



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 14 2006

Food and Drug Administration
Rockville MD 20857

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Imtiyaz Basade
Vice President, Regulatory Affairs
Orchid Healthcare
Plot No. B3-B6, B11-B14, SIPCOT Industrial Park,
Irungattukottai, Sriperumbudur (Tk.), PIN Code--602 105.
Kancheepuram District, Tamil Nadu.
INDIA

Re: Docket No. 2006P-0255/CP1

Dear Imtiyaz Basade:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated June 13, 2006. Your petition requests that FDA determine whether Duricef (cefadroxil) Tablets, 1 gram (NDA 50-528 held by Warner Chilcott), was withdrawn from sale for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your request because of 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 we have reached a decision on your request.

Sincerely,

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

2006P-0255

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