

resulting in an estimated 37 sponsors affected by the guidance annually.

Based on information provided to FDA by sponsors that have typically used DMCs for the kinds of studies for which this guidance recommends them, FDA estimates that the majority of sponsors have already prepared SOPs for DMCs, and only a minimum amount of time would be necessary to revise or update them for use for other clinical studies. Based on FDA's experience with clinical trials using DMCs, FDA estimates that the sponsor on average would issue two interim reports per clinical trial to the DMC. FDA estimates that the DMCs would hold two meetings per year per clinical trial resulting in the

issuance of two DMC reports of the meeting minutes to the sponsor. One set of both of the meeting records should be maintained per clinical trial. Based on FDA's experience with the submission of investigational new drug applications (INDs), FDA estimates that one statistical approach per clinical trial would be submitted to FDA.

The hours per response and hours per record are based on FDA's experience with comparable recordkeeping and reporting provisions applicable to FDA regulated industry. The hours per response include the time the respondent would spend reviewing, gathering, and preparing the information to be submitted to the DMC,

FDA, or the sponsor. Because clinical trials vary greatly in complexity, FDA estimates that the time needed to prepare and submit an interim report by a sponsor or sponsor's contractor to the DMC would generally range from 40 to 200 hours with an average of 120 hours for each report. The hours per record include the time to record, gather, and maintain the information.

The total estimated burden for both the reporting and recordkeeping burdens under the draft guidance are 93,684 hours.

FDA invites comments on this analysis of information collection burdens. FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Reporting Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
SOPs	37	1	37	4	148
Interim reports by the sponsor to a DMC	370	2	740	120	88,800
Statistical approach to FDA	370	1	370	8	2,960
DMC report of meeting minutes to the sponsor	370	2	740	1	740
Total					92,648

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
SOPs	37	1	37	8	296
Meeting records	370	1	370	2	740
Total					1,036

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

### III. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document and on the collection of information. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by February 19, 2002. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

### IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cber/guidelines.htm>, <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cdrh>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: November 14, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

[Docket No. 01N-0464]

#### Vaccine Adverse Event Reporting System; Revised Form VAERS-2; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a proposed revised form entitled "Vaccine Adverse Event Reporting System" (Form VAERS-2) dated July 2001. This proposed revised form is intended to facilitate electronic reporting. The form has been revised by deleting data fields that FDA considers redundant or unnecessary, and by

adding or revising data fields to ensure reporting clarity.

**DATES:** Submit written or electronic comments on the proposed revised Form VAERS-2 to ensure their adequate consideration in preparation of the final form by January 22, 2002.

**ADDRESSES:** Submit written requests for single copies of the proposed revised form to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The form may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the proposed revised Form VAERS-2.

Submit written comments on the proposed revised form to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Michael Anderson, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a proposed revised form entitled "Vaccine Adverse Event Reporting System" (Form VAERS-2) dated July 2001. The Vaccine Adverse Event Reporting System is a cooperative program for vaccine safety of FDA and the Centers for Disease Control and Prevention. VAERS is a postmarketing safety surveillance program collecting information about adverse events (side effects) that occur after the administration of U.S. licensed vaccines. Reports are welcome from all concerned individuals: Patients, parents, health care providers, pharmacists, and vaccine manufacturers. The proposed revised form is intended to facilitate electronic reporting. The form has been revised by deleting data fields that FDA considers redundant or unnecessary, and by adding or revising data fields to ensure reporting clarity.

##### **II. Comments**

The proposed revised form is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding the form. Submit written or electronic comments on the proposed revised form to ensure their adequate consideration in preparation of the final form by January 22, 2002. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the proposed revised form and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

##### **III. Electronic Access**

Persons with access to the Internet may obtain the proposed revised form at either <http://www.fda.gov/cber/vaers/report.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: November 7, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01-28884 Filed 11-19-01; 8:45 am]

**BILLING CODE 4160-01-S**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Health Resources and Services Administration**

##### **Public Hearing; Notice of Meeting**

In accordance with section 10(a) (2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of December.

*Name:* Advisory Commission on Childhood Vaccines (ACCV).

*Date and Time:* December 5, 2001; 9 a.m.-4 p.m.

*Place:* Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, Maryland 20857, and Audio Conference Call.

The full ACCV will meet on Wednesday, December 5, from 9:00 a.m. to 4:00 p.m. The public can join the meeting in person at the address listed above or by audio conference call by dialing 1-888-316-9406, and providing the following information:

*Leader's Name:* Thomas E. Balbier, Jr.

*Password:* ACCV.

The agenda items will include, but not limited to: a discussion of proposed legislation from the House Committee on Government Reform; a discussion of a possible alternative standard for the adjudication of claims for non-table injuries; a discussion on the interim payment of medical expenses; a presentation from petitioners attorneys' perspective; a discussion of the legislative proposal for reversionary trusts; a presentation on the Institute of Medicine's Report, "Thimerosal-Containing Vaccines and Neurodevelopmental Disorders"; and updates from the National Vaccine Injury Compensation Program, the Department of Justice, and the National Vaccine Program Office.

Public comment will be permitted at the end of the ACCV meeting on December 5, 2001. Oral presentations will be limited to 5 minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to:

Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Office of Special Programs, Health Resources and Services Administration, Room 8A-46, 5600 Fishers Lane, Rockville, MD 20857. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of their assigned presentation time.

Persons who do not file an advance request for a presentation, but desire to make an oral statement, may sign-up in Conference Rooms G and H on December 5, 2001. These persons will be allocated time as time permits.

Anyone requiring information regarding the ACCV should contact Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Office of Special Programs, Health Resources and Services Administration, Room 8A-46, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-2124 or e-mail: [clee@hrsa.gov](mailto:clee@hrsa.gov).

Agenda items are subject to change as priorities dictate.