Food and Drug Administration
Rockville, MD 20857

ANDA 090869

Actavis South Atlantic LLC
Attention: Monique Weitz
13800 N.W. 2nd Street
Suite 190
Sunrise, FL 33325

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 13, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ropinirole Hydrochloride Extended-release Tablets, 2 mg (base), 4 mg(base), 6 mg(base), 8 mg(base), and 12 mg(base).[1]

Reference is also made to your amendments dated March 2, November 29, and December 22, 2011; February 2 (two), February 27, 2012; and to your patent amendments dated January 5, March 27, April 3, August 31, and December 18, 2009; April 19, 20, 21, 22, 25, 26, 27; May 5, May 20, June 2, October 12, and November 9, 2011; March 6, March 8, and March 24, 2012.

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 Ropinirole Hydrochloride Extended-release Tablets, 2 mg(base), 4 mg(base), 6 mg(base), 8 mg(base), and 12 mg(base) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD) Requip XL Tablets of SmithKline Beecham (SmithKline).

Dissolution testing should be conducted in 500 mL of 0.1N HCl at 37°C +/- 0.5°C, using USP Apparatus II (paddle) with sinker. The test product should meet the following "interim" specifications:

[1] Actavis' ANDA 090869 for the 2 mg strength only was received on October 14, 2008. Amendments for the other strengths were submitted on October 31, 2008 (4 mg), November 3, 2008 (8 mg), February 5, 2009 (12 mg), and July 14, 2009 (6 mg).

Time (hours)	Percent Dissolved
1	NMT 25
6	40-60
12	65-85
24	NLT 80

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement - Changes Being Effected when there are no revisions to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, SmithKline's Requip XL Tablets, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 5,422,123 (the '123 patent) and 7,927,624 (the '624 patent) are scheduled to expire on June 6, 2012, and December 2, 2021, respectively. The agency notes that only the '123 patent was listed when your ANDA was submitted; the '624 patent was not listed until 2011.

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 Ropinirole Hydrochloride Extended-release Tablets, 2 mg(base),4 mg(base),6 mg(base), 8 mg(base), and 12 mg(base), under this ANDA. You have notified the agency that Actavis South Atlantic LLC (Actavis) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Actavis.

With respect to generic drug exclusivity, we note that Actavis was the first applicant to submit a substantially complete ANDA with a paragraph IV certification to the '123 patent. Therefore, with this approval, Actavis is eligible for generic drug exclusivity for Ropinirole Hydrochloride Extended-release Tablets, 2 mg(base),4 mg(base),6 mg(base), 8 mg (base), and 12 mg(base).[2] This exclusivity, which is provided for under section

[2] The exclusivity period will end upon the expiration of the '123 patent on June 6, 2012. As noted above, Actavis' ANDA 090869 for the 2 mg strength only was received on October 14, 2008; amendments for the other strengths were submitted on October 31, 2008 (4 mg), November 3, 2008 (8 mg), February 5, 2009 (12 mg), and July 14, 2009 (6 mg). This ANDA was not granted

505(j)(5)(B)(iv) of the Act, will begin to run from the commercial marketing date 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.

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(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

---

tentative approval within the 30-month periods described in section 505(j)(5)(D)(i)(IV) for any of these strengths. Nevertheless, the agency has determined that the failure to obtain tentative approval within the 30-month periods was caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application was filed, specifically a review of ANDA approval requirements with respect to the size of certain solid oral dosage form products. We therefore conclude that the exclusivity period described in section 505(j)(5)(B)(iv) of the Act was not forfeited by Actavis.

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/U_CM072392.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/

ROBERT L WEST
05/17/2012
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.