



NDA 21-081/S-024

Sanofi-aventis U.S. Inc.
Attention: Michael Lutz, MSci, MBA, RAC
Regulatory Development
400 Crossing Boulevard
Bridgewater, NJ 08807-0890

Dear Mr. Lutz:

Please refer to your supplemental new drug application dated April 21, 2006, received April 24, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lantus (insulin glargine [rDNA origin]) Injection, 100 U/mL.

We acknowledge receipt of your submissions dated October 24 and December 14, 2006, and March 14, 2007.

Your submission of October 24, 2006, constituted a complete response to our August 24, 2006, action letter.

This supplemental new drug application provides for the addition of the Lantus SoloStar disposable insulin injection device.

We have 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 submitted March 14, 2007, text for the Lantus SoloStar patient package insert (ppisolo) submitted March 14, 2007, text for the Lantus SoloStar Instruction Leaflet (il) submitted March 14, 2007, and the Lantus SoloStar immediate container label submitted March 14, 2007) and the submitted Lantus SoloStar carton label submitted March 14, 2007, and the submitted labeling for the cartridge patient package insert (ppic) submitted March 14, 2007, and the vial patient package insert (ppv) submitted April 21, 2006.

Please submit an electronic version of the FPL as soon as it is available but no more than 30 days after it is printed. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-081/S-024.**" Approval of this submission by FDA is not required before the labeling is used.

Upon verification, the content of labeling in structured product labeling (SPL) format for the package insert submitted March 14, 2007, will be transmitted to the National Library of Medicine for public dissemination.

We also refer to your April 10, 2007, agreement to implement the following changes to the Lantus SoloStar container and carton labels at the time of the next printing - in approximately 60 days.

- Delete the proposed “Initial Use Date” feature on the Lantus SoloStar pen (container) label.
- Display all the text on the primary display panel of the Lantus SoloStar carton in upper and lower case lettering. The labels submitted March 14, 2007, use all capital letters for the statements: “SOLUTION FOR INJECTION IN A DISPOSABLE INSULIN DELIVERY DEVICE” and “USE ONLY IF SOLUTION IS CLEAR AND COLORLESS WITH NO PARTICLES VISIBLE.” Display these statements in upper and lower case lettering.

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:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Enid Galliers, Chief, Project Management Staff, at 301-796-1211.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology
Products (DMEP)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:

- (1) Package Insert
- (2) Patient Package Insert – Lantus SoloStar
- (3) Instruction Leaflet (IL) – Lantus SoloStar
- (4) Container Label – Lantus SoloStar Injection Device

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

/s/

Mary Parks
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