DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 091224

Teva Pharmaceuticals USA
Attention: Jean W. Zwicker
Senior Director, Regulatory Affairs
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) received on December 30, 2008, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Pregabalin Capsules, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg.

Reference is also made to the tentative approval letter issued by this office on August 4, 2011.

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 Pregabalin Capsules, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Lyrica Capsules, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg, of PF Prism C.V. (Prism). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Prism's Lyrica Capsules, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
5,563,175 (the '175 patent)	October 8, 2013
6,001,876 (the '876 patent)	December 30, 2018
6,197,819 (the '819 patent)	December 30, 2018
RE 41,920 (the '920 patent)	December 30, 2018

With respect to the '175 patent, the U-819 claims of the '876 patent and certain claims of the '920 patent, your ANDA contains statements under section 505(j)(2)(A)(viii) of the Act that

these are method of use patents that do not claim any indication for which you are seeking approval.

With respect to the '819 patent, and the remaining claims of the ‘876 and '920 patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Pregabalin Capsules, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg, 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 '876, '819 and '920 patents within the statutory 45-day period in the United States District Court for the District of Delaware [Pfizer Inc., Warner-Lambert Co., CP Pharmaceuticals and Northwestern University v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd., Civil Action No. 09-307]. With respect to the litigation, the agency recognizes the expiration on June 30, 2012, of the 7½ year period identified in sections 505(j)(5)(F)(ii) and 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA.

Teva was one of the first applicants to submit a substantially complete ANDA with a paragraph IV certification to the one or more of the patents listed for the RLD. As a first applicant, therefore, Sun was eligible for 180 days of generic drug exclusivity for Pregabalin Capsules, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg. The Agency notes that 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)(i)(IV) of the Act. At least one first applicant, however, remains eligible for 180-days of generic drug exclusivity for Pregabalin Capsules, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of commercial marketing by any first applicant, as identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date you begin commercial marketing.

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

[1] Teva’s ANDA 091224 was received (filed) on December 30, 2008. 30 month from that date was June 30, 2011. As noted above, this ANDA was tentatively approved on August 4, 2011.

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.

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}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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/

KEITH O WEBBER
07/03/2012