



DUPLICATE ORIGINAL

Food and Drug Administration  
1401 Rockville Pike  
Rockville MD 20852-1448

APR 11 2002

Russell E. Dingle  
71 Shaughnessy Drive  
East Hartford, CT 06118

Docket No. 01P-0471/CPI

Dear Mr. Dingle:

Pursuant to 21 CFR 10.30(e)(2), this letter is a tentative response to your citizen petition dated October 12, 2001, that was filed with the Dockets Management Branch on October 15, 2001. Your petition requested that the Commissioner of Food and Drugs take the following actions: (1) Issue a final rule on the category placement of anthrax vaccine as Category II, amending a proposed rule which appeared in the Federal Register of December 13, 1985; (2) declare as adulterated all stockpiles of Anthrax Vaccine Adsorbed (AVA) in the possession of BioPort Corporation and all doses in private, public, U.S., or foreign government possession; (3) enforce the Food and Drug Administration (FDA) Compliance Policy Guide (CPG) regarding AVA; and (4) revoke the license for AVA.

Due to a heavy workload, the considerable amount of information in your petition, the importance of the issues raised, and the numerous comments received, we have been unable to complete our review of your petition. We are currently in the process of evaluating and responding to your petition. We will make every effort to so respond within 60 days.

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

cc: Dockets Management Branch (HFA-305)

01P-0471

LET 1