ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

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

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Submitting and Reviewing Complete Responses to Clinical Holds—(OMB Control Number 0910–0445—(Extension)

Section 117 of the Food and Drug Administration Modernization Act (Public Law 105–115), signed into law by the President on November 21, 1997, provides that a written request to FDA from the applicant of an investigation that a clinical hold be removed shall receive a decision in writing, specifying the reasons for that decision, within 30 days after receipt of such request. A clinical hold is an order issued by FDA to the applicant to delay a proposed clinical investigation or to suspend an ongoing investigation for a drug or biologic. An applicant may respond to a clinical hold.

Under section 505(i)(3)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(3)(C)), any written request to FDA from the sponsor of an investigation that a clinical hold be removed must receive a decision, in writing and specifying the reasons, within 30 days after receipt of the request. The request must include sufficient information to support the removal of the clinical hold.

In the **Federal Register** of May 14, 1998 (63 FR 26809), FDA published a notice of availability of a guidance that described how applicants should submit responses to clinical holds so that they may be identified as complete responses and the agency can track the time to respond.

FDA issued a revised guidance in October 2000 which states that FDA will respond in writing within 30-calendar days of receipt of a sponsor's request to release a clinical hold and a complete response to the issue(s) that led to the clinical hold. An applicant's complete response to an investigational new drug (IND) clinical hold is a response in which all clinical hold issues identified in the clinical hold letter have been addressed.

The guidance requests that applicants type ''Clinical Hold Complete Response'' in large, bold letters at the top of the cover letter of the complete response to expedite review of the response. The guidance also requests that applicants submit the complete response letter in triplicate to the IND, and that they fax a copy of the cover letter to the FDA contact listed in the clinical hold letter who is responsible for the IND. The guidance requests more than an original and 2 copies of the cover letter in order to ensure that the submission is received and handled in a timely manner.

Based on data concerning the number of complete responses to clinical holds received by the Center for Drug Evaluation and Research (CDER) in 2004 and 2005, CDER estimates that approximately 88 responses are submitted annually from approximately 67 applicants, and that it takes approximately 284 hours to prepare and submit to CDER each response.

Based on data concerning the number of complete responses to clinical holds received by the Center for Biologics Evaluation and Research (CBER) in 2004 and 2005, CBER estimates that approximately 92 responses are submitted annually from approximately 60 applicants, and that it takes approximately 284 hours to prepare and submit to CBER each response.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Complete Responses to Clinical Holds	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Hours Per Response	Total Hours
CDER	67	.76	88	284	24,992
CBER	60	1.53	92	284	26,128
Total					51,120

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

In the **Federal Register** of May 25, 2006 (71 FR 30142), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: September 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–16225 Filed 9–29–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0382]

Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarket Surveillance

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 information collection requirements for Postmarket Surveillance under 21 CFR part 822.

DATES: Submit written or electronic comments on the collection of information by December 1, 2006.

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: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Postmarket Surveillance—21 CFR Part 822 (OMB Control Number 0910–0449)—Extension

Section 522(a) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360(l)) authorizes FDA to require manufacturers to conduct postmarket surveillance of any device that meets the criteria set forth in the statute.

The postmarket surveillance (PS), regulation establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides specific, clear, and flexible instructions to manufacturers so they know what information is required in a postmarket surveillance plan submission. FDA reviews submissions in accordance with part 822 (21 CFR part 822) in §§ 822.15 to 822.18 of the regulation, which describe the grounds for approving or disapproving a PS plan. If this information is not collected, FDA would not be able to ensure that the PS plan could result in the collection of useful data which could reveal unforeseen adverse events or other information necessary to protect the public health.

