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Guidance for Industry

How to Complete the Vaccine Adverse Event Reporting System Form (VAERS-1)

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Additional copies are available from the Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, or from the Internet at <http://www.fda.gov/cber/guidelines.htm>

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Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)
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GUIDANCE FOR INDUSTRY¹

How to Complete the Vaccine Adverse Event Reporting System Form (VAERS-1)

I. INTRODUCTION

This guidance for industry has been developed to clarify what information should be obtained before an individual case of an adverse experience after immunization should be submitted to the Vaccine Adverse Event Reporting System (VAERS). The Food and Drug Administration (FDA) believes that the recommendations in this guidance document will improve the quality of postmarketing safety reports and clarify the industry's current safety reporting responsibility to assure public health.

This guidance document should be used in conjunction with the Center For Biologics Evaluation and Research (CBER's) *Guideline for Adverse Experience Reporting for Licensed Biological Products* (October 1993) and, ultimately, with any future guidance that supersedes the October 1993 guideline. Hard copies of the guidances are available from CBER's Office of Communication, Training and Manufacturers Assistance (address above). Electronic versions of these guidances are also available on the Internet at <http://www.fda.gov/medwatch/report/mfg.htm>.

II. GENERAL INSTRUCTIONS

Licensed manufacturers² of approved vaccines are required to report adverse experiences to the FDA under 21 CFR 600.80. These instructions for completing form VAERS-1 are for use by manufacturers for **mandatory** reporting of adverse events as designated in the applicable statutes and FDA regulations.

- All entries should be typed or printed in a font no smaller than 10 point
- All boxes should be completed

¹This guidance has been prepared by the Epidemiology Branch in the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration. This guidance represents the Agency's current thinking on reporting of certain postmarketing adverse experiences for licensed vaccines. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

² For purposes of this guidance, the term *licensed manufacturer* includes manufacturers, packers, distributors, shared manufacturers, joint manufacturers, or any other participant involved in divided manufacturing.

- To complete an item when information is not available, use:
 - **NA** for not applicable
 - **NI** for no information at this time (but may become available later)
 - **UNK** for unknown
- Dates should be entered as month, day, and year, formatted as MM/DD/YYYY (e.g., *June 3, 1997 = 06/03/1997*). If exact dates are unknown, provide the best estimate. If day is unknown, month and year is acceptable. If day and month are unknown, year is acceptable.
- Times should be reported as hour: minute (hh:mm) with AM or PM specified. If exact time is unknown, estimate AM or PM, if possible.
- For narrative entries, if the fields do not provide adequate space, attach an additional page(s).

The following specific information is to be incorporated:

- Identify all attached pages as *Page ___ of ___* using the page number and total
- Indicate the appropriate box number and field name next to the narrative continuation
- Include the phrase *continued* at the end of each field that has additional information continued onto another page
- Display the Manufacturer report number (see box 24) in the upper right corner of each page, with the VAERS identification number, if known, for follow-up reports.
- Include the firm's name in the upper right corner, if the report is from a distributor or manufacturer
- A computer-generated facsimile of the form may be submitted in lieu of the preprinted form dependent upon written preapproval by the Division of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research, FDA. It is not necessary for this form to be generated front and back like the preprinted form. Submission of the front of the form only is acceptable.

III. SPECIFIC INSTRUCTIONS

Patient Name - Provide the patient's full name (last name, first name, middle initial). Information identifying the person who received the vaccine or that person's legal representative is required by the National Childhood Vaccine Injury Act and will not be made available to the public.

- ***Complete a separate form for each patient***

N.B.: When a newborn baby is found to have a congenital anomaly that the initial reporter considers possibly associated with a vaccine administered to the mother during pregnancy, the patient is the newborn baby.

Parent-child/fetus report(s) are those cases in which *either* a fetus/suckling infant or the mother, or *both*, sustain an adverse event that the initial reporter considers possibly associated with a vaccine administered to the mother during pregnancy. Several general principles are used for filing these reports:

- If there has been NO event affecting the child/fetus, report ONLY on the parent
- For those cases describing fetal demise or early spontaneous abortion, ONLY a parent report is applicable
- When ONLY the child/fetus has an adverse reaction/event (other than early spontaneous abortion/fetal demise), the information in **boxes 3, 4, 5, 11, 22 and 23** applies to the child/fetus, and characteristics concerning the parent who was the source of exposure to the vaccine is to be provided in **boxes 10, 13, 14, 17, and 18**.
- If BOTH the parent and the child/fetus sustain adverse events, two reports should be provided and linked using the narrative (refer to the manufacturer control #'s in box 24)

N.B.: Submitted VAERS-1 report forms can be obtained under the Freedom of Information (FOI) Act, with patient and reporter identifying information redacted.

