DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 31 2003

Eric M. Mittleberg, Ph.D.
Vice President, Scientific/Medical Affairs
Ivax Pharmaceuticals, Inc.
140 Legrand Avenue
Northvale, NJ 07647

Re: Docket Nos. 00P-1445/CP1 & 00P-1443/PSA1

Dear Dr. Mittleberg:

This letter responds to your citizen petition and petition for stay of action, both dated August 8, 2000, in which you request that the Food and Drug Administration (FDA) (1) issue a statement clarifying that all abbreviated new drug applications (ANDAs) containing a Paragraph IV certification delivered to FDA's Office of Generic Drugs (OGD) on the same business day are submitted at the same time for 180-day exclusivity purposes and (2) stay the effective approval of any ANDA for alendronate sodium tablets, 5 mg, 10 mg, and 40 mg, until effective approval is granted to Ivax's ANDA 75-711 for this product.

FDA has carefully considered the issues raised in your petitions and is issuing a guidance document that essentially grants your request identified at (1) above. Enclosed is a copy of the guidance document, *180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day.* Whether Ivax is eligible for 180-day exclusivity for alendronate sodium tablets, 5 mg, 10 mg, and 40 mg, under the approach described in the guidance will be determined when one or more ANDAs for that drug are ready for approval.

Sincerely yours,

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

Enclosure

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