



ANDA 091589

Teva Pharmaceuticals USA
Attention: Scott Tomsky
Vice President, U.S. Generics Regulatory Affairs
425 Privet Road
Horsham, PA 19044

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) received on June 29, 2009, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Tobramycin Inhalation Solution USP, 300 mg/5 mL Single-use Ampules.

Reference is also made to your amendments dated October 1, 2009; October 14, December 6, December 9, December 20, and December 23, 2011; March 14, March 16, August 1, and August 29, 2012; and January 11, May 22, July 22, August 29, and October 3, 2013. We also acknowledge receipt of your correspondences dated October 29 and December 14, 2009; and April 3, 2012, pertaining to the patent issues associated with this ANDA.

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 Tobramycin Inhalation Solution USP, 300 mg/5 mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Tobi Inhalation Solution, 300 mg/5 mL, of Novartis Pharmaceuticals Corporation (Novartis).

The RLD upon which you have based your ANDA, Novartis' Tobi Inhalation Solution, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 5,508,269 (the '269 patent), is scheduled to expire on October 19, 2014.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '269 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Tobramycin Inhalation Solution USP, 300 mg/5 mL, under this ANDA. You have notified the agency that Teva Pharmaceuticals USA (Teva) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Teva for infringement of the '269 patent within the statutory 45-day period in the United States District Court for the District of Delaware [Seattle Children's Hospital, Novartis AG, Novartis Vaccines

and Diagnostics, Inc., and Novartis Pharmaceuticals Corporation v. Teva Parenteral Medicines, Inc. and Teva Pharmaceuticals USA, Inc., Civil Action No. 09-cv-00949-NLH-KW]. You have also notified the agency that the case was dismissed.

With respect to 180-day generic drug exclusivity, we note that Teva was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Tobramycin Inhalation Solution USP, 300 mg/5mL. As a first applicant, Teva was eligible for 180 days of generic drug exclusivity. The Agency has determined, however, that Teva has forfeited its 180-day exclusivity period because Teva failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed.¹ See section 505(j)(5)(D)(I)(IV) of the Act.

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.

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 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.

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

¹ Teva's ANDA 091589 was received (filed) on June 29, 2009. 30 months from that date was December 29, 2011. ANDA 091589 was never tentatively approved. The agency finds that this failure to obtain tentative approval by December 29, 2011, was not caused by a change in or a review of the requirements for approval, nor was a related citizen petition submitted that was subject to section 505(q) of the Act.

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,

{See appended electronic signature page}

Kathleen Uhl, M.D.
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST

10/10/2013

Deputy Director, Office of Generic Drugs, for
Kathleen Uhl, M.D.