HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 12 2007

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Joseph A. Carrado, M.Sc., R.Ph.
Vice President, Clinical Regulatory Affairs
Duramed Research, Inc.
One Belmont Avenue, 11th Floor
Bala Cynwyd, PA 19004

Re: Docket No. 2006P-0285/CP1

Dear Mr. Carrado:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition received on July 14, 2006. Your petition requests that the Agency refuse to approve an abbreviated new drug application (ANDA) referencing Seasonale (0.03 mg ethinyl estradiol/0.15 mg levonorgestrel) unless the ANDA contains sufficient data to establish bioequivalence in accordance with the Federal Food, Drug, and Cosmetic Act and FDA regulations (21 U.S.C. 355(j), 21 CFR 320.21, and 21 CFR 320.23).

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

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

2006P-0285

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