



ANDA 90081

Watson Laboratories, Inc.
Attention: Janie Gwinn
Director, Regulatory Affairs
311 Bonnie Circle
Corona, CA 92880

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 18, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Drospirenone and Ethinyl Estradiol Tablets, 3 mg/0.03 mg.

Reference is made to your amendments dated September 10, and September 26, 2008; April 7, and December 21, 2009; and February 5, and February 23, 2010.

We have completed the review of this ANDA, and based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval to your ANDA at this time because of the patent issue noted below. Therefore, the ANDA is **tentatively approved**. This determination is based upon information available to the agency at this time (i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The reference listed drug (RLD) upon which you have based your ANDA, Yasmin Tablets, of Bayer Healthcare Pharmaceuticals Inc., is subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
5,569,652 (the '652 patent)	October 29, 2013
6,787,531 (the '531 patent)	August 31, 2020
6,933,395 (the '395 patent)	August 11, 2017

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 Drospirenone and Ethinyl Estradiol Tablets, 3 mg/0.03 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against Watson Laboratories, Inc. (Watson) for infringement of one or more of the patents that were the subject of the paragraph IV certifications. You notified the agency that Watson complied with the requirements of section 505(j)(2)(B) of the Act, and litigation for infringement of the '652 patent was brought against Watson in the United States District Court for the Southern District of New York [Bayer Schering Pharma AG and Bayer Healthcare Pharmaceuticals Inc. v. Sandoz, Inc., Watson Pharmaceuticals, Inc., and Watson Laboratories, Inc., Civil Action No. 08-3710].

Therefore, final approval cannot be granted until:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii)¹
- b. the date the court decides² that the patents are invalid or not infringed (see sections 505(j)(5)(B)(iii)(I), (II), and (III) of the Act) or,
- c. the listed patents have expired, and
2. The agency is assured there is no new information that would affect whether final approval should be granted.

¹ Because information on the '652, '531, and '395 patents was submitted to FDA before August 18, 2003, this reference to section 505(j)(5)(B)(iii) is to that section of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) was enacted. See MMA § 1101(c)(3).

² This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

To reactivate your ANDA prior to final approval, please submit a "MINOR AMENDMENT - FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT - FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (cGMPs) are subject to agency review before final approval of the application will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book."

For further information on the status of this application, or prior to submitting additional amendments, please contact Sarah Nguyen, Project Manager, at (240)276-8467.

Sincerely yours,

{See appended electronic signature page}

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

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

ANDA-90081

ORIG-1

WATSON
LABORATORIES
INC

DROSPIRENONE AND ETHINYL
ESTRADIOL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GARY J BUEHLER
03/18/2010