BLA 103964/S-5273

SUPPLEMENT APPROVAL

Hoffmann-La Roche, Inc.
c/o Genentech, Inc.
Attention: Sonia De Rubeis
Program Manager, Regulatory Affairs
1 DNA Way
South San Francisco, CA 94080-4990

Dear Ms. De Rubeis:

Please refer to your supplemental biologics license application (sBLA), dated and received July 28, 2020, and your amendments dated August 12, 2020 and September 30, 2020, submitted under section 351(a) of the Public Health Service Act for Pegasys (peginterferon alfa-2a), injection for subcutaneous use, 180 mcg/mL in a vial, 180 mcg/0.5 mL in a prefilled syringe, 180 mcg/mL in an autoinjector, and 135 mcg/0.5 mL in an autoinjector.

This Prior Approval supplemental biologics application provides for the removal of the Pegasys 135 mcg/0.5 mL and 180 mcg/0.5 mL ProClick Autoinjectors from the Package Insert, Medication Guide, and Instructions for Use because this packaging configuration will no longer be marketed or distributed in the United States.

APPROVAL & LABELING

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.

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov,[1] that is identical to the enclosed labeling (text for the Prescribing Information,

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Instructions for Use, and Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

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*.[2]

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Saebyeol Jang, Regulatory Project Manager, at (240) 402-9953 or (301) 796-1500.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, MD
Director
Division of Antivirals
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

POONAM MISHRA
10/15/2020 12:36:41 PM
on behalf of Division Director