DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-012/SCF-007

Berlex Inc.
Attention: James M. Hoover
Director, Drug Regulatory Affairs
P.O. Box 1000
Montville, NJ 07045-1000

Dear Mr. Hoover:

Please refer to your supplemental new drug application dated May 28, 2004, received June 1, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NeoTect® (Kit for the Preparation of Technetium Tc99m Depreotide Injection).

We acknowledge receipt of your submissions dated July 1 and 29, and September 13, 27 and 30, 2004.

This supplemental new drug application provides for formulation changes affecting the inactive components used in NeoTect®, a change to the (b)(4) closure system, change in the glass vial manufacturer, and a procedural change in the reconstitution procedure.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (immediate container and carton labels submitted May 28, 2004).

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 heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-012/SCF-007." 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 Patricia A. Stewart, Regulatory Project Manager, at (301) 827-7496.

Sincerely,

{See appended electronic signature page}

George Q. Mills, 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: labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

George Mills
10/1/04 12:35:26 PM