public health emergency such as a bioterrorist incident.

On January 24, 2003, due to concerns that terrorists may have access to the smallpox virus and attempt to use it against the American public and U.S. Government facilities abroad, the Secretary issued a declaration making section 224's legal protections available. The declaration was effective until and including January 23, 2004; it included in section VI a number of definitions, which are no longer appropriate because of the statutory amendments in section 3 of SEPPA. The Secretary issues the amendment below to: (1) Delete the section VI definitions, and (2) extend the January 24, 2003, declaration pursuant to section 224(p)(2)(A) of the Public Health Service Act. In deleting the definitions, the Secretary does not intend to adopt an interpretation of the statutory amendments as limiting or denying the remedy of section 224(a) in any situation where it would have been available under the statute as originally enacted and the January 24, 2003, declaration.

**Amendment To Extend January 24, 2003 Declaration Regarding Administration of Smallpox Countermeasures**

I. *Policy Determination:* The underlying policy determinations of the January 24, 2003 declaration continue to exist, including the heightened concern that terrorists may have access to the smallpox virus and attempt to use it against the American public and U.S. Government facilities abroad.

II. *Amendment of Declaration:* I, Tommy G. Thompson, Secretary of the Department of Health and Human Services, have concluded, in accordance with the authority vested in me under section 224(p)(2)(A) of the Public Health Service Act, that a potential bioterrorist incident makes it advisable to extend the January 24, 2003 declaration regarding administration of smallpox countermeasures until and including January 23, 2005. The January 24, 2003, declaration as hereby amended may be further amended as circumstances require.

III. *Definitions:* The definitions of the January 24, 2003 declaration are deleted; terms that are used in the declaration and that are defined in section 224(p) of the Public Health Service Act shall have the meanings given in those definitions.

IV. *Effective Dates:* This extension is effective January 24, 2004 until and including January 23, 2005. The effective period may be extended or shortened by subsequent amendment to the January 24, 2003, declaration as hereby amended.

Dated: January 21, 2004.

**Tommy G. Thompson,**

*Secretary.*

[FR Doc. 04–1631 Filed 1–26–04; 8:45 am]

**BILLING CODE 4160–17–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003N–0575]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; 2004 National Tracking Survey of Prescription Drug Information Provided to Patients

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a national tracking survey, conducted every 2 years, of prescription drug information received by patients.

**DATES:** Submit written or electronic comments on the collection of information by March 29, 2004.

**ADDRESSES:** Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*2004 National Tracking Survey of Prescription Drug Information Provided to Patients*

FDA implements the provisions of the Federal Food, Drug, and Cosmetic Act (the act) designed to assure the adequate labeling of prescription (Rx) drugs. Under section 502(a) of the act (21 U.S.C. 352(a)), a drug product is misbranded if its labeling is false or misleading in any particular, and under section 201(n) of the act (21 U.S.C. 321(n)), a drug's labeling is misleading if its labeling or advertising fails to reveal material facts. FDA also has the authority to collect this information under Title VI of Public Law 104–180 (Related Agencies and Food and Drug Administration) section 601 (Effective Medication Guides), which directs the development of ''a mechanism to assess periodically * * * the frequency with which the [oral and written prescription] information is provided to consumers.''

To assure that Rx drugs are not misbranded, FDA has historically asserted that adequate labeling requires certain information be provided to patients. In 1982, when FDA revoked a planned initiative to require mandatory patient package inserts for all Rx drugs

in favor of private sector initiatives, the agency indicated that it will periodically conduct surveys to evaluate the availability of adequate patient information on a nationwide basis. In addition, FDA has been responsible for setting and tracking Healthy People 2010 goals for the receipt of medication information by patients.

Surveys of consumers about their receipt of Rx drug information were carried out in 1992, 1994, 1996, 1998, and 2001. This notice is in regard to conducting the survey in 2004.

The survey is conducted by telephone on a national random sample of adults who received a new prescription for themselves or a household member within the past 4 weeks. The interview assesses the extent to which information was received from the doctor, the pharmacist, and other sources. Survey respondents are also asked attitudinal questions, and demographic and other background characteristics are obtained. The survey enables FDA to determine the frequency with which such information is provided to consumers. Without this information, the agency would be unable to assess the degree to which adequate oral patient information about Rx drugs is provided.

Respondents to this collection of information are adults (18 years or older) in the continental United States who have obtained a new (nonrefill) prescription at a pharmacy for themselves or a member of their household in the last 4 weeks.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| Year | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Screener | | | | | |
| 2004 | 15,319 | 1 | 15,319 | 02 | 306 |
| Survey | | | | | |
| 2004 | 1,000 | 1 | 1,000 | .32 | 320 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This total estimate of 626 total annual burden hours is based on the 2001 survey administration, in which 15,319 potential respondents were contacted to obtain 1,000 interviews.

Dated: January 16, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–1586 Filed 1–26–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004N–0425]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Pilot Program for Medical Devices

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements related to the adverse event pilot program for medical devices.

**DATES:** Submit written or electronic comments on the collection of information byMarch 29, 2004.

**ADDRESSES:** Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.