



NDA 21-081/S-014

Aventis Pharmaceuticals Inc.
Attention: Kumara Sekar, Ph.D.
Metabolism
Mail Stop BX2-406B
200 Crossing Boulevard
Bridgewater, NJ 08807

Dear Dr. Sekar:

Please refer to your supplemental new drug application dated September 10, 2004, received September 13, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lantus[®] (insulin glargine [rDNA origin] injection).

This “Changes Being Effected” supplemental new drug application provides for the following changes:

1. Deletion of the cartridge cover, which is part of the cartridge holder for the OptiClik insulin delivery device, and
2. Revision to the “Instruction Leaflet for OptiClik” to reflect the deletion of the cartridge cover.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 10, 2004.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Julie Rhee, Regulatory Project Manager, at (301) 827-6424.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic
and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: OptiClik Instruction Leaflet (50072880)

**This is a representation of an electronic record that was signed electronically and
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/s/

David Orloff
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