



NDA 21-629/S-008

SUPPLEMENT APPROVAL

sanofi aventis U.S., Inc.
Attention: Rima Nassar, Ph.D.
Regulatory Development
200 Crossing Boulevard, Mailstop: BX4-206A
Bridgewater, NJ 08807

Dear Dr. Nassar:

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 Apidra (insulin glulisine [rDNA origin] injection), which provided for the addition of the Apidra SoloStar disposable injector pen.

We acknowledge receipt of your submission dated September 15, 2008, which constituted a complete response to our July 3, 2008, action letter.

We also acknowledge receipt of your submissions dated August 19, September 15, and November 10, 2008, and January 30, 2009.

During review of Supplement 015 (approved October 24, 2008) we requested via email on April 21, 2008, you to revise the multiple patient package inserts for Apidra into a single patient package insert with multiple instructions for use leaflets. Your April 24, 2008, submission requested deferring these labeling changes and combining them with Supplement 008. We approved your request, thus the vial and cartridge instruction for use leaflets are included.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling text for the package insert, patient package insert, instruction for use leaflets (Apidra SoloStar Pen, Apidra Cartridge, and Apidra Vial) submitted January 30, 2009. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 21-629/S-008.**"

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels submitted on September 15, 2008, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 21-629/S-008.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

Please submit one market package of the drug product when it is available.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

If you have any questions, call Rachel Hartford, Regulatory Project Manager, at (301) 796-0331.

Sincerely,

{See appended electronic signature page}

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

Enclosures:

Package Insert

Patient Package Insert

Instructions for Use Leaflet – Apidra SoloStar Pen

Instructions for Use Leaflet – Apidra Cartridge

Instructions for Use Leaflet – Apidra Vial

SoloStar Pen Carton

SoloStar Pen Container

**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
2/24/2009 04:07:28 PM