



NDA 206538

NDA APPROVAL

Sanofi-Aventis U.S. LLC
Attention: Antonella Lozito, Pharm.D.
Associate Director, Global Regulatory Affairs
55 Corporate Drive
Mail Stop: 55D-225A
Bridgewater, NJ 08807

Dear Dr. Lozito:

Please refer to your New Drug Application (NDA) dated and received April 25, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Toujeo (insulin glargine injection) U-300.

We also refer to our approval letter dated February 25, 2015, which contained the following error:

Toujeo (insulin glargine injection) U-300 is indicated to improve glycemic control in pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.

The indication in our approval letter dated February 25, 2015, should have read:

Toujeo is a long- acting human insulin analog indicated to improve glycemic control in adults with diabetes mellitus.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain February 25, 2015, the date of the original approval letter.

We acknowledge receipt of your amendments dated April 30, June 3, July 29, August 21, September 9, and 23, October 8, and 24, November 25, December 3, and 16, 2014, January 8, 9, and 15, and February 2, 4, 6, 11, 20, and 24, 2015. We also acknowledge receipt of your email dated February 25, 2015 that included the agreed-upon labeling.

This new drug application provides for the use of Toujeo (insulin glargine injection) U-300 to improve glycemic control in adults 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.

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your February 25, 2015, submission containing final printed carton and container labels.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
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. Form FDA 2253 is available at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>.

Information and Instructions for completing the form can be found at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For

more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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 Richard Whitehead, M.S., Regulatory Project Manager, at (301) 796-4945.

Sincerely,

{See appended electronic signature page}

Jean-Marc Guettier, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:

Content of Labeling
Carton and Container Labeling

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

/s/

JEAN-MARC P GUETTIER
02/25/2015