- Thus, when a patient or parent *is* the reporter, the patient name should be provided in case follow-up might be needed, since such information is NOT releasable under FOI. However, a company can use the term "Consumer-Confidential," provided that should FDA request to contact that patient, the information would be made available to FDA.

Address - Provide the patient's current address and telephone number.

Vaccine Administered by - Provide the name of the health care provider who administered the vaccination (not prescribing health care provider, unless it is the same person).

Responsible physician - Name of prescribing or responsible physician in the health care setting where the vaccine was given

Form completed by - Provide the name, mailing address and phone number of the *initial* reporter (the person who initially reported the adverse event to the manufacturer) who can be contacted to provide information on the event if follow up is necessary. If a report is provided anonymously, so indicate.

- 1: **State** - Provide two-letter postal abbreviation for state where vaccine was administered. Use patient's home state if state where administered is not known. Use "FR" if vaccine was not administered in the United States.
- 2: **County where administered** - Provide full name of county where vaccine was administered, if known.
- 3: **Date of birth** - Enter the patient's birth date, if known; otherwise enter the patient's age at the time of vaccination in Box 4.
- 4: **Patient age** - Provide patient's age at time of vaccination. Identify units as years, months, or days.
 - if the patient is **3 years or older**, use **years** (e.g., 4 years).
 - if the patient is **less than 3 years old**, use **months** (e.g., 24 months).
 - if the patient is **less than 1 month old**, use **days** (e.g., 5 days).

Provide the best estimate if exact age is unknown. For example, if age can be estimated as 18 years or older, code **AD** for adult; if under 18 years, code **PD** for pediatric.

- 5: **Sex** - Check box for the patient's gender.
- 6: **Date form completed** - Enter the date the report is filled out.
- 7: **Describe adverse event(s)** - Describe the event in detail using the **reporter's own words**, including a description of what happened and a summary of all relevant clinical information (signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). If relevant and available, include synopses of any office visit notes or the hospital discharge summary. To save time (and if permitted by the institution), attach copies of these records.
 - Include a list of adverse event terms that most accurately characterizes the adverse event described in this narrative. List the most important terms first. The terminology should be an accepted standard (e.g., Medical Dictionary for Drug Regulatory Affairs (MedDRA) or FDA's Coding Symbols for a Thesaurus of Adverse Reaction Terms (COSTART)).

- The adverse event should *at a minimum* consist of signs, symptoms, and/or disease diagnosis. If it is initially known only that a patient “experienced unspecified injury,” active investigation should be conducted to obtain more specific information about the adverse event before it is submitted. The only exception occurs with a fatal outcome, where the FDA expects manufacturers to submit all reports of patient deaths (outcome) even if the causal adverse event is unknown.
- *Results of relevant tests and laboratory data* should be entered in box 12. *Previous and concurrent treatments, pre-existing medical conditions and other relevant history* belong in boxes 14, 17, 18, 19. (See instructions for those specific boxes).

8: **Check all appropriate** - Check all boxes that apply.

Patient Died - Check *only* if the death was an *outcome* of the adverse event and include the date of death, if known.

Do NOT check if

- the patient happened to die but there was no suspected association between the death and vaccine;
- a fetus is aborted because of a congenital anomaly, or is miscarried.

Life-threatening illness - Check if the patient was at substantial risk of dying at the time of the adverse event.

Required emergency room/doctor visit - Check if an emergency room or physician was visited as a result of the adverse event.

Hospitalization (initial or prolonged) - Check if the adverse event resulted in admission to the hospital or prolongation of hospitalization. *Note number of days hospitalized.*

DO NOT check if:

- A patient in the hospital received a vaccine and subsequently developed an otherwise nonserious adverse event, UNLESS the adverse event prolonged the hospital stay

Resulted in permanent disability - Check if the adverse event resulted in a substantial disruption of the person’s ability to conduct normal life functions. Such would be the case if the adverse event resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient’s body function/structure, physical activities and/or quality of life.

None of the above - Check only if the other categories are not applicable to the report.

- 9: **Patient recovered** - Check status of patient at time form was completed. Check “yes” if the patient’s health condition is the same as it was prior to the vaccination, “no” if the patient has not returned to the pre-vaccination state of health.
- 10: **Date of vaccination** - Provide date of last vaccination before event.
- 11: **Adverse event onset** - Provide date and time of onset of event symptoms following vaccination. If more than one adverse event occurred, provide information for the most serious event.
- When a newborn baby is found to have a congenital anomaly, the event onset date is the date of birth of the child.
 - When a fetus is aborted because of a congenital anomaly, or is miscarried, the event onset date is the date pregnancy is terminated.

