

March 25, 2005
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Attention: FDA Docket #1980N-0208; and Federal Register Docket #04-28322

Dear Dr. Lester Crawford, Acting Commissioner of Food and Drugs:

The following comments serve as my inputs for the FDA Dockets Management Branch case # 1980N-0208, as well as Federal Register Docket #04-28322. The inputs submitted in this letter were signed and faxed to 301-827-6870. In commenting on this docket I will cross-reference Citizen Petition Docket #2001P-0471, a document co-authored by Thomas Rempfer and Russell Dingle and submitted to the FDA on October 15, 2001

The FDA did not act on the Citizen Petition requested actions, instead having to be compelled to perform this congressionally chartered obligation following two federal court injunctions. The "FDA's primary mission for 90 years has been to promote and protect the public health," Since the Agency was found by a federal court to have acted in an arbitrary manner regarding the actions requested in our Citizen Petition, I respectfully request the following actions prior to final rulemaking for anthrax vaccine adsorbed (also known as "AVA"):

1. The FDA must reconstitute the expert review panel, in accordance with Agency rules, prior to finalizing the license rulemaking for anthrax vaccine adsorbed.
2. The FDA must investigate DoD Inspector General Hotline Case #84142, referred to the Agency, as well as to the FBI's Public Corruption Squad, for investigation by the Defense Criminal Investigative Service (DCIS) per memo dated November 20th, 2002.
3. The FDA must review the investigation, if any, conducted by Mr. Stewart Simonson, DHHS Deputy General Counsel, resulting from an January 18, 2002 briefing by USAF Officers at DHHS HQ about the illegalities of anthrax vaccine adsorbed's license and the AVIP.
4. The FDA should review a risk management analysis regarding anthrax vaccine adsorbed's use by the DoD. The analysis, prepared in accordance with DOD directives, reviews the institutional and ethical risks faced by the DoD and FDA for knowingly implementing the AVIP in violation of U.S. law.

This analysis has also been separately submitted to FDA's Docket #1980N-0208. The remainder of the present docket entry concentrates on the 1st of the aforementioned requested actions, i.e., that the FDA must reconstitute the expert review panel, in accordance with Agency rules, prior to finalizing the license rulemaking for anthrax vaccine adsorbed. Requested actions #2 through #4 merely require the FDA to forthrightly investigate complaints referred to the Agency by the DCIS, as well as review the risks associated with ignoring the improprieties brought to the attention of the government.

The FDA had to be pushed into doing it's stated job in the licensing of this vaccine. It has failed on several points and it has undermined its own credibility with its inaction that seems to be done on purpose in support of a DOD program.

Was the FDA acting in the public interest and in the interest of safety when it sat silent by as women took this vaccine? The FDA finally acted on SOME of the various data and produced a new package insert warning all involved in taking it that it was a "Category D" AT Risk For Child Birth Defects.

The October 15, 2001 Citizen Petition, Docket #2001P-0471, cross referenced in this docket entry, requested action by FDA to finalize the anthrax vaccine license. Though acknowledging the need to do so, the FDA did not on its own accomplish this action to: "(1) Issue a Final Rule on the drug category placement of anthrax vaccine as Category II (unsafe, ineffective, or misbranded) amending the as yet to be finalized Proposed Rule as published in the Federal Register 13 December 1985." In addition to disregarding this primary requested action of Citizen Petition Docket #2001P-0471, until compelled to do so after being enjoined by federal court, the core issue of the anthrax vaccine's experimental use for inhalation anthrax also remains unresolved.

The FDA rebuffed the Citizen Petition's requests regarding this pivotal issue as well. As a result, the FDA's final rulemaking must clarify that any new licensing does not include this previously acknowledged experimental use.

The 1973 expert review panel did not recommend inhalation anthrax protection as a use for anthrax vaccine adsorbed. This use is also known as aerosolized anthrax protection, and is also referred to as a weaponized biological defense indication for the vaccine. Because the DoD knew the vaccine was experimental or investigational for use against inhalation anthrax, from 1996 to 2005 the Department attempted unsuccessfully to gain specific approval for this investigational use by submitting an Investigational New Drug (IND) Application to the FDA. The DoD's objective was to modify the product's labeling. The federal court documented its conclusions about these events in its 2003 injunction: "In the case of AVA, the 1985 panel found insufficient data to license the drug for use against inhalation anthrax. To date, no additional studies have been performed and AVA's label does not specify use of the vaccine for this purpose. Moreover, the Court is persuaded that the 1996 IND application remains pending today. The introduction to the application expressly states that one objective of the application is to obtain a specific indication for use of AVA against inhalation anthrax. While the government states that the inhalation anthrax aspect of the IND is no longer active, the documents submitted to this Court under seal suggest otherwise.

Finally, statements made by DoD officials suggest that the agency itself has, at some point at least, considered AVA experimental with respect to inhalation anthrax. Given all these factors, the Court would be remiss to conclude that the original license included inhalation anthrax. Having reached that conclusion, the DoD's administration of the inoculation without consent of those vaccinated amounts to arbitrary action." Despite the federal court's initial warning to the FDA through the injunction on December 22, 2003, the Agency attempted to disregard and circumvent the need for a renewed expert panel review in finalizing the anthrax vaccine license. The FDA had similarly disregarded cautions from the U.S. Congress in its 2000 House Report regarding the issue at question — the "experimental" use of anthrax vaccine adsorbed for inhalation anthrax

The federal court's second injunction, a permanent one based on summary judgment, on October 27, 2004 reaffirmed improper rulemaking and licensure. The court explained: 'Under the Administrative Procedure Act, a reviewing court may hold unlawful and set aside final agency action found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law," or "without observance of procedure required by law." 5 U.S.C. § 706(2).'

With these findings the federal court ruled against the FDA, remanding the license back to the Agency for proper rulemaking, and again found that the anthrax vaccine immunization program (AVIP) was "illegal," and in violation of the Administrative Procedures Act — for the exact same reasons articulated in the 2000 Congressional Report and the 2001 Citizen Petition.

I have asked the FDA to follow its own rules before. It has not. I have asked for information under FOIA, it was never answered. I will be following this closely.

Respectfully,

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