



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 25 2007

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Sapna Lohiya
Royal Medical Group
1120 W. Warner Avenue, #A
Santa Ana, CA 92707

Re: Docket No. 2006P-0307/CP1

Dear Ms. Lohiya,

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 by the Agency on August 2, 2006. Your petition requests that we amend our regulations to add requirements concerning the location and appearance of expiration dates on drug product containers.

We have 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

2006P-0307

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