TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Total Reporting Burden Hours					3,678.50

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Applications submitted under § 601.2.
[3] Supplements submitted under § 601.12(f)(1) and (f)(2).
[4] Annual reports submitted under § 601.12(f)(3).

Dated: December 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–21132 Filed 12–12–06; 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; Submission for Office of Management and Budget Review; Comment Request; Postmarket Surveillance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 12, 2007.

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: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Postmarket Surveillance—21 CFR Part 822 (OMB No. 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 (PS) of any device that meets the criteria set forth in the statute.

The 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 PS 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 will result in the collection of useful data that 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 PS of their products.

In the **Federal Register** of October 2, 2006 (71 FR 57973), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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 PS 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 Device 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 (3 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: December 7, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–21167 Filed 12–12–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Exchange Workshop on Food and Drug Administration Clinical Trial Requirements; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) Los Angeles District, in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA clinical trial statutory and regulatory requirements. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA-regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

Date and Time: The public workshop is scheduled for Wednesday, February 7, 2007, from 8:30 a.m. to 5 p.m. and Thursday, February 8, 2007, from 8:30 a.m. to 4:30 p.m.

Location: The public workshop will be held at the Wyndham San Diego at Emerald Plaza, 400 West Broadway, San Diego, CA 92101, 619–239–4500, FAX: 619–239–3274.

Contact: Marshalette Edwards, Food and Drug Administration, 1431 Harbor Bay Parkwy., Alameda, CA 94502, 510–337–6794, FAX: 510–337–6703 e-mail: *MO.Edwards@fda.hhs.gov*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of $575 (member), $650 (nonmember), $525 (Government employee nonmember) or $450 (Government employee member) to SoCRA , P.O. Box 101, Furlong, PA 18925. The registration fee for nonmembers includes a 1-year membership). The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA.To register via the Internet go to *http://www.socra.org/html/FDA_Conference.htm* (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

The registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800–SoCRA92 (800–762–7292), or 215–822–8644, or via e-mail: *socramail@aol.com*. Attendees are responsible for their own accommodations. To make reservations at the Wyndham San Diego at Emerald Plaza at the reduced conference rate, contact the hotel (see *Location*) before January 7, 2007. The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials.

Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please contact Marshalette Edwards (see *Contact*) at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The workshop on FDA clinical trials statutory and regulatory requirements helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating researchers on proper conduct of clinical trials. Topics for discussion include the following: (1) FDA regulation of the conduct of clinical research; (2) medical device, drug, biological product and food aspects of clinical research; (3) investigator initiated research; (4) pre-investigational new drug application meetings and the FDA meeting process; (5) informed consent requirements; (6) ethics in subject enrollment; (7) FDA regulation of institutional review boards; (8) electronic records requirements; (9) adverse event reporting; (10) how FDA conducts