



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 15 2002

Food and Drug Administration
Rockville MD 20857

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Sharon W. Brown
Director, Drug Regulatory Affairs
Berlex Laboratories, Inc.
P. O. Box 1000
Montville, NJ 07045

Florence N. Wong, Pharm. D
Director, Regulatory Affairs/Quality Assurance
3M Pharmaceuticals
Building 275-3W-07
St. Paul, MN 55144-1000

Docket No. 02P-0029/CP1

Dear Ms. Brown and Dr. Wong:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated January 16, 2002, asking FDA to change the therapeutic equivalence code of the Mylan estradiol transdermal system (Mylan ETS) from A-rated to B-rated, to change the labeling for the Mylan ETS to not permit placement of the patch on the buttock, and to "render the Mylan ETS misbranded" under section 502(a), (f), and (j) of the Federal Food, Drug, and Cosmetic Act.

FDA has been unable to reach a decision on your petition because it raises significant issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

02P-0029

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