



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HFA-305

APR 4 2002

Food and Drug Administration
Rockville MD 20857

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Donald O. Beers
Arnold & Porter
555 Twelfth Street, N.W.
Washington, DC 20004-1206

Docket No.: 01P-0470/CP1 & PSA1

Dear Mr. Beers:

This letter responds to your citizen petition and petition for stay of action dated October 10, 2001, and supplement dated February 20, 2002, requesting that the Food and Drug Administration

- deny approval of Elan Pharmaceutical Research Corporation's and Mylan Technologies, Inc.'s "paragraph iv" ANDAs for a transdermal patch using Boehringer Ingelheim Pharmaceutical's (BI's) Catapres-TTS as the reference listed drug;
- not approve any ANDA for a patch that (a) differs from the BI patch, (b) does not meet BI's proposed BE requirements, or (c) has a substantially larger reservoir than BI's product; and
- determine whether 180-day exclusivity is applicable and to whom.

I am writing to inform you that we have not yet resolved the issues raised in your petition because it identifies significant matters 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

01P-0470

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