



BLA 103132/S-5195

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp.
Attention: Nicholas Andrew, M.S.
Director, Global Regulatory Affairs
126 E. Lincoln Ave. P.O. Box 2000
RY34-B292
Rahway, NJ 07065

Dear Mr. Andrew:

Please refer to your Supplemental Biologics License Application (sBLA), dated December 14, 2016, received December 14, 2016, submitted under section 351(a) of the Public Health Service Act for Intron A (interferon alfa-2b).

This Prior Approval labeling supplemental biologics application revises the ADVERSE REACTIONS, Postmarketing Experience subsection to add Infections and Infestations, hepatitis B virus reactivation in HCV/HBV co-infected patients, and revises the Dosage and Administration section, to include a new subsection, Adults –HCV/HBV co-infection, that states that the safety and efficacy of Intron A alone or in combination with boceprevir or ribavirin for the treatment of chronic hepatitis C genotype 1 infection in patients co-infected with hepatitis B virus (HBV) and HCV have not been studied.

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 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.

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.

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, please call Ms. Sharon Sickafuse, Senior Regulatory Health Project Manager, at (301) 796-2320.

Sincerely,

{See appended electronic signature page}

Jeffery Summers, M.D.
Deputy Director for Safety
Division of Oncology Products 2
Office of Hematology and Oncology 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/

JEFFERY L SUMMERS
06/12/2017