The annual burden estimate for this information collection is 1,414 hours. The estimated reporting burden for this collection is 754 hours and the estimated recordkeeping burden is 660 hours.

In the **Federal Register** of July 5, 2005 (70 FR 38689), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received on the information collection.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Request for Consideration; Pending application on file	1	1	1	15	15
Request for Consideration; No application pending	1	1	1	50	50
Pre-emergency submissions; Pending application on file	10	1	10	20	200
Pre-emergency submissions; No application pending	3	1	3	75	225
Manufacturers of an unapproved EUA product	3	4	12	2	24
State and local public health officials; Unapproved EUA product	30	4	120	2	240
Total					754

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Manufacturers of an unapproved EUA product	3	4	12	25	300
State and local public health officials; Unapproved EUA product	30	4	120	3	360
Total					660

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

Dated: July 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–11287 Filed 7–17–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting Members on a Public Advisory Committee; Pediatric Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Pediatric Advisory Committee in the Office of the Commissioner. Nominations will be accepted for vacancies that have occurred on or before June 30, 2006.

FDA has special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: No cutoff date is established for the receipt of nominations. However, nominations received on or before July 28, 2006, will be given first consideration for membership on the Pediatric Advisory Committee.

ADDRESSES: All nominations for membership should be sent to Jan Johannessen (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Jan N. Johannessen, Office of Science and Health Coordination (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, FAX 301–827–3042, e-mail: *Jan.Johannessen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members on the Pediatric Advisory Committee. There are currently six vacancies on this committee. These vacancies need to be filled as soon as possible.

I. Function of the Pediatric Advisory Committee

The committee advises the Commissioner of Food and Drugs on pediatric therapeutics, pediatric research, and other matters involving pediatrics for which FDA has regulatory responsibility. The Committee also advises and makes recommendations to the Secretary of Health and Human Services under 21 CFR 50.54 for products regulated by FDA and 45 CFR 46.407 on research involving children as

subjects that is conducted or supported by the Department of Health and Human Services and involves a product regulated by FDA.

II. Qualifications

Persons nominated for membership on the committees shall have scientific expertise in one or more of the following areas: Pediatric research, pediatric subspecialties, pediatric therapeutics, statistics, and/or biomedical ethics. There is a particular need for clinical and/or scientific expertise in pediatric neurology, adolescent medicine or statistics. The term of office is up to 4 years, depending on the appointment date.

III. Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on the Pediatric Advisory Committee. Self-nominations are also accepted. Nominations shall include the name of the committee, a complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 10, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. 06–6276 Filed 7–17–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0169]

Guidance on Useful Written Consumer Medication Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Useful Written Consumer Medication Information (CMI).'' CMI is written information developed for consumers about prescription drugs that is distributed to consumers when they have prescriptions filled. The guidance discusses general issues and makes recommendations on the content of useful written CMI.

DATES: Submit written or electronic comments on agency guidance at any time

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling the Center for Biologics Evaluation and Research at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist the offices in processing your request. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Paul Seligman, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5620.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Useful Written Consumer Medication Information (CMI).'' This guidance is intended to assist individuals or organizations (e.g., pharmacies, private vendors, healthcare associations) in developing useful written consumer medication information to comply with Public Law 104–180. CMI is written information about prescription drugs developed by organizations or individuals, other than a drug's manufacturer, that is intended for distribution to consumers at the time of dispensing. Since neither FDA nor the drug's manufacturer reviews or approves CMI, FDA recommends that the developers of written medication information use the factors discussed in this guidance to help ensure that their CMI is useful to consumers.

In the **Federal Register** of May 26, 2005 (70 FR 30467) (the May 2005 guidance), FDA announced the availability of a draft version of this guidance. The May 2005 guidance gave interested persons an opportunity to submit comments through July 25, 2005. All comments received during the comment period have been carefully reviewed and incorporated in this revised guidance where appropriate. As a result of the public comment, we hope that the guidance is clearer and more concise than the draft version.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on useful written CMI. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

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

Dated: July 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–11329 Filed 7–17–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: June 2006

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.