



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Center for Biologics Evaluation and Research  
1401 Rockville Pike  
Rockville, MD 20852-1448

2110 00 AUG 15 09:45

Mark S. Zaid, P.C.  
Executive Director  
The James Madison Project  
1275 K Street, N.W.  
Washington, D.C. 20005

AUG -9 2000

Re: 00P-0653/CP1

Dear Mr. Zaid:

This letter is to inform you about the status of your citizen petition dated February 11, 2000, that was filed with the Dockets Management Branch on February 16, 2000. In your petition you requested that the Commissioner of Food and Drugs amend the product insert and/or label for Anthrax Vaccine Absorbed, U.S. license number 1260 (rev. 3/99), that is currently manufactured by the BioPort Corporation.

Your petition includes information that is currently under FDA review. We expect to respond to your petition after evaluating this information.

Sincerely,

Kathryn C. Zoon, Ph.D.  
Director, Center for Biologics  
Evaluation and Research

cc: Dockets Management Branch (HFA-305)

00P-0653

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