



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 22 2002

Food and Drug Administration  
Rockville MD 20857

James W. Simmons, Jr.  
President  
ChymoCorp  
12770 Cimarron Path, Suite 132  
San Antonio, Texas 78249

Re: Docket No. 02P-0068/CP1

Dear Mr. Simmons:

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February 8, 2002, requesting that FDA determine whether chymopapain 10,000 units/vial injection (Chymodiactin) was withdrawn from sale for reasons of safety or effectiveness.

FDA has yet to reach a decision on your petition 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,

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

02P-0068

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