



NDA 21-081/S-017

Aventis Pharmaceuticals Inc.
Attention: Kumara Sekar, Ph.D.
Metabolism
Mail Stop BX2-406B
200 Crossing Boulevard
Bridgewater, NJ 08807-0890

Dear Dr. Sekar

Please refer to your supplemental new drug application dated November 15, 2004, received November 16, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lantus (insulin glargine [rDNA origin] injection), 10 mL vials and 3 mL cartridges.

This supplemental new drug application provides for an additional stabilizing agent, 20 ppm of polysorbate 20, added to the drug product formulation for the 10 mL vial presentation.

We completed our review of this application. 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 10 mL vials, and carton label for 10 mL vials). 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 an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-081/S-017.**" Approval of this submission by FDA is not required before the labeling is used.

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

/s/

David Orloff
3/15/05 04:00:39 PM