



NDA 21-629/S-010

sanofi-aventis U.S. Inc.  
Attention: Michael Lutz, M.Sc., MBA, RAC  
400 Crossing Boulevard  
P.O. Box 6890  
Mail Stop BX4-209A  
Bridgewater, NJ 08807-0890

Dear Mr. Lutz:

Please refer to your supplemental new drug application dated June 9, 2006, received June 12, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Apidra (insulin glulisine [rDNA origin]) Injection, 100 IU/mL.

We acknowledge receipt of your submissions dated April 6 and secure email dated April 10 and 11 (2), 2007.

This supplemental new drug application provides for the use of Apidra (insulin glulisine [rDNA origin]) Injection for intravenous administration in a controlled clinical setting for the control of hyperglycemia.

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.

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling (text for the package insert submitted April 6, 2007, text for the patient package insert for vials and the patient package insert for cartridges submitted April 6, 2007). Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

Submit final printed labeling (FPL) in electronic format that is identical to the enclosed labeling as soon as it is available. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-629/S-010.**" Approval of this submission by FDA is not required before the labeling is used.

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 through 7 years and deferring pediatric studies for ages 8 through 16 years for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA of the intravenous administration of Apidra for the treatment of hyperglycemia in pediatric patients ages 8 through 16 years, inclusive.

Final Report Submission: April 30, 2011.

Submit your pediatric study plans within 60 days after the date of this letter.

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated “**Required Pediatric Study Commitments.**”

Submit clinical protocols to your IND for this product. Submit all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled “**Postmarketing Study Commitment Protocol**”, “**Postmarketing Study Commitment Final Report**”, or “**Postmarketing Study Commitment Correspondence.**”

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).

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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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