If information is available as to time during pregnancy when exposure occurred, indicate that information in narrative box 7.

- 12: **Relevant diagnostic tests/laboratory data** - Provide all appropriate information, including relevant *negative* test and laboratory findings, in order to convey most completely how the medical work-up and assessment led to consideration of vaccine as a possible etiology for clinical status, as other differential diagnostic considerations were being eliminated. In addition to providing the laboratory values, identify normal results with “NL,” abnormal results with “ABNL” or provide the normal range for the laboratory. Standard, unambiguous medical abbreviations should be used; otherwise terms should be spelled out.

Include relevant laboratory data:

- Providing baseline prior to the vaccine administration
- Used in diagnosing the event
- Providing information on the course of the event.

Also include:

- Synopses of any relevant autopsy, pathology, or lab reports
- Pre- and post-event levels of concomitant medication and dates (if applicable, such as for suspected interactions)

If preferred, copies of any reports may be submitted as attachments (put a note in this box), with all confidential information deleted.

- 13: **Enter all vaccines given on date listed in item 10** - Enter all known vaccines administered on that date, regardless of presumption of causal relationship to event.

Vaccine (type) - Use the abbreviations provided in Appendix A of this guidance. If unknown or if no trade name, use the generic name (with the **manufacturer's** name if known). For foreign reports, use the foreign trade name and the U.S. generic name.

Lot number - Include the lot number(s) for all vaccines.

Route/site - Describe how the vaccine was administered to the patient (e.g., IM/rt. leg).

No. Previous doses - Indicate the number of previous doses of each vaccine. If event occurred after a series of several vaccinations (e.g., 3 doses of hepatitis B vaccine), give details of prior immunizations in box 14.

Route of Administration	Code
Intramuscular	IM
Oral	PO
Subcutaneous	SC
Other	See Appendix B

- 14: **Any other vaccinations within 4 weeks prior to the date listed in item 10** - See instructions for box 13. Also include information regarding any previous injections of a vaccine listed in box 13 that were given to *an adult patient* in a series (e.g., 2 prior doses of hepatitis B vaccine).

- 15: **Vaccinated at** - Check appropriate box.

- 16: **Vaccine purchased with** - Check appropriate box based on how the facility or person who administered the vaccine purchased it, not to payment by the patient's health insurance.
- **Private funds** - purchased by the administering facility with private funds
 - **Public funds** - purchased by state or local health department or the Centers for Disease Control and Prevention (CDC)
 - **Military funds** - purchased by US military.

- 17: **Other medications** - List and provide therapy dates for any other medical products (drugs, biologics, and medical devices) that a patient was using at the time of the event. Include routine medications, prophylactic medications such as over-the-counter (OTC)

antipyretics, and medications given before the onset of symptoms. Include tuberculin skin test if given on the date of vaccination. Do NOT include products used to treat the event, which should be reported in Box 7.

- 18: **Illness at time of vaccination** - Provide information on any short-term illness, condition or symptom present at or about the time of vaccination (e.g., cold, fever, ear infection).
- 19: **Pre-existing physician-diagnosed allergies, birth defects, medical conditions** - If available, provide information on other known physician-diagnosed medical conditions in the patient (e.g., asthma, seizure disorder, immunosuppression, etc.) and significant historical information (allergies, birth defects, etc.).
- 20: **Have you reported this adverse event previously?** - Indicate if the initial reporter has also notified the patient's physician or health department. Check "**To manufacturer**" if another manufacturer has been notified by initial reporter or by reporting manufacturer. Otherwise leave blank.
- 21: **Adverse event following prior vaccination** - List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations, specifying the implicated vaccine, if possible. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain.
- 22: **Birth weight** - Provide the patient's birth weight (in pounds and ounces) for children 5 years of age or younger. Current weight, if relevant, should be noted in the narrative (Box 7).
- 23: **No. of brothers and sisters** - Provide the number of patient's brothers and sisters, as of the date of vaccination, if the patient is 5 years of age or younger.
- 24: **Mfr/imm. proj. report no.** - Provide manufacturer's name and unique identification number for this event. All follow-up reports should have the same number as the initial report.
- 25: **Date received by mfr./imm. proj** - Provide the date when the manufacturer received adequate information to determine that the adverse event was reportable; namely that a patient, vaccine, adverse event, and reporter can be identified. For follow-up reports, use the date that the follow-up information was received.
- 26: **15 Day report?** - Check yes if this report meets criteria specified in the biologic regulations for reports of serious and unexpected adverse events (21 CFR section 600.80). If original report did not meet criteria for an expedited report, indicate date that such information was received in narrative summary (Box 7) and/or in cover letter.

