DEPARTMENT OF HEALTH & HUMAN SERVICES

JAN 29 2001

Food and Drug Administration
Rockville MD 20857

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Eric S. Somers, Esq.
Lexington Law Group
151 Vermont Street, Suite 11A
San Francisco, CA 94103

Re: Docket No. 00P-1432/CP1

Dear Mr. Somers:

This letter is sent in reference to a citizen petition submitted by Lexington Law Group on behalf of Paul Dowhal, dated August 1, 2000, and filed on August 2, 2000 under Docket No. 00P-1432 in FDA's Dockets Management Branch. This petition requested the agency to provide a consistent pregnancy warning label on all nicotine products that more broadly communicates all of the potential reproductive harm associated with nicotine use.

The procedures governing the review of citizen petitions are set out in regulations found at 21 CFR §10.30. The regulations provide, among other things, that the Commissioner will furnish a response to a petition within 180 days of receipt of the petition, agency resources and priorities permitting. See 21 CFR §10.30(e).

The agency is completing its review of the material submitted in support of this petition and the comments submitted to the public docket. The response to this petition is in the final stages of completion and the agency intends to issue the response shortly. If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852.

Sincerely yours,

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

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