



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 12 2004

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James Q. Maloy
Fulcrum, Inc.
23 Carol Street
Clifton, NJ 07014

Re: Docket No. 2003P-0531/CP1

Dear Mr. Maloy:

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 November 19, 2003. Your petition requests that the Agency issue a report specifying the typical range of batch-to-batch and single batch tolerances on pill weights based on information reported to the Agency by drug manufacturers.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

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

2003P-0531

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