DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 75-435

Food and Drug Administration
Rockville MD 20857

OCT 8 2004

TEVA Pharmaceuticals USA
Attention: Philip Erickson
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 August 13, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act) for Gabapentin Capsules, 100 mg, 300 mg, and 400 mg.

Reference is made to our approvable letter dated July 18, 2002, and to our Tentative Approval letter dated August 7, 2003. Reference is also made to your amendments dated March 9, June 30, July 8, and October 8, 2004. We also refer to our letter dated January 28, 2003, addressing issues associated with 180-day generic drug exclusivity for this drug product.

The listed drug product (RLD) referenced in your application, Neurontin® Capsules 100 mg, 300 mg, and 400 mg, of Pfizer, Inc., is subject to periods of patent protection and exclusivity. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", U.S. Patent No. 4,894,476, the '476 patent, is scheduled to expire on November 2, 2008, and U.S. Patent No. 6,054,482, the '482 patent, is scheduled to expire on October 25, 2017. Your application contains paragraph IV patent certifications to each of these patents under Section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents will not be infringed by your manufacture, use, or sale of Gabapentin Capsules 100 mg, 300 mg, and 400 mg under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA may 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. This action must have been brought against TEVA prior to the expiration of forty-five (45) days from the date the notice(s) you provided under paragraph (2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that TEVA complied with the requirements of Section 505(j)(2)(B) of the Act. As a result, TEVA was sued for infringement of the '482 patent in the United States District Court for the District of New Jersey [Pfizer Inc., Warner Lambert Company, and Godecke Aktiengesellschaft v. TEVA Pharmaceuticals USA and TEVA Pharmaceuticals Industries Ltd., Civil Action No. 00 4589 (JCL)]. With respect to this ongoing litigation involving the '482 patent, the Agency recognizes that the 30-month period identified in Section 505(j)(5)(B)(iii) of the Act, during which time the Agency was precluded from approving your application, has expired. In addition, you have informed the Agency that no litigation with respect to infringement of the '476 patent was brought against TEVA within the statutory 45-day period.

With respect to Gabapentin Capsules 100 mg, 300 mg, and 400 mg, the Office of Generic Drugs (OGD) received an ANDA containing a paragraph IV certification to the '476 and '482 patents from Purepac Pharmaceutical Company (Purepac) prior to the receipt of your ANDA. Thus, the Act provides that approval of your ANDA, which seeks approval for the same drug product as that for which Purepac was seeking approval, shall be made effective not earlier than 180-days after:

1. the date the Secretary receives notice from Purepac that commercial marketing of the drug product approved under the application was initiated, or

2. the date of a decision of a court holding that the patents which were the subject of the paragraph IV certifications to be invalid or not infringed;

3. whichever option occurs first [Section 505(j)(5)(B)(iv)].

However, we are able to grant final approval to this ANDA based upon your letter to the Agency dated October 8, 2004, and information submitted in conjunction with that correspondence, indicating that the Purepac Pharmaceutical Company (Purepac) commercially launched its Gabapentin Capsules 100 mg, 300 mg, and 400 mg under its approved ANDA on October 8, 2004. This launch served to trigger the 180-day generic drug exclusivity for this drug product. In addition, the Agency was informed that Purepac selectively waived the 180-day generic drug exclusivity to which Purepac is entitled to TEVA Pharmaceuticals USA. Thus, upon receipt of this waiver the Agency is permitted to grant final approval to your ANDA for Gabapentin Capsules 100 mg, 300 mg, and 400 mg.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Gabapentin Capsules, 100 mg, 300 mg, and 400 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Neurontin Capsules, 100 mg, 300 mg, and 400 mg, respectively, of Pfizer, Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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

Post-marketing reporting requirements for this abbreviated application 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
Division of Drug Marketing, Advertising, and
Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

(b)(6)

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research