Respondents to this collection of information are those manufacturers who require postmarket surveillance of their products.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
822.9, 822.10	5	1	5	120	600
822.21	3	1	3	40	120
822.26	1	1	1	8	8
822.27	1	1	1	40	40
822.28	1	1	1	40	40
822.29	1	1	1	120	120
822.30	1	1	1	40	40
822.34	1	1	1	20	20
822.38	10	2	20	120	2,400
Total					3,338

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
822.31	10	1	10	20	200
822.32	30	1	30	10	300
Total					500

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

FDA estimates that, based on current staffing and resources and experience with five actual postmarket surveillance actions over the past 3 years, five PS actions will be issued for generic devices, comprised of approximately five manufacturers. Each manufacturer will be required to submit a PS plan (§§ 822.9 and 822.10) and interim and final reports on the progress of the PS (§ 822.38). FDA anticipates that, on a case-by-case basis, requests for additional information may be made from a manufacturer. FDA expects that a small number of respondents will propose changes to their PS plans (§ 822.21), request a waiver of a specific requirement of this regulation (§ 822.29), or request exemption from the requirement to conduct PS of their device (§ 822.30). FDA's experience has

shown that a few respondents will go out of business (§ 822.26) or cease marketing the device subject to PS (§ 822.28) each year. In addition, manufacturers must certify transfer of records when ownership changes § 822.34.

FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically-based PS plan, using three investigators. These estimates are based on FDA's knowledge and experience with limited implementation of section 522 under the Safe Medical Devices Act of 1990. Therefore, FDA would expect that the recordkeeping requirements would apply to a maximum of 10 manufacturers (3 to 4 added each year) and 30 investigators (three per PS plan). After 3 years, FDA would expect these numbers to remain level as the PS plans conducted under the earliest orders reach completion and new orders are issued.

Dated: September 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–16231 Filed 9–29–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting and Nonvoting Consumer Representative Members on Public Advisory Committees and Panels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting and nonvoting consumer representatives to serve on its advisory committees/panels that are under the purview of the Office of the Commissioner, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the National Center for Toxicological and Research (NCTR).

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

DATES: Nominations will be accepted for current vacancies and for those that will or may occur through December 31, 2006. Because vacancies occur on various dates throughout the year, there is no cutoff date for the receipt of nominations.

ADDRESSES: Send all nominations and curricula vitae to the following contact persons listed in table 1 of this document:

TABLE 1.

Contact Person	Committee/Panel
Jan Johannessen, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane, rm. 14B–08, Rockville, MD 20857, 301–827–6687, e-mail: *jan.johannessen@fda.hhs.gov*	Pediatric Advisory Committee
Igor Cerny, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301–827–6763, e-mail: *igor.cerny@fda.hhs.gov*	Arthritis Advisory Committee
Collin L. Figueroa, Center for Devices and Radiological Health (HFZ–342), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850	Device Good Manufacturing Practice Advisory Committee
Geretta Wood, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., rm. 110D, Rockville, MD 20850, 301–594–2022, x 133, e-mail: *geretta.wood@fda.hhs.gov*	General Hospital and Personal Use Devices Panel, Gastroenterology-Urology Devices Panel, General and Plastic Surgery Devices Panel, and the Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee
Leonard M. Schechtman, National Center for Toxicological Research (HFT–10), Food and Drug Administration, 5600 Fishers Lane, rm. 16–85, Rockville, MD 20857, 301–827–6696, e-mail: *leonard.schechtman@fda.hhs.gov*	Science Advisory Board to NCTR

FOR FURTHER GENERAL INFORMATION CONTACT: Doreen Brandes, Office of the Commissioner (HF–4), Food and Drug Administration, 5600 Fishers Lane, rm. 15A–12, Rockville, MD 20853, 301–827–1220, e-mail *doreen.brandes@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting and nonvoting consumer representatives for the vacancies listed in table 2 of this document.

TABLE 2.

Committee/Panel Expertise Needed	Current and Upcoming Vacancies	Approximate Date Needed
Pediatric Advisory Committee—knowledgeable in pediatric research, pediatric subspecialties, statistics, and/or biomedical ethics	1—Voting Consumer Representative	Immediately
Arthritis Advisory Committee—knowledgeable in the fields of arthritis, rheumatology, orthopedics, epidemiology or statistics, analgesics, and related specialties	1—Voting Consumer Representative	Immediately