



BLA 103949/S-5311

SUPPLEMENT APPROVAL

Merck Sharp and Dohme Corporation
a subsidiary of Merck & Company, Incorporated
Attention: Sophia Lin, Associate Director, Global Regulatory Affairs
126 East Lincoln Avenue, P. O. Box 2000, RY34-B2144J
Rahway, NJ 07065-0900

Dear Ms. Lin:

Please refer to your Supplemental Biologics License Application (sBLA), dated and received December 6, 2017, submitted under section 351(a) of the Public Health Service Act for PEGINTRON® (peginterferon alfa-2b), injection, 50 mcg per 0.5 mL, 80 mcg per 0.5 mL, 120 mcg per 0.5 mL, 150 mcg per 0.5 mL in single-use vial (with 5 mL diluent) and single-use pre-filled pens.

This Prior Approval supplemental biologics application was submitted to add tongue pigmentation to the ADVERSE REACTIONS, Postmarketing Experience subsection of the Prescribing Information.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the prescribing information 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 titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

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 MS Word format that includes the changes approved in this supplemental application.

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 Victoria Tyson, Regulatory Project Manager, at (301) 796-0827 or (301) 796-1500.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

POONAM MISHRA
05/25/2018
on behalf of Debra Birnkrant, M.D.