



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-870/S-015

Novartis Pharmaceuticals Corporation  
Attention: Gregory King  
Sr. Therapeutic Area Manager, Drug Regulatory Affairs  
One Health Plaza  
East Hanover, NJ 07936-1080

Dear Mr. King:

Please refer to your supplemental new drug application dated May 13, 2005, received May 16, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Combipatch® (estradiol/norethindrone acetate transdermal system).

This "Changes Being Effected" supplemental new drug application provides for revisions in the "What are the ingredients in Combipatch" section of the patient labeling approved January 13, 2005.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the attached agreed-upon labeling text.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-870/S-015. Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call George Lyght, R.Ph., Regulatory Health Project Manager, at  
(301) 796-2130

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D. F.A.C.S.  
Division Director  
Division of Reproductive and Urologic Drug Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

Enclosure

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/s/

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Margaret Kober  
11/16/2005 03:13:43 PM  
signed for Dr. Shames