



ANDA 218031

**ANDA APPROVAL/TENTATIVE APPROVAL**

Novast Laboratories Inc.  
U.S. Agent for Novast Laboratories Ltd.  
Attention: Brian Berry  
VP, Scientific and Regulatory Affairs

Dear Brian Berry:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on April 27, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Drospirenone and Estradiol Tablets, 0.25 mg/0.5 mg and 0.5 mg/1 mg.

Reference is also made to the complete response letter issued by this office on April 25, 2025, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. We have determined your Drospirenone and Estradiol Tablets, 0.25 mg/0.5 mg and 0.5 mg/1 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Angeliq Tablets, 0.25 mg/0.5 mg and 0.5 mg/1 mg, of Bayer HealthCare Pharmaceuticals Inc. (Bayer) NDA - 021355.

However, we are unable to grant final approval to your Drospirenone and Estradiol Tablets, 0.25 mg/0.5 mg, at this time because of the patent issue noted below. Therefore, your ANDA is **approved** insofar as it pertains to Drospirenone and Estradiol Tablets, 0.5 mg/1 mg. Your Drospirenone and Estradiol Tablets, 0.25 mg/0.5 mg, is **tentatively approved**. This determination is based upon information available to the Agency at this time (e.g., 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). This determination is 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 FD&C Act for the 0.25 mg/0.5 mg product.

The reference listed drug (RLD) upon which you have based your ANDA, Bayer's Angeliq Tablets, 0.25 mg/0.5 mg and 0.5 mg/1 mg, is subject to a period of patent protection. The following patent and expiration date is 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>
8,906,890 (the '890 patent)	October 22, 2031*

\*0.25 mg/0.5 mg strength only

With respect to the '890 patent, your ANDA contains a paragraph III certification to the patent under section 505(j)(2)(A)(vii)(III) of the FD&C Act stating that Novast Laboratories Ltd. (Novast) will not market Drospirenone and Estradiol Tablets, 0.25 mg/0.5 mg prior to the expiration of the patent. Therefore, final approval of your ANDA with respect to the 0.25 mg/0.5 mg strength product may not be granted pursuant to section 505(j)(5)(B)(ii) of the FD&C Act until the '890 patent has expired, currently October 22, 2031.

Upon the foregoing, your ANDA is **approved** insofar as it pertains to the 0.5 mg/1 mg product. Your 0.25 mg/0.5 mg product is **tentatively approved**.

### **I. Approval of Drospirenone and Estradiol Tablets, 0.5 mg/1 mg**

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

### **COMPENDIAL STANDARDS**

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as <https://www.uspnf.com/>.

### **II. Tentative Approval of Drospirenone and Estradiol Tablets, 0.25 mg/0.5 mg**

Our decision to tentatively approve your Drospirenone and Estradiol Tablets, 0.25 mg/0.5 mg, is based upon information currently available to the agency (i.e., data in your ANDA and the status of current good manufacturing practice (cGMP) of the facilities used in the manufacture and testing of the drug product). This decision is subject to change on the basis of new information that may come to our attention.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

## **RESUBMISSION**

To request final approval, please submit an amendment titled "FINAL APPROVAL REQUESTED" with enough time to permit FDA review prior to the date you believe that your ANDA will be eligible for final approval. A request for final approval that contains no new data, information, or other changes to the ANDA generally requires a period of 3 months for Agency review. Accordingly, such a request for final approval should be submitted no later than 3 months prior to the date on which you seek approval. A request for final approval that contains substantive changes to this ANDA or changes in the status of the manufacturing and testing facilities' compliance with cGMPs will be classified and reviewed according to OGD policy in effect at the time of receipt. Applicants should review available agency guidance for industry related to amendments under the generic drug user fee program to determine the duration of Agency review needed to review the changes submitted. As part of this consideration, applicants should monitor any changes to the RLD that occur after tentative approval, including changes in labeling, patent or exclusivity information, or marketing status. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

The amendment requesting final approval should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, settlement or licensing agreement, or other information described in 21 CFR 314.107, 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/MAJOR AMENDMENT TO ORIGINAL #2 – 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 information as specified by the Agency. Failure to submit either or, if requested, both types of amendments described above may 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(j) of the FD&C 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 FD&C Act. Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under section 505(j) of the FD&C Act, and will not be listed in the Orange Book.

**REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL**

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas>.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Uzoma Nnebe, Regulatory Project Manager, at (240) 402 - 5828.

Sincerely yours,

*{See appended electronic signature page}*

For Kendra S. Stewart, R.Ph., Pharm.D.  
CAPT, United States Public Health Service  
Director  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research



Paul  
Levine

Digitally signed by Paul Levine

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