NDA 18337/S-035

SUPPLEMENT APPROVAL

Taro Pharmaceutical Industries, Ltd.
Attention: Chitesh Naik
Manager, Regulatory Affairs
3 Skyline Drive
Hawthorne, NY 10532

Dear Mr. Naik:

Please refer to your supplemental new drug application (sNDA) dated and received August 9, 2019, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for FeverAll (acetaminophen) suppository, 80 mg, 120 mg, 325 mg, and 650 mg.

This Changes Being Effected supplemental new drug application provides for the addition of two minor statements to the outer carton labeling for the following strengths: 80 mg, 120 mg, and 325 mg.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 18337/S-035**." Approval of this submission by FDA is not required before the labeling is used.

[1] 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.

Submitted Labeling for Approval	Date Submitted
120 mg outer carton (6-count)	August 9, 2019
325 mg outer carton (6-count)	August 9, 2019
80 mg outer carton (6-count)	August 9, 2019

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at FDA.gov.[2] 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*. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

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 LT Sally Doan, Regulatory Project Manager, at (301) 796-8025.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director, Safety
Division of Nonprescription Drugs I
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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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/

VALERIE S PRATT
02/07/2020 04:34:55 PM
Signing on behalf of Dr. Karen Mahoney