NDA 18066/S-021

SUPPLEMENT APPROVAL

Chattem, Inc., d/b/a Sanofi Consumer Healthcare
Attention: Wendy McManus, MS, RAC
US Regulatory Head, Pain and Mental & Physical Wellness
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. McManus:

Please refer to your supplemental new drug application (sNDA) dated and received June 23, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Unisom (doxylamine succinate) tablet, 25 mg.

This "Changes Being Effected" supplemental new drug application provides for the addition of six warnings to the Drug Facts label in response to the Agency's Supplement Request letter dated December 20, 2021, as well as other labeling changes. These warnings have been added to the **"*Do not use*"**, **"*Ask a doctor before use if you have*"**, **"*Ask a doctor or pharmacist before use if you are*"**, and **"*When using this product*"** subheadings.

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 in the "Drug Facts" format (21 CFR 201.66), where applicable, and identical to the following labels submitted on September 16, 2022:

1. 16-count immediate container (blister)
2. 16-count outer carton
3. 32-count outer carton
4. 48-count outer carton
5. 80-count outer carton

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 18066/S-021**." Approval of this submission by FDA is not required before the labeling is used.

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).

[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.

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

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

If you have any questions, call Helen Lee, PharmD, Safety Regulatory Project Manager, at 301-796-6848

Sincerely,

{See appended electronic signature page}

Jody Green, MD
Deputy Director for Safety
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container 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/

JODY E GREEN
12/01/2022 01:28:06 PM