NDA 020923/S-026

SUPPLEMENT APPROVAL

Liebel-Flarsheim Company LLC
Attention: Alpa Jain
Senior Regulatory Associate
1034 South Brentwood Blvd. Suite 800
Richmond Heights, MO 63117

Dear Ms. Jain:

Please refer to your supplemental new drug application (sNDA) dated June 22, 2020, received June 22, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Optiray (ioversol) Injection, Pharmacy Bulk Package, 300 mg Iodine/mL, 320 mg Iodine/mL and 350 mg Iodine/mL.

This Prior Approval supplemental new drug application provides for a new presentation (Imaging Bulk Package) of Optiray (ioversol) contrast media to be used with the the Liebel-Flarsheim IBP Transfer Set (K193010).

APPROVAL & LABELING

We have completed our review of this application. 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 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.

[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.

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).

CARTON AND CONTAINER LABELING

We acknowledge your November 16, 2020, submission containing final printed carton and container labeling.

REPORTING REQUIREMENTS

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

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.[3]

If you have any questions, please contact Ms. Sharon Thomas, Regulatory Project Manager, at 301-796-1994 or by email (sharon.thomas@fda.hhs.gov).

Sincerely,

{See appended electronic signature page}

Libero Marzella, M.D., Ph.D.
Director
Division of Imaging and Radiation Medicine
Office of Specialty Medicine
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
- Carton and Container Labeling

[3] https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products

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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/

LIBERO L MARZELLA
11/18/2020 12:13:44 PM