DEPARTMENT OF HEALTH & HUMAN SERVICES

DEC 10 2001

Food and Drug Administration
Rockville MD 20857

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Charles J. Cooper
Cooper & Carvin
Suite 401
2000 K Street, N.W.
Washington, D.C. 20006

Re: Docket No. 97N-0325/HER1

Dear Mr. Cooper:

According to the records of FDA's Dockets Management Branch, the hearing request referenced above, submitted on September 8, 1997, on behalf of Duramed Pharmaceuticals, Inc. (Duramed), is still formally unresolved.

You requested a hearing on the Center for Drug Evaluation and Research's (CDER's) refusal to approve Duramed's abbreviated new drug application (ANDA) 40-115 for synthetic conjugated estrogens USP tablets.

As you are aware, on May 5, 1997, CDER made public a memo explaining its position on the approvability of a synthetic generic version of Premarin. This memo is available on CDER's website at: http://www.fda.gov/cder/news/celetterjw.htm. In the memo, CDER outlined its current position on Premarin's active ingredients, stating that Premarin is not sufficiently characterized to determine all of its active ingredients and concluding that until the active ingredients of Premarin are sufficiently defined, a synthetic generic version of Premarin cannot be approved.

On March 24, 1999, CDER approved Duramed's new drug application (NDA) for Cenestin™ (synthetic conjugated estrogens, A) tablets, 0.625 mg and 0.9 mg.

A number of years have passed since your original hearing request. During that time Duramed's synthetic conjugated estrogens drug product was approved as a new drug. If you wish to pursue this hearing request, we are asking that you respond to Docket No. 97N-0325, Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,

97N-0325

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Rockville, MD 20852. If you decide to pursue your hearing request, we ask that you provide a detailed explanation of the reasons for pursuing your request at this time. If we do not receive a written response from you within 30 days, a copy of this letter will be filed in the docket with instructions that your hearing request be considered voluntarily withdrawn. If you have any questions, please contact me at 301-594-5400.

Sincerely,

Jane A. Axelrad

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