

# WYETH LEDERLE

## VACCINES

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Business Unit of Wyeth-Ayerst Pharmaceuticals  
Division of American Home Products Corporation

January 21, 2002

Dockets Management Branch  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Comments on Docket No. 01N-0464  
Proposed revised form entitled "Vaccine Adverse Event Reporting  
System" (Form VAERS-2) dated July 2001, published in the Federal  
Register / Vol. 66, No. 224 / Tuesday, November 20, 2001 / Notices**

Dear Sir or Madam:

Wyeth-Ayerst Pharmaceuticals, a Division of American Home Products Corporation, hereby submits comments to the FDA regarding the Federal Register Notice pertaining to the proposed revision of the "Vaccine Adverse Event Reporting System" (Form VAERS-2) dated July 2001, Docket No. 01N-0464.

Wyeth-Ayerst is a major research-oriented pharmaceutical company with leading products in the areas of women's health, cardiovascular disease therapies, central nervous system drugs, anti-inflammatory agents, anti-infective agents, vaccines, and biopharmaceuticals. American Home Products Corporation is one of the world's largest research-based pharmaceutical and healthcare products companies, and is a leading developer, manufacturer, and marketer of prescription drugs and over-the-counter medications.

The following comments, summarized in tabular format in Attachment I, summarize the Company's suggestions on the proposed revision of the "Vaccine Adverse Event Reporting System" (Form VAERS-2) dated July 2001. In addition to the specific comments contained in Attachment I, the Company has the following comments regarding the implementation of the Form VAERS-2:

CBER's recent proposal to initiate an Electronic Pilot Program compliant with E2B/M2 Standards mandates that additional changes to the Form VAERS-1 be made at this time. The Company recognizes the need to group related data entry fields for purposes of clarification on the Form; however, initiating these changes would require significant reprogramming and revalidation of the Form to make it compliant with E2B/M2 Standards and would divert resources that are needed for the Electronic Pilot Program.

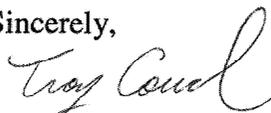
The Company believes it is essential to coordinate the timing of these changes to the Form VAERS-2 to coincide with the implementation of the Electronic Pilot Program utilizing the ICH E2B/M2 Standards.

01N-0464

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This letter, along with Attachment I, is submitted in duplicate. Wyeth-Ayerst appreciates the opportunity to provide this constructive input to the rulemaking process. Please contact the undersigned at 845-602-4482 if there are any questions regarding the submitted comments.

Sincerely,

A handwritten signature in cursive script that reads "Troy Couch".

Troy L. Couch, Ph.D.  
Senior Director  
Worldwide Regulatory Affairs

## Comments On Vaccine Adverse Event Reporting System Draft VAERS-2 Form

Box	Line #'s	Issues	Comments
A : Patient Information	2	Parent/Guardian Name	We suggest adding (s) after <i>Parent, Guardian, and Name</i> ; eg. <b>Parents/Guardians Names</b> . Then it would include the possibility of 2 divorced parents or guardians.
E : Adverse Event Information	1	Describe signs and symptoms that occurred after this vaccination.....	In addition to this narrative text box, we recommend the addition of a <b>separate box to list the primary and secondary adverse events</b> as they appear on the MedWatch form.
E. Adverse Event Information	6	Not Yet	For purposes of clarification, we suggest replacing <i>Not Yet</i> with <b>Recovering</b> .
E. Adverse Event Information	7	Check below if the patient:	We recommend changing the wording to imply that this is an outcome to an adverse event box; eg., <b>Outcome attributed to adverse event (check all that apply)</b> .
E. Adverse Event Information	7	Was hospitalized after vaccination	We suggest additional wording to indicate this was an outcome to the adverse event; eg. <i>Was hospitalized due to the event after vaccination</i> .
E. Adverse Event Information	7	Was hospitalized and his/her stay was prolonged by ____ days	We suggest additional wording to indicate this was as outcome to the adverse event; eg. <i>Was hospitalized and his/her stay was prolonged by ____ days due to the event</i> .
E. Adverse Event Information	7	Died	<i>After Date: ____/____/____</i> , we recommend adding another line <b>List cause of death:</b> _____

ATTACHMENT I

Comments On Vaccine Adverse Event Reporting System Draft VAERS-2 Form

Box	Line #'s	Issues	Comments
F. Patient's Prior Health History	3	....at the time of the vaccination(s) given in box D.	This only covers medications given at the time of the vaccination. It should also cover the period from the time of the vaccination to the time of the event.
G. For Secondary Reporters' Use Only	1	FDA Lic. # _____	Clarification of the information desired is needed. Does VAERS want the PLA/BLA numbers or another number?
G. For Secondary Reporters' Use Only	2	Tracking Number	Definition of Tracking Number is required. Does it refer to the Manufacturer's Control Number, which does not appear anywhere else on the form, or another number such as the Submission Tracking Number?
G. For Secondary Reporters' Use Only	4	Type of secondary report	After <i>Type of secondary report</i> , we suggest the addition of <b>(check all that apply)</b> .
G. For Secondary Reporters' Use Only	<b>6 (new)</b>	Need another box added.	We recommend adding an additional box : <b>6. Type of Report Environment</b> <input type="checkbox"/> Spontaneous <input type="checkbox"/> Study <input type="checkbox"/> Literature

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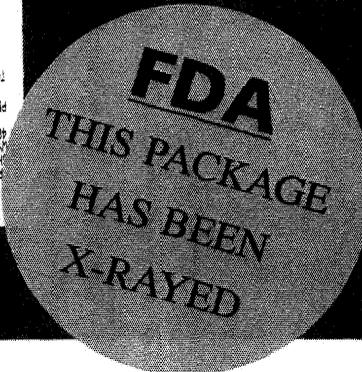
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 401 NORTH MIDDLETOWN ROAD  
 PEARL RIVER, NY 10965-1299  
 (845) 732-5000

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