HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 2 5 2003

Ms. Patricia Jaworski
Associate Director, Regulatory Affairs
New Product Submissions
IVAX Pharmaceuticals, Inc.
140 Legrand Avenue
Northvale, NJ 07647

Re: Docket No. 02P-0391/CP1

Dear Ms. Jaworski:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition received on September 3, 2002. Your petition requests that FDA determine whether Alphagan (brimonidine tartrate ophthalmic solution) 0.2% was withdrawn from sale for safety and efficacy reasons.

FDA has been unable to reach a decision on your petition because it raises issues that require additional review and analysis by the Agency. 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,

Jane A. Axelrad for

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

02P-0391

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