BLA 020032/S-047

SUPPLEMENT APPROVAL

Abbvie Inc
Attention: Pei Miao
Associate Director, Regulatory Affairs
1 N. Waukegan Road
Dept. PA72 / Bldg. AP30
North Chicago, IL 60064

Dear Mr. Miao:

Please refer to your supplemental biologics license application (sBLA) dated and received December 3, 2021, submitted under section 351(a) of the Public Health Service Act for Survanta (beractant) suspension.

This Prior Approval supplemental biologics license application provides to position the proper name above the trade name on the Survanta (beractant) 25 mg/mL phospholipids, 4 mL and 8 mL product containers and carton labels.

APPROVAL & LABELING

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

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on December 3, 2021, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved BLA 020032/S-047.**" Approval of this submission by FDA is not required before the labeling is used.

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, call Anita Brown, Regulatory Business Process Manager, at Anita.Brown@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Jennifer Swisher, Ph.D.
On behalf of
Gibbes Johnson, Ph.D.
Director
Division of Biotechnology Review and Research IV
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:
Carton and Container Labeling

Jennifer Swisher

Digitally signed by Jennifer Swisher
Date: 7/15/2022 04:03:09PM
GUID: 508da6d7000262dc015dcdc5f6541612