27: **Report type** - Check applicable box.

Initial - check if the report is the first submission of a report.

Follow-up - Check if the report is a follow-up to a previously submitted report. Follow-up reports **should** contain information that was submitted in the original report if the information is still correct.

If a follow-up report, make sure that the manufacturer report number for the previously submitted initial report has been recorded in box 24.

IV. HOW TO OBTAIN FORM VAERS-1 AND INSTRUCTIONS

Copies of Form VAERS-1 can be obtained from:

VAERS
P.O. Box 1100
Rockville, MD 20849-1100

Copies of Form VAERS-1 and Instructions may also be obtained by:

- Mail or fax: Call 1-800-822-7967
- If no access to 800 number, call (301) 217-9660
- Internet: <http://www.fda.gov/cber/vaers.html>

Copies of blank Form VAERS-1 may also be duplicated by the manufacturer.

V. QUESTIONS ABOUT REPORTING?

Epidemiology Branch (HFM-220), Attention: VAERS
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448
Phone 301-827-3974; fax 301-827-3529.

VI. WHERE TO SEND COMPLETED VAERS-1 FORMS

VAERS
P.O. Box 1100
Rockville, MD 20849-1100

APPENDIX A: VAERS ABBREVIATIONS FOR VACCINE TYPE

N.B. In addition to vaccines licensed in the U.S., this list includes abbreviations for some vaccines not licensed in the U.S., but which have been the subject of VAERS reports

ADEN	Adenovirus Vaccine Live Oral Type 7
ANTH	Anthrax Vaccine
BCG	BCG Vaccine
CHOL	Cholera Vaccine
DT	Diphtheria and Tetanus Toxoids Adsorbed Pediatric
DTAP	Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Pediatric
DTAPH	Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Pediatric and Hemophilus B Conjugate Vaccine
DTIPV	Diphtheria and Tetanus Toxoids and Inactivated Polio Virus Vaccine
DTOX	Diphtheria Toxoid Adsorbed
DTP	Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed Pediatric
DTPH	Diphtheria and Tetanus Toxoids and Pertussis and Hemophilus B Conjugate Vaccine Adsorbed Pediatric
DTPIPV	Diphtheria and Tetanus Toxoids and Pertussis Adsorbed Pediatric and Inactivated Polio Virus Vaccine
FLU	Influenza Virus Vaccine
HBHEPB	Hemophilus B Conjugate Vaccine and Hepatitis B Vaccine
HEPA	Hepatitis A Vaccine
HEPB	Hepatitis B Vaccine
HIBV	Hemophilus B Vaccine
IPV	Inactivated Polio Virus Vaccine
JEV	Japanese Encephalitis virus Vaccine Inactivated
M	Measles Virus Vaccine Live
MEN	Meningococcal Polysaccharide Vaccine
MM	Measles and Mumps Virus Vaccine Live
MMR	Measles, Mumps, and Rubella Virus Vaccine Live
MR	Measles and Rubella Virus Vaccine Live
MU	Mumps Virus Vaccine Live
MUR	Rubella and Mumps Virus Vaccine Live
OPV	Polio Virus Vaccine Live Oral Trivalent
P	Pertussis Vaccine
PLAGUE	Plague Vaccine
PPV	Pneumococcal Vaccine Polyvalent
R	Rubella Virus Vaccine Live
RAB	Rabies Vaccine
RSV	Respiratory Syncytial Virus Vaccine
SMALL	Smallpox Vaccine

TD	Tetanus and Diphtheria Toxoids Adsorbed Adults
TTOX	Tetanus Toxoid
TYP	Typhoid Vaccine
VARCEL	Varicella Vaccine Live
YF	Yellow Fever Vaccine

APPENDIX B: ROUTES OF ADMINISTRATION LIST AND NUMERIC CODES

Description	ICH-M2 Numeric Codes
Auricular (otic)	001
Buccal	002
Cutaneous	003
Dental	004
Endocervical	005
Endosinusial	006
Endotracheal	007
Epidural	008
Extra-amniotic	009
Hemodialysis	010
Intra corpus cavernosum	011
Intra-amniotic	012
Intra-arterial	013
Intra-articular	014
Intra-uterine	015
Intracardiac	016
Intracavernous	017
Intracerebral	018
Intracervical	019
Intracisternal	020
Intracorneal	021
Intracoronary	022
Intradermal	023
Intradiscal (intraspinal)	024
Intrahepatic	025
Intralesional	026
Intralymphatic	027
Intramedullar (bone marrow)	028
Intrameningeal	029
Intramuscular	030
Intraocular	031
Intrapericardial	032
Intraperitoneal	033
Intrapleural	034
Intrasynovial	035
Intratumor	036
Intrathecal	037
Intrathoracic	038
Intratracheal	039
Intravenous bolus	040

