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STATE OF CONNECTICUT
COMMISSIONER OF CONSUMER PROTECTION
165 Capitol Avenue, Hartford, Connecticut 06106

JAMES T. FLEMING
COMMISSIONER

August 2, 2000

Richard Blumenthal
Attorney General
Office of the Attorney General
55 Elm Street
Hartford, CT 06106

Dear Attorney General Blumenthal;

In May of this year I received a letter from you concerning the possible mislabeling of Anthrax vaccine administered to Connecticut National Guardsmen. In response to your concerns, I wrote to Dr. Henney, Commissioner of the Food & Drugs Administration ("FDA").

I am enclosing a copy of a response I recently received from Director Mary T. Meyer of the Center for Biologics Evaluation and Research of the FDA. It appears that the Anthrax vaccine has met all the requirements set forth by the FDA for approval and is available for use under its licensure.

If I can be further assistance, or if you have additional concerns, please feel free to contact me.

Very truly yours,

James T. Fleming
Commissioner

JTF/af

Enclosure

STATE OF CONNECTICUT
COMMISSIONER OF CONSUMER PROTECTION
165 Capitol Avenue, Hartford, Connecticut 06106

JAMES T. FLEMING
COMMISSIONER

May 31, 2000

Commissioner Jane Henney, M.D.
U.S. Food and Drug Administration
5600 Fishers Lane
Room 1471, Mail Routing Code HF1
Rockville, MD 20857

Dear Commissioner Henney:

I am writing you to seek your assurance that the Anthrax Vaccine Adsorbed, manufactured by Bioport Corporation of Michigan under U.S. License 1260 is safe and effective for use by all citizens of our state who may require it. Specifically the controversy surrounding its use in the military's AVA Inoculation program has raised the public awareness concerning this products' safety and use. One specific complaint received by the Auditors of Public Accounts describes in detail alleged violations of current good manufacturing process in the reconditioning labeling and stability testing of lots FAV030 and FAV024, purportedly resulting in the release of misbranded and adulterated product as per the requirements of CFR21 (see attached complaint).

This product has been available for use by the civilian and military populations for several years. As it is the charge of your agency to insure the safety and efficacy of drug products released into the marketplace, a timely response is appreciated to insure our citizens safety and well being.

Respectfully,

James T. Fleming
Commissioner

cc: Sidney Holbrook, Chief of Staff
Major General William A. Cugno,
The Adjutant General
Richard Blumenthal, Attorney General

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUL 19 2000

James T. Fleming
Commissioner of Consumer Protection
State of Connecticut
165 Capitol Avenue
Hartford, Connecticut 06106

Dear Mr. Fleming:

This is in response to your May 31, 2000, letter to Dr. Henney, Commissioner of Food and Drugs. Because the Center for Biologics Evaluation and Research (CBER) reviews vaccines, your letter was referred to me for reply. You expressed concerns about the safety and effectiveness of anthrax vaccine adsorbed (AVA) and requested information on Lots FAV030 and FAV024. I hope the following explanation will respond to your concerns.

It is important to note that the commercially available AVA is a licensed product. On November 10, 1970, the Division of Biologics Standards (now known as CBER) issued a product license to the Michigan Department of Health to manufacture AVA. The product license was transferred to Bioport on November 12, 1998. The fact that a product is approved indicates data submitted supported safety and efficacy for labeled use. The agency's regulatory oversight covers advertising/labeling of the manufacturer, distributor, or repacker of the regulated product.

The approved labeling for the AVA states that immunization with this product is recommended for individuals who may come in contact with animal products that may be contaminated with Bacillus anthracis spores, and for individuals engaged in diagnostic or investigational activities which may bring them in contact with Bacillus anthracis spores. I have enclosed a copy of the label for your information.

Because of the complex manufacturing processes for most biological products, each product lot undergoes thorough testing for purity, potency, identity, and sterility. In addition, the AVA is subject to lot release. Under the lot release regulations, 21 CFR 610.2, FDA reviews the manufacturer's lot release protocols showing results of applicable tests, and lot samples are submitted for possible testing by FDA. The manufacturer may not distribute a lot of the product until FDA's Center for Biologics Evaluation and Research releases it. The lot release program is part of CBER's multi-part strategy that helps assure product safety by providing a quality control check on product specifications.

The expiration date of a biological product may be changed pursuant to 21 CFR 610.50, which states in part that the date of manufacture shall be the date of initiation by the manufacturer of the last valid potency test. Under 21 CFR 610.53 (b), the dating period for a product shall begin on the date of manufacture, as prescribed in section 610.50. A valid potency assay is required prior to an extension of dating. The expiration date is based on the last valid potency assay.

With regards to the two lots mentioned in your letter:

FAV030 has never had the expiration date extended. In fact our records indicate that the entire lot expired in July 1999. FAV024 had the expiration date extended one time in 1997, and the last of this lot expired in April 2000. Neither lot has been quarantined. Neither of these lots have been listed on any of the Inspectional Observations for the last three FDA inspections at Bioport.

As I have indicated previously, the FDA has allowed Bioport to extend the expiration date if they follow the appropriate Standard Operating Procedures and follow FDA regulations concerning the extension of the expiration date. By extending the expiration date, the FDA determines the lot's continued potency. This does not mean the lots are reconditioned or relabeled. The undistributed portions of the lots are stored as unlabeled vials in labeled boxes. When the expiration date is extended, these vials are labeled for the first time, not relabeled. Reconditioning implies that something is done to the contents of a vial or the vial itself. This is not the case when lots have their expiration dates extended.

Thank you very much for your inquiry. I hope you find the information provided useful. I would also suggest that you contact Bioport if you have specific questions concerning the AVA. If I can be of any further assistance please do not hesitate to contact me.

Sincerely,

Mary T. Meyer
Director
Office of Communication, Training
and Manufacturers Assistance
Center for Biologics Evaluation and Research
Food and Drug Administration

Enclosure