DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019710/S-039
NDA 020923/S-009

SUPPLEMENT APPROVAL

Liebel-Flarsheim Company LLC
Attention: Alice Lorenzo, MJ, MBe, RAC
Compliance Officer, North America Head Regulatory and Quality
821 Alexander Road, Suite 204
Princeton, NJ 08540

Dear Ms. Lorenzo:

Please refer to your Supplemental New Drug Applications (sNDAs) dated June 10, 2014, received June 10, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Optiray™ 240, Optiray™ 300, Optiray™ 320, Optiray™ 350 (Ioversol Injection), Optiray™ 300 Pharmacy Bulk Pack (PBP), Optiray™ 320 PBP, and Optiray™ 350 PBP.

Application	Submission Date	Resubmission Date	Received Date
NDA 019710/S-039	May 28, 2010	May 28, 2014	May 28, 2014
NDA 020927/S-009	May 28, 2010	May 28, 2014	May 28, 2014

These "Prior Approval" supplements provide for revisions to the Prescribing Information that include:

In the Adverse Reactions section:

1. Only nausea will be listed in the paragraph as the most common reaction and any other reactions (occurring at less than 1%) will be listed in the Adverse Reactions table.
2. State the reactions are listed by organ system according to clinical importance
3. Remove language from the label such as: (b) (4)
4. Omit the paragraph under the Adverse Reactions table (b) (4)

In the Post Marketing Experience section:

1. Under Immune System Disorders: removal of the term urticaria from the general disorders and placed under immune and replace the term (b) (4) with "anaphylactic /hypersensitivity" reaction. Remove (b) (4) as it is not supported by the data.
2. Replace the term (b) (4)
3. Removing the information (b) (4) as it's presented under the Immune section.
4. Remove (b) (4) Replace the wording (b) (4) with the product name.
5. Flip the order of presentation of the postmarketing experience so that the most serious disorders are place first.

We acknowledge receipt of your amendments dated November 17, 2011, August 15, 2012, August 23, 2013, May 28, 2014, June 27, 2014, November 25, 2014, February 18, 2015, August 4, 2015, and January 6, 2016.

APPROVAL & LABELING

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

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), 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 titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U CM072392.pdf

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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. 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).

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REPORTING REQUIREMENTS

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

If you have any questions, call Su-Lin Sun, PharmD, Regulatory Project Manager, at (301) 796-0036 or email su-lin.sun@fda.hhs.gov .

Sincerely,

{See appended electronic signature page}

Alex Gorovets, M.D.
Deputy Director
Division of Medical Imaging Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ALEXANDER GOROVETS
08/12/2016