



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 8 2004

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The Honorable Charlie Ryan
Mayor, City of Springfield
36 Court Street
Springfield, MA 01103

Re: Docket No. 2003P-0479/CP1

Dear Mayor Ryan:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in the citizen petition submitted to the Agency on October 15, 2003, by your predecessor, Mayor Michael Albano. The petition asks FDA to, among other things, use its enforcement discretion to allow importation of Canadian versions of drugs that are approved in the United States and issue regulations on drug importation in accordance with the Medicine Equity and Drug Safety Act of 2000.

FDA has been unable to reach a decision on the petition because it raises significant issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to the petition as soon as we have reached a decision on the petition's requests.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2003P-0479

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