



NDA 205692

TENTATIVE APPROVAL

Eli Lilly and Company
Attention: Joerg Pfeifer, Ph.D.
Advisor, Global Regulatory Affairs- U.S.
Lilly Corporate Center
Indianapolis, Indiana 46285

Dear Dr. Pfeifer:

Please refer to your New Drug Application (NDA) dated October 17, 2014, and received October 18, 2014, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Basaglar (insulin glargine injection).

We acknowledge receipt of your amendments dated December 6 (2), 9, 16, and 19, 2013, January 10, 16, 21, 22, 24, 27, and 29, February 17, 21, 25, and 27, March 20, and 27, April 22, May 6, 8, 13, 15 (2), 16 (2), and 27, June 13, 23, and 24, July 10 (2), 14, and 30, August 15 (2), and August 18, 2014.

This NDA provides for the use of Basaglar (insulin glargine injection) for improvement of glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the submitted labeling (text for the package insert, submitted August 15, 2014, text for the patient package insert, submitted August 18, 2014, instructions for use, submitted August 18, 2014, and, carton and immediate container labels, submitted August 15, 2014). This determination is based upon information available to the Agency at this time, i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product. This determination is subject to change on the basis of any new information that may come to our attention.

The listed drug upon which your application relies is subject to a period of patent protection and therefore final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] may not be made effective until the period has expired.

Your application also contains certifications to patents under section 505(b)(2)(A)(iv) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of, this drug product under this application ("Paragraph IV certifications").

Section 505(c)(3)(C) of the Act provides that approval of a new drug application submitted pursuant to section 505(b)(2) of the Act shall be made effective immediately, unless an action is brought for infringement of one or more of the patents that were the subject of the paragraph IV certifications. This action must be taken prior to the expiration of forty-five days from the date the notice provided under section 505(b)(3) is received by the patent owner/approved application holder. You notified us that you complied with the requirements of section 505(b)(3) of the Act.

In addition, you have notified the Agency that the patent owner and/or approved application holder has initiated a patent infringement suit against you with respect to U.S. Patent Numbers 7,476,652 and 7,713,930 and 7,918,833 and 8,512,297 and 8,556,864 and 8,603,044 and 8,679,069 in the United States District Court for the District of Delaware. (Sanofi-Aventis U.S. LLC and Sanofi-Aventis Deutschland GMBH, Plaintiffs, v. Eli Lilly and Company, Defendant. C.A. No. 14-884-RGA). Therefore, final approval cannot be granted until:

1. a. expiration of the 30-month period provided for in Section 505(c)(3)(C) beginning on the date of receipt of the 45-day notice required under Section 505(b)(3), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or
- b. the date the court decides that the patents are invalid or not infringed as described in section 505(c)(3)(C)(i), (ii), (iii,) or (iv) of the Act, or,
- c. the listed patents expired, and
2. we are assured there is no new information that would affect whether final approval should be granted.

To obtain final approval of this application, submit an amendment two or six months prior to the: 1.) expiration of the patent or 2.) date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **“REQUEST FOR FINAL APPROVAL”**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; and chemistry, manufacturing, and controls data. If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not deemed approved.

Please note that this drug product may not be marketed in the United States without final agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d).

If you have any questions, call Callie Cappel-Lynch, Regulatory Project Manager, at (301) 796-8436.

Sincerely,

{See appended electronic signature page}

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

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
08/18/2014