Description	ICH-M2 Numeric Codes
Intravenous drip	041
Intravenous(not otherwise specified)	042
Intravesical	043
Iontophoresis	044
Occlusive dressing technique	045
Ophthalmic	046
Oral	047
Oropharyngeal	048
Other	049
Parenteral	050
Periarticular	051
Perineural	052
Rectal	053
Respiratory (inhalation)	054
Retrobulbar	055
Subconjunctival	056
Subcutaneous	057
Subdermal	058
Sublingual	059
Topical	060
Transdermal	061
Transmammary	062
Transplacental	063
Unknown	064
Urethral	065
Vaginal	066

APPENDIX C: FORM VAERS-1



VACCINE ADVERSE EVENT REPORTING SYSTEM

24 Hour Toll Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100

PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only

VAERS Number _____

Date Received _____

Patient Name: _____
 Last First M.I.
 Address _____

 City State Zip
 Telephone no. (____) _____

Vaccine administered by (Name): _____
 Responsible Physician _____
 Facility Name/Address _____

 City State Zip
 Telephone no. (____) _____

Form completed by (Name): _____
 Relation Vaccine Provider Patient/Parent
 to Patient Manufacturer Other
 Address (if different from patient or provider)

 City State Zip
 Telephone no. (____) _____

1 State _____ 2 County where administered _____ 3 Date of birth / / 4 Patient age _____
 mm dd yy

5 Sex M F 6 Date form completed / /
 mm dd yy

7 Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8 Check all appropriate
 Patient died (date / /)
 Life threatening illness mm dd yy
 Required emergency room/doctor visit
 Required hospitalization (____ days)
 Resulted in prolongation of hospitalization
 Resulted in permanent disability
 None of the above

9 Patient recovered YES NO UNKNOWN

10 Date of vaccination / / AM/PM
 mm dd yy
 Time _____ AM/PM

12 Relevant diagnostic tests/laboratory data

11 Adverse event onset / / AM/PM
 mm dd yy
 Time _____ AM/PM

13 Enter all vaccines given on date listed in no. 10

Vaccine (type)	Manufacturer	Lot number	Route/Site	No Previous Doses
a _____	_____	_____	_____	_____
b _____	_____	_____	_____	_____
c _____	_____	_____	_____	_____
d _____	_____	_____	_____	_____

14 Any other vaccinations within 4 weeks prior to the date listed in no. 10

Vaccine (type)	Manufacturer	Lot number	Route/Site	No Previous doses	Date given
a _____	_____	_____	_____	_____	_____
b _____	_____	_____	_____	_____	_____

15 Vaccinated at Private doctor's office/hospital Military clinic/hospital Public health clinic/hospital Other/unknown
 16 Vaccine purchased with Private funds Military funds Public funds Other/unknown
 17 Other medications _____

18 Illness at time of vaccination (specify) _____ 19 Pre-existing physician-diagnosed allergies, birth defects, medial conditions(specify) _____

20 Have you reported this adverse event previously? No To health department To doctor To manufacturer

Only for children 5 and under
 22 Birth weight _____ lb _____ oz
 23 No of brother and sisters _____

21 Adverse event following prior vaccination (check all applicable, specify)

Adverse Event	Onset Age	Type Vaccine	Dose no in series
<input type="checkbox"/> In patient _____	_____	_____	_____
<input type="checkbox"/> In brother or sister _____	_____	_____	_____

Only for reports submitted by manufacturer/immunization project
 24 Mfr/imm proj report no _____ 25 Date received by mfr/imm proj _____
 26 15 day report? Yes No
 27 Report type Initial Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

"Fold in thirds, tape & mail - DO NOT STAPLE FORM"



NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES
OR APO/FPO

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD

POSTAGE WILL BE PAID BY ADDRESSEE



VAERS
P.O. Box 1100
Rockville MD 20849-1100

Series of horizontal lines for postal sorting



DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed)

GENERAL

Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)

Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.

Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.

These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.

Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

- Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms diagnosis, treatment and recovery should be noted.
- Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.
- Item 10: Give dates and times as specifically as you can remember. If you do not know the exact time, please
- Item 11: indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.
- Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.
- Item 13: List ONLY those vaccines given on the day listed in Item 10.
- Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.
- Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.
- Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.
- Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).
- Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.
- Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.
- Item 26: This space is for manufacturers' use only.