



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
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FALLS CHURCH VA 22041-3258



5445 '02 JAN 22 P2:41

Anthrax Vaccine Immunization
Program Agency

Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane
Room 1061
Rockville MD 20852

www.fda.gov/dockets/ecomments

Subject: Revised Form VAERS-2 for the Vaccine Adverse Event Reporting
System

Thank you for the opportunity to review the proposed draft of Form VAERS-2.
We propose the following items be considered before issuing the revised form.

VAERS Form

- Make item A10 ("Sex") a piece of "essential epidemiological information," using a black circle with a white numeral.
- In item A11, the text "(may be of any" requires completion of thought and a closing parenthesis.
- Health-care financing is poorly understood by the public, let alone health-care providers. You may wish to add a "Provided by VFC" option.
- Item C7, "Date form completed" could be overlooked by the reporting individual, if the reporting individual is listed in Box A or Box B and does not spend much time looking at Box C. Recommend moving location of this item.
- Item E7: Please consider adding space for reporters to indicate the reason for the hospitalization. Presumably, the reason for prolongation of hospitalization can be discerned from box E1.

VAERS Instruction Sheet

General Information:

- Third bullet - add item A10 to the "essential epidemiological information" list for completion whenever possible.
- Last bullet - small "V" in www.vaers.org (for consistency).

01N-0464

C6

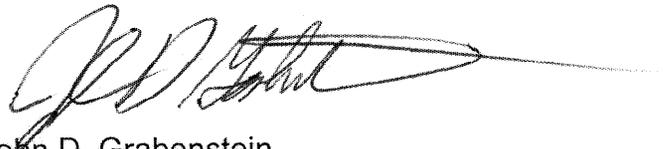
Specific Instructions:

- The entry for item A7 should be listed as "Item A8."
- Item B8: will parents/guardians/other interested individuals understand the difference between "Private" and "Public" funds? You may wish to phrase this as "...purchase the vaccine product(s)..."
- Item D6 "(e.g., IC, IM)" uses a rarely utilized abbreviation to indicate subcutaneous injections more commonly identified as "SC." To discourage the use of potentially misunderstood abbreviations, recommend spelling out the words subcutaneous and intramuscular.
- Item E2 [end of bullet] "(hours, days, weeks or months" requires a closing parenthesis.
- Item E3 should be "Item E4."
- Item E6 - Change "returned" to "return."
- Item E8 does not exist on the VAERS form. Do you mean for this to be E7?

If we can assist your effort in any way, please call us at 703-681-5101.



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