



NDA 21-081/S-011

Aventis Pharmaceuticals Inc.
Attention: Craig Ostroff, Pharm.D.
Regulatory Liaison
P.O. Box 6890
200 Crossing Boulevard
Bridgewater, NJ 08807-0890

Dear Dr. Ostroff:

Please refer to your supplemental new drug application dated February 9, 2004, received February 10, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lantus[®] (insulin glargine [rDNA origin] injection).

We acknowledge receipt of your submissions dated February 20, June 4 and 8, July 8, and August 4, 5, 6, and 10, 2004.

This supplemental new drug application provides for a new insulin delivery device, OptiClik Pen, for use with the 3 mL Lantus cartridge.

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, text for the patient package insert for 3 mL cartridge system, text for the patient package insert for 10 mL vial, OptiClik Instruction Leaflet, immediate container and carton labels for 3 mL cartridge and OptiClik Pen). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs*. 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 21-081/S-011." Approval of this submission by FDA is not required before the labeling is used.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be submitted in *pdf* format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

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 inserts 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 reporting requirements for an approved NDA (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:
1. Physician insert
 2. Patient Information for 3 mL cartridge system
 3. Patient Information for 10 mL vial
 4. OptiClik Instruction Leaflet
 5. Carton label for 3 mL cartridge system
 6. Container label for 3 mL cartridge system
 7. Carton label for OptiClik Pen
 8. Container label for OptiClik Pen

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

/s/

Eric Colman
8/10/04 07:14:43 PM
Eric Colman for David Orloff