



NDA 022450/S-011

SUPPLEMENT APPROVAL

Mallinckrodt Inc.
Perryville III Corporate Park
53 Frontage Rd, Third Floor
P.O. Box 9001
Hampton, NJ 08827

Attention: Lori Fiorentino
Director, Global Regulatory Affairs

Dear Ms. Fiorentino:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 28, 2018, submitted under Section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ofirmev (Acetaminophen) Injection 10mg/mL.

We also refer to our letter dated March 14, 2018, requesting that you revise the labeling for OFIRMEV by reinserting text which was inadvertently removed from our January 27, 2017, approval letter for Supplement S-010.

This “Changes Being Effected” supplemental new drug application provides for revisions to the labeling consistent with our March 14, 2018, supplement request letter, to revise section 8.1, **SPECIFIC POPULATIONS- Pregnancy, Data, Animal Data.**

APPROVAL & LABELING

We have completed our review of this supplemental application. 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 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/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 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).

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 Shelly Kapoor, PharmD, Regulatory Project Manager, at (240) 402-2787.

Sincerely,

{See appended electronic signature page}

Sharon Hertz, MD
Director
Division of Anesthesia, Analgesia, and
Addiction Products
Office of Drug Evaluation II
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/

SHARON H HERTZ
04/06/2018