HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 11 2003

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Pauliana C. Hall, RAC
President/Principal Consultant
PCH Integrated Regulatory Services, Inc.
30412 Le Port
Laguna Niguel, CA 92677

Re: Docket No. 02P-0464/CP1

Dear Ms. Hall:

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 October 20, 2002. Your petition requests that FDA determine whether it is suitable to file an abbreviated new drug application for diethylstilbestrol (DES) tablets, 1.0 and 5.0 milligrams, that were voluntarily withdrawn from sale in the United States by Eli Lilly & Co., and Bristol-Myers Squibb. Your petition also requests a waiver of the requirements to conduct pediatric studies in accordance with 21 CFR 314.55(c)(2).

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 yours,

Jane A. Axelrad

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

02P-0464

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