



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville MD 20852-1448

MAR 28 2000

Bernard D. Saxe
Foley & Lardner
Suite 500
3000 K Street, N.W.
Washington, D.C. 20007-5109

Re: Docket Number: 97P-0373 - Citizen Petition Submitted on Behalf of Immunomedics, Inc.

Dear Mr. Saxe:

This letter concerns the petition that you submitted to the United States Food and Drug Administration (FDA) on September 4, 1997. Your petition is one of a backlog of citizen petitions, to which FDA has not responded.

Recently, the Office of the Inspector General (OIG) in the Department of Health and Human Services reviewed FDA's citizen petitions process to assess the agency's effectiveness in handling citizen petitions and to identify ways that the process can be improved. The OIG noted that FDA had examined various options for reducing the citizen petition backlog and suggested those options be thoroughly discussed within the agency and "implemented where practical." On November 30, 1999, FDA published a proposed rule to amend its regulations pertaining to citizen petitions. 64 Fed. Reg. 66822 (Nov. 30, 1999). This proposed rule is intended to facilitate and to improve interactions between FDA and interested persons. In addition, FDA is taking various administrative approaches to reduce its citizen petition backlog and improve its handling of citizen petitions.

We are contacting you now to inquire whether you still wish FDA to take action on your long-standing petition. Please contact me by telephone (301-827-6343) or in writing, to advise us of your decision.

Sincerely yours,

Steven F. Falter

Director

Regulations and Policy Staff (HFM-17)

Enclosure

97P-0373

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CC:

Yetter, HFM-10

Cook, GCF-1

Dockets Management Branch, HFA-305