



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-071

Actavis Totowa LLC
Attention: Jacob Haroon, Ph.D.
Senior Director, Regulatory Affairs
101 East Main Street
Little Falls, NJ 07424

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 22, 2005, 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 May 16, July 17, and October 27, 2006; March 6, March 7, March 13, April 30, and August 27, 2007; March 14, August 13, September 30, October 13, and November 6, 2008; and January 5, and April 20, 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 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 Ortho McNeil Janssen Pharmaceuticals, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

As indicated in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), the RLD upon which you have based your ANDA, Janssen's Risperdal Tablets, is no longer subject to any periods of unexpired patent protection. U.S. Patent No. 4,804,663 has expired, and the pediatric exclusivity period attaching to this patent has also expired. U.S. Patent No. 5,158,952, which had

been listed previously in the Orange Book pursuant to the order in *Teva Pharm. v. Leavitt*, No. 08-395 (D.D.C., Apr. 11, 2008), has been removed from the Orange Book pursuant to the judgment in *Teva Pharm. v. Leavitt*, No. 08-5141 (D.C. Cir., Sept. 12, 2008).

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 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 78-071"**.

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
6/17/2009 09:21:36 AM
Deputy Director, for Gary Buehler