DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-840

TEVA Pharmaceuticals USA
Attention: Philip Erickson, R.Ph.
Senior Director, Regulatory Affairs
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated September 4, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Sumatriptan Succinate Tablets, 25 mg (base), 50 mg (base), and 100 mg (base).

Reference is also made to the tentative approval letter issued by this office on November 28, 2006, and to your amendments dated September 14, 2005; February 23, and June 7, 2006; June 16, October 15, November 26, and December 12, 2008; and January 15, and January 23, 2009.

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 Sumatriptan Succinate Tablets, 25 mg (base), 50 mg (base), and 100 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Imitrex Tablets, 25 mg (base), 50 mg (base) and 100 mg (base), of GlaxoSmithKline (GSK). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The RLD upon which you have based your ANDA, GSK's Imitrex Tablets, is subject to periods of patent protection. The following unexpired patents and their expiration dates (with pediatric exclusivity added) are currently listed in the agency's publication titled Approved Drug Products with

Therapeutic Equivalence Evaluations, (the "Orange Book") for this drug product:

U.S. Patent No.	Expiration Date
5,863,559 (the '559 patent)	July 26, 2016
6,020,001 (the '001 patent)	September 2, 2012
6,368,627 (the '627 patent)	September 2, 2012

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable or will not be infringed by the manufacture, use, or sale of Sumatriptan Succinate Tablets, 25 mg (base), 50 mg (base), or 100 mg (base), under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against TEVA Pharmaceuticals USA (TEVA) for infringement of one or more of the patents that were the subjects of the paragraph IV certifications. You have notified the agency that TEVA complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '559, '001, or '627 patents was brought against TEVA within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, we note that TEVA was the first ANDA applicant to submit a substantially complete ANDA for Sumatriptan Succinate Tablets, 25 mg (base), 50 mg (base), and 100 mg (base), with a paragraph IV certification to the '001 and '559 patents. Therefore, with this approval, TEVA is eligible for 180 days of shared generic drug exclusivity for Sumatriptan Succinate Tablets, 25 mg (base), 50 mg (base), and 100 mg (base). (Teva will share this exclusivity with another applicant who was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '627 patent.) This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv).[1] Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

[1] Because the other applicant's ANDA, like yours, was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(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.

We 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
Division of Drug Marketing, Advertising, and Communications
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 Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National

Library of Medicine for public dissemination. For administrative purposes, please designate this submission as "***Miscellaneous Correspondence - SPL for Approved ANDA 76-840***".

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
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
2/9/2009 03:18:37 PM
Deputy Director, for Gary Buehler