



AUG 12 2002

Bruce N. Kuhlik, Esq.  
Covington & Burling  
1201 Pennsylvania Ave., N.W.  
Washington, DC 20004

Re: Docket No. 02P-0059/CP1

Dear Mr. Kuhlik:

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 February 5, 2002, submitted on behalf of Hoffmann-LaRoche, Inc. (Roche), asking FDA to refrain from approving abbreviated new drug applications for isotretinoin drug products until adequate procedures and standards have been developed to ensure that (1) the risk management programs for those products will comply with statutory requirements and be coordinated with Roche's SMART (System to Manage Accutane Related Teratogenicity) program, (2) each program can be linked to the specific drug product actually dispensed by the pharmacy, and (3) each data collection system has been developed to ensure that performance metrics can be accurately measured for the specific drug product.

FDA has been unable to reach a decision on your petition because it raises significant 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 we have reached a decision on your request.

Sincerely yours,

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

02P-0059

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