DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-228

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 August 28, 2001, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Risperidone Tablets USP, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg.

Reference is also made to your amendments dated July 15, and December 19, 2003; January 19, and August 9, 2004; August 3, 2006; February 21, May 10, and October 31, 2007; and January 25, April 9, May 14, May 21, and June 23, 2008.

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 Risperidone Tablets USP, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Risperdal Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg 3 mg, and 4 mg, respectively, of Janssen Pharmaceutica Products, L.P. (Janssen). 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, Janssen's Risperdal Tablets, 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. 5,158,952 (the '952 patent) is scheduled to expire (with pediatric exclusivity added) on April 27, 2010.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '952 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Risperidone Tablets USP, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg, under this ANDA. 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 '952 patent 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 Risperidone Tablets USP, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg, with a paragraph IV certification to the '952 patent. Therefore, with this approval, TEVA is eligible for 180 days of generic drug exclusivity for Risperidone Tablets USP, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg. 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). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.[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.

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.

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[1]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).

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.

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
6/30/2008 03:04:40 PM
Deputy Director, for Gary Buehler