



NDA 021569/S-009

SUPPLEMENT APPROVAL

Libel-Flarsheim Company, LLC.
Attention: Alice Lorenzo
Compliance Officer
Head of North American Regulatory and Quality
821 Alexander Road, Suite 204,
Princeton, NJ 08540

Dear Ms. Lorenzo:

We have received your Prior Approval Supplemental New Drug Application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for sodium chloride 0.9% injection.

The following changes are approved:

Proposed changes	Labeling sections
PLLR format	n/a
Replacing Mallinckrodt with Liebel-Flarsheim	HIGHLIGHTS OF PRESCRIBING INFORMATION, INDICATION AND USAGE, and DOSAGE AND ADMINISTRATION
Trademark logo “™” is replaced with “®” for all power injectors	INDICATION AND USAGE and HOW SUPPLIED/STORAGE AND HANDLING
Update information for 125mL syringe to include the power injector Illumena® Néó	INDICATION AND USAGE

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is 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 Prescribing Information), with the addition of any labeling changes in pending “Changes Being Effectuated” (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/UCM072392.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 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 and annual report date.

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, please contact Su-Lin Sun, Regulatory Project Manager, by email su-lin.sun@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Alexander 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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ALEXANDER GOROVETS
12/29/2018 02:03:24 PM