-414/SCM-006

Bracco Diagnostics, Inc.
Attention: Mr. Larry Callan
Senior Director, Regulatory Affairs
P.O. Box 5225
Princeton, NJ 08543-5225

Dear Mr. Callan:

Please refer to your supplemental new drug application dated May 17, 2000, received May 18, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CardioGen-82®.

We acknowledge receipt of your submissions dated November 27, 2000; February 20 and March 8, 2001. Your submission of February 20, 2001, constituted a complete response to our November 16, 2000 action letter.

This supplemental new drug application provides for the use of the South Plainfield site of Nycomed Amersham for the manufacture and distribution of CardioGen-82®.

We have completed the review of this supplemental application, and it is approved.

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 Thuy M. Nguyen, M.P.H., Regulatory Health Project Manager, at (301) 827-7510.

Sincerely,

{See appended electronic signature page}

Eldon E. Leutzinger, Ph.D.
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