



JUN 7 2002

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David M. Fox
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004

Re: Docket Number 01P-0560/CP1

Dear Mr. Fox:

I am writing to inform you that the Food and Drug Administration has not yet resolved the issues raised in your citizen petition dated December 11, 2001. You request that the Agency refrain from approving, under section 505 of the Federal Food Drug and Cosmetic Act, any buprenorphine drug product prior to:

1. FDA presenting buprenorphine, and the issues involved in its use for the treatment of narcotic addiction, to an advisory committee;
2. FDA preparing a recommendation for the Drug Enforcement Administration (DEA) that buprenorphine be placed in a schedule under the Controlled Substances Act (CSA) more restrictive than Schedule V;
3. DEA placing buprenorphine in a schedule more restrictive than Schedule V.

We have been unable to reach a decision on your petition because it raises significant/complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with our 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

OIP-0560

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