



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

OCT 6 2002

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*Docket*

Ms. Audrey Bialeski  
Manager, Regulatory Affairs  
Altana, Inc.  
60 Baylis Road  
Melville, NY 11747

Re: Docket No. 02P-0219/CP1

Dear Ms. Bialeski:

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 9, 2002, on behalf of Altana, Inc. You request that the Agency amend the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) for fluocinonide emulsified base. You specifically request that Lidex-E, NDA 16-908, also be designated as the reference listed drug for this 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 possible given the numerous demands on the Agency's resources.

Sincerely yours,

Janet Woodcock, M.D.  
Director  
Center for Drug Evaluation and Research

02P-0219

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