



NDA 21-629/S-015

**SUPPLEMENT APPROVAL**

sanofi-aventis, U.S. LLC  
Attention: Michael Lutz, M.Sc., MBA, RAC  
Director, Regulatory Development  
200 Crossings Blvd., Mailstop BX4-209A  
Bridgewater, NJ 09907-0890

Dear Mr. Lutz:

Please refer to your supplemental new drug application (sNDA) dated June 27, 2007, received June 28, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Apidra (insulin glulisine [rDNA origin] injection).

We acknowledge receipt of your submissions dated November 19 and December 12, 2007, April 17 & 24, May 6, June 13, August 14 & 29 (2), and October 9 & 16, 2008.

This supplemental new drug application provides for revision of the Pediatric Use subsection of the prescribing information for use of Apidra in patients 4 through 17 years old with diabetes mellitus.

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 submitted October 17, 2008, vial and cartridge patient package inserts submitted August 14, 2008, and vial and cartridge patient instructions for use submitted August 14, 2008.) 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-015.**"

**PEDIATRIC RESEARCH EQUITY ACT (PREA)**

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and

effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for ages 0 up to 4 years. We note that you have fulfilled the pediatric study requirement for this application for ages 4 to 17 years old.

### **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 inserts 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](http://www.fda.gov/cder/ddmac).

### **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

### **REPORTING REQUIREMENTS**

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 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 and Research II

Center for Drug Evaluation and Research

Enclosures:

Package Insert

Patient Package Insert and Instructions for Use Leaflet – Vial

Patient Package Insert and Instructions for Use Leaflet – Cartridge

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

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Mary Parks

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