



APR 17 2006

Eliseo O. Salinas, M.D., M.Sc.
Shire Pharmaceuticals Group, plc
725 Chesterbrook Blvd.
Wayne, PA 19087-5637

Re: Docket No. 2005P-0420/CP1 & SUP1

Dear Dr. Salinas:

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 October 18, 2005. Your petition requests that the FDA apply a more stringent bioequivalence requirement, plus additional partial area under the curve pharmacokinetic profile measurements, to any abbreviated new drug application or 505(b)(2) new drug application seeking approval of a drug product referencing Adderall XR MASP (mixed amphetamine salts product).

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 we have reached a decision on your request.

Sincerely,

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

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