ANDA 75-863 November 29, 2001

Duramed Pharmaceuticals, Inc.
Attention: John R. Rapoza, M.S.
5040 Lester Road
Cincinnati, OH 45213

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated May 5, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Desogestrel/Ethinyl Estradiol and Ethinyl Estradiol Tablets, 0.15 mg/0.02 mg and 0.01 mg (28-day regimen).

Reference is also made to your amendments dated October 20, and November 3, 2000; and February 16 (2 amendments), May 10, April 11, July 18, August 10, November 27, and November 28, 2001.

We have completed the review of this abbreviated application and have concluded that based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacture and testing of the drug product. The determination is subject to change on the basis of new information that may come to our attention. This letter does not address notice issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product referenced in your application, Mircette Tablets (28-day cycle), is subject to a period of patent protection which expires on October 20, 2008, (U.S. Patent No. 4,921,843, the “Pasquale original patent”, and U.S. Patent No. RE 35724, the “Pasquale reissue patent”). Your application contains Paragraph IV Certifications to each of these patents under Section 505(j)(2)(A)(vii)(IV) of the Act stating that they are invalid, unenforceable, or will not be infringed by

Duramed's manufacture, use, or sale of this drug product. Section 505(j)(5)(B)(iii) of the Act provides that approval of this abbreviated new drug application shall be made effective immediately, unless an action is brought against Duramed Pharmaceuticals, Inc. (Duramed) for infringement of one or more of the patents. This action is to be brought before the expiration of forty-five days from the date the notice provided by Duramed under paragraph (2)(B)(I) is received by the patent and new drug application (NDA) holder. You have notified the agency that Duramed has complied with the requirements of Section 505 (j)(2)(B) of the Act. Subsequently, you notified the agency that patent infringement litigation is underway in the United States District Court for the District of New Jersey involving a challenge to the '724 Pasquale reissue patent (Bio-Technology General Corp. v. Duramed Pharmaceuticals, Inc., Civil Action No. 00CV4509). 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) since the date of receipt of the 45-day notice required under section 505(j)(2)(B)(i), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or,

   b. the date of court decision [505(j)(5)(B)(iii)(I), (II), or (III)], which has been interpreted by the Agency to mean the date of the final order or judgement of that court from which no appeal can be or has been taken, or,

   c. the patents have expired, and

2. The Agency is assured there is no new information that would affect whether final approval should be granted.

In order to reactivate this application for final approval, please submit a MINOR AMENDMENT – FINAL APPROVAL REQUESTED between 60 to 90 days prior to the date you believe your application may be approved. This amendment should describe the circumstances that have occurred that may affect the effective date of final approval. In addition, this amendment must provide:

1. A copy of a final order or judgement from which no appeal may be taken (which might not be the one from the district court), or a settlement agreement between the parties, whichever is applicable, or a licensing agreement between you and the patent holder, or any other relevant information, and

2. a. updated information related to final-printed labeling or chemistry, manufacturing and controls data, or any other change in the conditions outlined in this abbreviated application, or

   b. a statement that no such changes have been made to the application since the date of tentative approval.

Any changes in the conditions outlined in this abbreviated application and the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures are subject to Agency review before final approval of the application will be made.

In addition to, or instead of, the amendments referred to above, the Agency may, at any time prior to the final date of approval, request that you submit amendments containing the information requested above.

Failure to submit either or both amendments may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

The drug product that is the subject of this abbreviated application 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 before the effective final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list.

For further information on the status of this application, or prior to submitting the amendment(s) requested above, please contact Ruby Wu R.Ph., Project Manager, at 301-827-5848, for further instructions.

Sincerely yours,

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

cc: ANDA 75-863
Division File
Field Copy
HFD-610/R. West
HFD-330
HFD-205

Endorsements:
HFD-623/N.Takiar/6/18/01
HFD-623/D.Gill/6/18/01
HFD-617/R.Yu/6/7/01;6/18/01
HFD-613/D.Catterson/6/18/01
HFD-613/J.Grace/6/18/01

V:\FIRMSAM\DURAMED\LTRS&REV\75863.ta.doc
F/T by: DJ 6/7/01

TENTATIVE APPROVAL