



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

MAY 31 2002

Kathleen M. Sanzo, Esq.  
Lawrence S. Ganslaw, Esq.  
Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue, NW  
Washington, DC 20004

Re: 01P-0546/PSA1 & SUP1

Dear Ms. Sanzo and Mr. Ganslaw:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition dated December 7, 2001. You request that the Agency not approve or accept abbreviated new drug applications or section 505(b)(2) applications for Covera-HS (verapamil hydrochloride (HCl)) without first establishing bioequivalence using appropriate measures and methods.

FDA has been unable to reach a decision on your petition because it raises issues that require additional review and analysis by the Agency. 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

01P-0546

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