



August 21, 2008

Meryl Nass, M.D.
10 Wayman Ln.
Bar Harbor, ME 04609

Re: F06-8463

Dear Dr. Nass:

This is in response to your Freedom of Information Act (FOIA) request dated May 19, 2006 regarding the Anthrax Vaccine Adsorbed (AVA). I apologize for the delay in this response. Your questions are restated below (**in bold**) followed by the CBER response. Please note that a FOIA request should describe documents that are sought. Other written inquiries are more appropriately sent to the:

Center for Biologics Evaluation and Research (CBER)
Office of Communication, Training and Manufacturers Assistance
Division of Communication and Consumer Affairs, Consumer Affairs Branch
1401 Rockville Pike
Rockville, MD 20852

or by email at octma@cber.fda.gov.

1) What is the total number of VAERS reports filed for anthrax vaccine, and how many have been designated serious?

Total # of VAERS reports after Anthrax vaccination through 7/22/08: 5,931
Total # of Serious VAERS reports after Anthrax vaccination through 7/22/08: 618

2) What targeted studies, if any, have been started and/or completed by FDA to assess whether there is a causal relationship between anthrax vaccine and symptoms or diagnoses reported to VAERS.

There are no FDA studies to assess whether there is a causal relationship between the Anthrax Vaccine and symptoms/diagnoses reported to VAERS.

3) Has FDA required the manufacturer to perform the type of studies described in #2 above?

The FDA has not required the manufacturer to perform the type of studies described in #2.

4) Are any US government agencies performing such targeted studies to determine causality for any specific symptoms or diagnoses?

The CDC/DoD are performing such studies. Please refer to the CDC for details or go to the website below.

5) Has a vaccine surveillance summary, or similar FDA review, been prepared for anthrax vaccine?

The Anthrax Vaccine summary: "Review of VAERS Anthrax Vaccine Reports Received Through 8/15/05, and Adverse Event Reports submitted to Docket No. 1980N-0208, December 13, 2005," may be accessed

on the FDA Weblink: <http://www.fda.gov/ohrms/dockets/dockets/80n0208/80n-0208-bkg0006-19-Ref-17-VAERS-Vol225.pdf>. An Anthrax vaccine summary has been submitted for publication.

I hope this information is helpful.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Marites Gabuten', with a long horizontal flourish extending to the right.

Marites Gabuten, Consumer Safety Officer
Center for Biologics Evaluation and Research