HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 2 0 2003

Robert J. Anderson, Esq.
Senior Director, Scientific Affairs
Altana, Inc.
60 Baylis Road
Melville, NY 11747

Re: Docket No. 2002P-0219/CP1

Dear Mr. Anderson:

This letter responds to your citizen petition dated May 8, 2002, requesting that we revise the current edition of *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) to indicate that the fluocinonide topical cream products Lidex and Lidex-E are not bioequivalent and to designate Lidex-E a reference listed drug.

We have reviewed the bioequivalence study you submitted with your petition and have concluded that the study does demonstrate that Lidex and Lidex-E are not bioequivalent. Accordingly, we changed the therapeutic equivalence code for Lidex, and drugs that are therapeutically equivalent to Lidex, from "AB" to "AB1" and the therapeutic equivalence code for Lidex-E, and drugs that are therapeutically equivalent to Lidex-E, from "AB" to "AB2" in *Supplement 5* (May 2003) to the 23rd edition of the Orange Book. We also designated Lidex-E a reference listed drug. The significance of reference listed drugs and therapeutic equivalence codes is explained in paragraphs 1.4 and 1.7 of the Introduction to the Orange Book. Since we have essentially taken the action you requested, your petition is granted.

Sincerely yours,

/s/

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

Enclosure

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