BLA 020986/S-095

APPROVAL LETTER

Novo Nordisk Inc
Attention: Elizabeth D'Amato, PhD
Director, Regulatory Affairs
800 Scudders Mill Road
Plainsboro, NJ 08536

Dear Ms. D'Amato:

Please refer to your supplemental biologics license application (sBLA) dated and received June 25, 2021, and your amendments, submitted under section 351(a) of the Public Health Service Act, for NovoLog (insulin aspart) injection.

This Prior Approval sBLA provides for changes to the product labeling to allow for extension of the in-use time for NovoLog in an insulin infusion pump reservoir to 7 days or as recommended by the insulin infusion pump manufacturer user manual, whichever is shorter; for an infusion set/site change as recommended by the insulin infusion pump manufacturer user manual; and for a total NovoLog vial in-use time for pump use revised to 19 days which includes the 7 days of NovoLog in the pump reservoir.

APPROVAL & LABELING

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

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 instructions for use) 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, 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).

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

If you have any questions, call Anika Lalmansingh, Senior Regulatory Business Process Manager, at (240) 402 - 0356.

Sincerely,

{See appended electronic signature page}

Patrick Lynch, Ph.D.
On behalf of
Cyrus Agarabi, Pharm.D. Ph.D., CAPT, USPHS
Acting Director
Division of Biotechnology Review and Research II
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling

[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.

Patrick Lynch

Digitally signed by Patrick Lynch
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