DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 17 2006

Barbara Zinck, Chair
Bulk Pharmaceuticals Task Force
Synthetic Organic Chemical Manufacturers Association
1850 M Street, NW, Suite 700
Washington, DC 20036

Re: Docket No. 2006P-0049/CP1

Dear Ms. Zinck:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on January 24, 2006. Your petition requests that the Agency take specific actions designed to manage the risks to public health associated with the use of drugs manufactured or processed at foreign facilities. Specifically, you request that FDA:

1. Rank foreign and domestic drug manufacturing firms together according to FDA's risk-based approach to inspections;
2. List "foreign facility" as a significant risk factor for purposes of its risk-based approach; and
3. Implement a program of monitoring the impurity profiles of imported over-the-counter drugs for patterns that create the appearance of underlying problems with current good manufacturing practices.

FDA has been unable to reach a decision on your 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 your petition as soon as we have reached a decision on your request

Sincerely,

Jane A. Axelrad

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

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