HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

FEB 25 2007

Food and Drug Administration
Rockville MD 20857

John C. Kulli, M.D.
6908 Benedict Beach
Hamlin, NY 14464

Re: Docket No. 2006P-0364/CP1

Dear Dr. Kulli:

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 August 31, 2006. Your petition requests that the Agency issue a regulation requiring manufacturers to reformulate central nervous system stimulant drugs (e.g., Ritalin, Adderall, Dexedrine, Focalin, Concerta, and others) to make it difficult for them to be converted into a powder, which can be insufflated (snorted), or converted into a water-soluble liquid, which can be injected.

FDA has been unable to reach a decision on your petition because it raises complex 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 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

2006P-0364

LET 1