NDA 20678/S-042
NDA 20734/S-037
NDA 204508/S-015

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Anne Arhold
Senior Manager, Global Regulatory Affairs
25212 W. Illinois Route 120
Round Lake, IL 60073

Dear Ms. Arhold,

Please refer to your supplemental new drug applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Application	Supplement	Product Name	Date of Submission	Date of Receipt
NDA 20678	S-042	CLINIMIX E (Amino Acid with Electrolytes in Dextrose with Calcium) Injections	10/12/2020	10/13/2020
NDA 20734	S-037	CLINIMIX (Amino Acid in Dextrose with Calcium) Injections	10/12/2020	10/13/2020
NDA 204508	S-015	Clinolipid (lipid injectable emulsion, USP) 20%	10/19/2020	10/19/2020

These “Changes Being Effected” supplemental applications provide for revisions to the stability and storage information in the Dosage and Administration section of the Prescribing Information (PI) to recommend protection of the admixed parenteral nutrition solution from light. Additional revisions were made to the Dosage and Administration section, as well as the Contraindications, Warnings and Precautions, and References sections of the PI.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions reflected in the enclosed labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] 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(s), 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).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[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, call Thao Vu, Regulatory Project Manager, at (240) 402-2690.

Sincerely,

{See appended electronic signature page}

Judith A. Racoosin, M.D., M.P.H.
Deputy Director for Safety
Division of Hepatology and Nutrition
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
    - Prescribing Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JUDITH A RACOOSIN
04/13/2021 08:14:53 AM