



ANDA 076898

Teva Pharmaceuticals USA
Attention: Scott D. Tomsy
Vice President, Regulatory Affairs
425 Privet Road
Horsham, PA 19044

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated November 13, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Celecoxib Capsules, 50 mg, 100 mg, 200 mg, and 400 mg.

Reference is also made to the tentative approval letter issued by this office on April 27, 2012, and to the Complete Response letter dated May 22, 2014, and to your amendments dated May 23 and 27, 2014.

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 Celecoxib Capsules, 50 mg, 100 mg, 200 mg, and 400 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Celebrex Capsules, 50 mg, 100 mg, 200 mg and 400 mg, respectively, of GD Searle LLC (Searle). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The reference listed drug (RLD) upon which you have based your ANDA, Celebrex Capsules of GD Searle LLC (Searle), is subject to a period of unexpired patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 5,760,068 (the '068 patent) and its reissue, U.S.

Patent No. RE44,048 (the 'RE048 patent), are scheduled to expire (with pediatric exclusivity added) on December 2, 2015.

With respect to each of these patent listings, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Celecoxib Capsules, 50 mg, 100 mg, 200 mg, and 400, under this ANDA. You notified the agency that Teva complied with the requirements of section 505(j)(2)(B) of the Act, and litigation for infringement of the '068 patent was brought against Teva within the statutory 45-day period in the United States District Court for the District of New Jersey [Pfizer Inc., Pharmacia, G.D. Searle, etc. v. Teva Pharmaceuticals USA, Inc., Civil Action No. 04-754]. The Court of Appeals for the Federal Circuit, in a mandate issued on May 13, 2008, determined that the asserted claims of the '068 patent were invalid. Litigation for infringement of the 'RE048 patent was brought against Teva in the United States District Court for the Eastern District of Virginia [G.D. Searle LLC and Pfizer Asia Pacific Pte. Ltd. v. Lupin Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., Mylan Pharmaceuticals Inc., Watson Laboratories, Inc., Apotex Inc., and Apotex Corp., Civil Action No. 2:13cv121]. This case is ongoing.¹

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 to Celecoxib Capsules, 100 mg, 200 mg, and 400 mg. Therefore, with this approval, Teva is eligible for 180-days of generic drug exclusivity for Celecoxib Capsules, 100 mg, 200 mg, and 400 mg.²

¹The 'RE048 patent was listed in the Orange Book on March 7, 2013, and your paragraph IV certification to the 'RE048 patent was submitted in an amendment to your ANDA. Litigation with respect to the 'RE048 patent, therefore, does not give rise to a statutory bar to approval. See section 505(j)(5)(B)(iii) of the Act.

²It is noted that Teva and one or more other applicants filed paragraph IV certifications to the 'RE048 patent on March 7, 2013. Under the facts of this case, the agency has explained why 180-day eligibility is only available to the applicant that filed a paragraph IV certification to the original patent, i.e., the '068 patent. See letter dated April 24, 2014, from K. Uhl, Acting Director, OGD, to Celecoxib ANDA Applicant. On May 29, 2014, in a case challenging the agency's April 24 decision (*Mylan Pharmaceuticals Inc., et al. v. U.S. Food and Drug Administration, and Teva Pharmaceuticals, USA, Inc.* (Civil Action No. 1:14CV75)), the United States District Court for the Northern District of West Virginia denied plaintiff's motion for preliminary injunction seeking to enjoin FDA from withholding final approval to any

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).³ Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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. You should advise the Office of Generic Drugs 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 Amundson 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.

celecoxib ANDA applicant that submitted a paragraph IV certification to the 'RE048 patent on March 7, 2013.

³ Because your ANDA 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).

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,

{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

05/30/2014

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