BLA 208157/S-002

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Glenn Dennis
Associate Director, Regulatory Affairs
1 Baxter Parkway
Mail Stop Df5-3e
Deerfield, IL 60015

Dear Mr. Dennis:

Please refer to your supplemental biologics license application (sBLA) dated and received February 7, 2020, submitted as a supplemental new drug application (sNDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act, and administratively converted on March 23, 2020, to an sBLA under section 351(a) of the Public Health Service Act for Myxredlin (insulin human) in 0.9% Sodium Chloride injection (100 Units/ 100 ml), and your amendments. Please also refer to our Notification of "Deemed" BLA letter dated March 23, 2020.

This Prior Approval sBLA provides for changes to the drug product labeling that include an update to the room temperature storage statement to allow the Myxredlin (insulin human) in 0.9% sodium chloride injection 100 Units/100ml infusion bag to be stored without the original carton at room temperature for up to 30 days. This Prior Approval sBLA also provides for BLA-specific labeling revisions to container labels, carton labeling, and prescribing information to conform to labeling requirements for biological products regulated under section 351 of the PHS Act.

APPROVAL & LABELING

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

We note that your May 29, 2020, submission includes final printed labeling (FPL) for your prescribing information. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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) 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*.[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 MS Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission, 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).

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your May 29, 2020, 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.

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).

This information will be included in your biologics license application file.

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

If you have any questions, contact Anika Lalmansingh, Senior Regulatory Business Process Manager, at (240) 402 – 0356 or anika.lalmansingh@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

David Frucht, MD
Director
Division of Biotechnology Review and Research II
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:

- Prescribing Information
- Carton and Container Labeling

David Frucht

Digitally signed by David Frucht
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