DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 202565

APPROVED

Sandoz Inc.
U.S. Agent for: Alcon Research, Ltd.
100 College Road West
Princeton, New Jersey 08540
Attention: Gregory Seitz
Director, Regulatory Affairs

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 10, 2010, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Bimatoprost Ophthalmic Solution, 0.03%.

Reference is also made to the Complete Response letter issued by the agency on October 23, 2013, and to your amendments dated April 2, 2014; January 20, January 22, April 24, and May 4, 2015.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is **approved**, effective on the date of this letter. The Division of Bioequivalence has determined your Bimatoprost Ophthalmic Solution, 0.03% to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug product (RLD), Lumigan Ophthalmic Solution, 0.03%, of Allergan, Inc.[1].

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

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

[1] We note that the reference listed drug product (RLD) upon which you have based this ANDA, Lumigan Ophthalmic Solution, 0.03%, is no longer being marketed in the United States, and has been moved to the Discontinued section of the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book." We refer to the Federal Register notice dated October 31, 2014 (Volume 79, No. 211) in which the agency announced its determination that Lumigan Ophthalmic Solution, 0.03%, was not withdrawn from sale for reasons of safety or effectiveness. This determination allows the agency to approve ANDAs for the discontinued drug product.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

You have been requested to provide information after the drug application has been approved. Any information submitted to meet the conditions requested in this letter is considered a "Post Approval Commitment Response". To alert the Office of Generic Drug staff to the fact that you are providing post approval commitment information, please designate your submission in your cover letter as "POST APPROVAL COMMITMENT RESPONSE".

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions 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 1 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.

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 http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

Carol A. Holquist -S

Digitally signed by Carol A. Holquist -S
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Date: 2015.05.05 15:20:42 -04'00'

Carol A. Holquist, RPh
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research