



ANDA 214836

ANDA APPROVAL

L. Perrigo Company
515 Eastern Avenue
Allegan, MI 49010
Attention: Jesse Evans
Associate Director, Regulatory Affairs

Dear Jesse Evans:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on February 11, 2021, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Acetaminophen and Ibuprofen Tablets, 250 mg/125 mg (OTC).

Reference is also made to the tentative approval letter issued by this office on November 23, 2022, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act for over-the-counter (OTC) use. Accordingly, the ANDA is **approved**, effective on the date of this letter. We have determined your Acetaminophen and Ibuprofen Tablets, 250 mg/125 mg (OTC), to be bioequivalent to the reference listed drug (RLD), Advil Dual Action with Acetaminophen Tablets, 250 mg/125 mg, of GlaxoSmithKline Consumer Healthcare Holdings (US) LLC.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated May 29, 2020.

We note that L. Perrigo Company (L. Perrigo) was granted a Competitive Generic Therapy (CGT) designation for Acetaminophen and Ibuprofen Tablets, 250 mg/125 mg (OTC). However, as noted in the May 29, 2020, CGT Designation – Grant Letter, your drug product is not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act because there were unexpired patents or exclusivities listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) for the RLD at the time of submission of your ANDA.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

REPORTING REQUIREMENTS

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506I of the FD&C Act. The Agency should be advised of any change in the marketing status of this drug or if this drug will not be available for sale after approval. In particular, under section 506I(b) of the FD&C Act, you are required to notify the Agency in writing within 180 days from the date of this letter if this drug will not be available for sale within 180 days from the date of approval. As part of such written notification, you must include (1) the identity of the drug by established name and proprietary name (if any); (2) the ANDA number; (3) the strength of the drug; (4) the date on which the drug will be available for sale, if known; and (5) the reason for not marketing the drug after approval.

ANNUAL FACILITY FEES

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions¹ with respect to self-identification of facilities and payment of annual facility fees. ANDAs that identify at least one facility that is referenced in an approved ANDA are subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1st of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the *Federal Register* notice announcing facility fee amounts.

All finished dosage forms or active pharmaceutical ingredients manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

In addition, we note that GDUFA requires that certain non-manufacturing sites and organizations listed in generic drug submissions comply with the self-identification requirement. The failure of any facility, site, or organization to comply with its obligation to self-identify and/or to pay fees when due may raise significant concerns about that site or organization and is a factor that may increase the likelihood of a site inspection prior to approval. FDA does not expect to give priority to completion of inspections that are required simply because facilities, sites, or organizations fail to comply with the law requiring self-identification or fee payment.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at: <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>,

that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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: <https://www.fda.gov/media/71211/download>. The SPL will be accessible via publicly available labeling repositories.

We remind you that you must continually monitor available labeling resources such as DRUGS@FDA for changes to your RLD’s labels and labeling and make any necessary revisions to your labels and labeling. More information on post-approval labeling changes may be found in the guidance for industry titled “Changes to an Approved NDA or ANDA” at: <https://www.fda.gov/media/71846/download>.

Sincerely yours,

{See appended electronic signature page}

For Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

¹ Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).



John
Ibrahim

Digitally signed by John Ibrahim

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