DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Rockville MD 20857

MAR 28 2000

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The Honorable Jack Metcalf
House of Representatives
Washington, D.C. 20515-4702

Dear Mr. Metcalf:

Thank you for your letter dated January 31, 2000, addressed to Dr. Jane E. Henney, requesting information from the Food and Drug Administration (FDA) concerning squalene and vaccines used during the Gulf War. We apologize for the delay in responding.

Your letter referenced a Department of Defense (DOD) Report to Congress which you indicated had included the statement that "The FDA verified that none of the vaccines used during the Gulf War contained squalene as an adjuvant." Your letter requested both that verification to DOD and responses to a number of questions. FDA was unfamiliar with the DOD report you cited. On March 9, Ms. Jarilyn Dupont of my staff discussed this with Ms. Norma Smith of your district office and she provided FDA with the DOD Executive Summary referred to in your letter. In reviewing the DOD Executive Summary, it appears that the statement DOD made was in reference to a statement contained in a report from the Senate Special Investigation Unit (SIU) of the Senate Veterans' Affairs Committee which conducted a comprehensive review of Gulf War illnesses. That report indicated that the FDA verified that none of the vaccines used during the Gulf War contained squalene as an adjuvant. (*Report of the Special Investigation Unit on Gulf War Illnesses*, page 123, footnote 331).

In fact, FDA did verify to the Senate Special Investigations Unit on July 23, 1997, in a telephone conversation with Committee staff of the SIU, not with DOD, that neither the licensed vaccines known to be used in the Gulf War, nor the one investigational product known to have been used, contained squalene as an adjuvant in the formulations on file with FDA. FDA also has provided this information, and the information provided below, to the General Accounting Office (GAO) as part of an audit on squalene and Gulf War illness.

Currently, the only adjuvant in licensed vaccine formulations are aluminum compounds. Squalene, an intermediate in the

biosynthesis of cholesterol, is not approved for use as an adjuvant in licensed vaccines. Vaccines are not routinely tested for the presence or absence of squalene by the manufacturer or by FDA's Center for Biologics Evaluation and Research (CBER). Manufacturers perform specific tests as outlined in their license application. The tests for Anthrax Vaccine Adsorbed include Sterility, General Safety, Potency, Aluminum, Formaldehyde, and Benzethonium Chloride. Samples for the Anthrax lots and corresponding protocols containing the test results are submitted to CBER. CBER has the option to perform additional testing on lots submitted for lot release.

Very limited testing of Anthrax Vaccine, Adsorbed, conducted by CBER in 1999 determined that there were only trace amounts of squalene in the lots tested. After an article appeared in the May 1999 issue of Vanity Fair entitled "The Pentagon's Toxic Secret," CBER tested in its laboratories the two lots mentioned in the article (FAV020 and FAV030) for squalene. Three other Anthrax lots (FAV038, FAV043, FAV047) and two other lots of other bacterial vaccines (Wyeth Diphtheria and Connaught Tetanus) containing alum adjuvants were randomly selected for comparative purposes. Due to the inability to detect trace amounts of squalene parts per million, CBER developed a test to detect the substance in parts per billion. The trace amounts of squalene were determined by gas chromatography with flame ionization detection. The squalene content of the lots was determined to be in the level of low parts-per-billion and was comparable to levels determined in three other lots of the anthrax vaccine and the other biological products that were tested. In addition to squalene, lots FAV020 and FAV030 were also tested for aluminum, formaldehyde and benzethonium chloride.

We trust this information responds to your concerns. If we may be of any further assistance, please contact us again.

Sincerely,

for Melinda K. Plaisier
Associate Commissioner
of Legislation