



NDA 21-081/S-034

SUPPLEMENT APPROVAL

sanofi-aventis Inc.
Attention: Rima Nassar, Ph.D.
Global Director of Diabetes
200 Crossing Boulevard
P.O. Box 6890, Mailstop: BX2-700B
Bridgewater, NJ 08807

Dear Dr. Nassar:

Please refer to your supplemental new drug application dated and received December 21, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lantus, insulin glargine [rDNA origin] injection.

We acknowledge receipt of your submissions dated August 8, October 3 and 31, and December 22, 2008, and January 14, 28, and 30, and June 9, 2009.

This "Prior Approval" supplemental new drug application provides information from clinical study HOE901/4016, titled "*Evaluation of Diabetic Retinopathy Progression in Subjects with Type 2 Diabetes Mellitus Treated with Oral Agents Plus Insulin*" and converts the Package Insert to the Physician's Labeling Rule format.

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 and with the minor editorial revision changing the revision date from June to September.

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)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to, except for including the revision listed, the enclosed labeling text for the package insert submitted June 9, 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 21-081/S-034.**"

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, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instructions 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, see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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
5600 Fishers Lane, Room 12B-05
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 II
Center for Drug Evaluation

Enclosure:
Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21081	SUPPL-34	SANOFI AVENTIS US LLC	LANTUS

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

/s/

MARY H PARKS
09/09/2009