ANDA 208158

ANDA APPROVAL

Bausch Health US, LLC
400 Somerset Corporate Boulevard
Bridgewater, NJ 08807
Attention: Shaun Mbithi
Associate Director, Global Regulatory Affairs

Dear Madam:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on January 19, 2016, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Alaway Preservative Free (Ketotifen Fumarate) Ophthalmic Solution, 0.035% (OTC).[1]

Reference is also made to the complete response letter issued by this office on July 10, 2019, 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 and is safe and effective for over-the-counter (OTC) use as recommended in the submitted labeling. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Alaway Preservative Free (Ketotifen Fumarate) Ophthalmic Solution, 0.035% (OTC), to be bioequivalent to the reference listed drug (RLD), Zaditor Ophthalmic Solution, 0.035%, of Alcon Laboratories Inc. (Alcon).

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 provisions[2] with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is 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 (FDFs) or active pharmaceutical ingredients (APIs) 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.

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.

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] We note that the reference listed drug (RLD) upon which you have based this ANDA, Alcon's Zaditor Ophthalmic Solution, 0.035%, is no longer being marketed in the United States and is currently listed in the discontinued section of FDA's Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book"). The Agency has determined that Alcon's Zaditor Ophthalmic Solution, 0.035%, was not withdrawn from sale for reasons of safety or effectiveness. FDA published this determination in the *Federal Register* (82 FR 19735; April 28, 2017). This determination allows the Agency to approve ANDAs for the discontinued drug product.

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

Catherine Poole

Digitally signed by Catherine Poole
Date: 9/24/2020 01:33:51PM
GUID: 5407887a000a1c0c26055eafb8e3258a