



NDA 22565/S-6

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC
Attention: Wendy McManus, MS, RAC
Director, Regulatory Strategy, Innovation
184 Liberty Corner Road
Suite 200
Warren, NJ 07059

Dear Ms. McManus:

Please refer to your supplemental new drug application (sNDA) dated and received February 13, 2020, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil Sinus Congestion & Pain (ibuprofen 200 mg, phenylephrine hydrochloride 10 mg) tablets.

This “Prior Approval” supplemental new drug application provides for a 2-count outer container (carton) to contain previously approved 1-count tablet pouches and also provides for a peel-back Drug Facts label.

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, described in the table below, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Submitted Draft Labeling	Date of submission
2-count outer container (hangtag carton to contain two 1-count tablet pouches)	2/13/2020
Drug Facts label (peel-back to be affixed to above 2-count outer container (carton))	2/13/2020

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 22565/S-6.**” 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).

If you have any questions, call Sherry Stewart, Regulatory Project Manager, at (301) 796-9618.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Deputy Director (Acting)
Division of Nonprescription Drug Products I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE:

- Carton Labeling

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>

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/

NUSHIN F TODD
07/30/2020 04:08:00 PM