



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 20 2004

Norman D. LaFrance, M.D., FACP, FACNP
Senior Vice President,
Medical and Regulatory Affairs
Celltech Americas, Inc.
755 Jefferson Road
P.O. Box 31710
Rochester, NY 14603-1710

Re: Docket No. 2004P-0225/CP1

Dear Dr. LaFrance:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on May 7, 2004. Your petition requests that the Agency apply additional bioequivalence metrics beyond conventional bioequivalence metrics to assure that generic versions of Metadate CD (extended release methylphenidate HCl) are not inappropriately characterized as bioequivalent to the reference product based on insufficiently descriptive pharmacokinetic criteria.

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

2004P-0225

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