ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Baseline Survey	1,750	1	.33 hours (approx. 20 minutes)	577.5
Follow-up Survey	1,750	1	.42 hours (approx. 25 minutes)	735
Estimated Total Annual Burden Hours	3,500			1,312.5

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *grjohnson@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, *E-mail address: Katherine_T._Astrich@omb.eop.gov*.

Dated: September 13, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05–18735 Filed 9–19–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Exchange Workshop on Food and Drug Administration Clinical Trials Statutory and Regulatory Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati 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 will be held on Wednesday, December 7, 2005, from 8:15 a.m. to 5 p.m. and Thursday, December 8, 2005, from 8:15 a.m. to 4 p.m.

Location: The public workshop will be held at The Westin Cincinnati, 21 East 5th St., Cincinnati, OH 45202–3160, 513–621–7700, FAX: 513–852–5670.

Contact: Marie Falcone, Food and Drug Administration, rm. 900, U.S. Customhouse, 200 Chestnut St., Philadelphia, PA 19106, 215–717–3703, FAX: 215–597–5798, e-mail: *mfalcone@ora.fda.gov*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number), and the registration fee of $485 (member), $560 (nonmember), or $460 (government employee nonmember) (includes a 1-year membership). The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, P.O. Box 101, Furlong, PA 18925. To register via the Internet go to *http://www.socra.org/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 215–345–7749, or FAX: 215–345–7369, or e-mail: *socramail@aol.com*. Attendees are responsible for their own accommodations. To make reservations at The Westin Cincinnati at the reduced conference rate, contact The Westin Cincinnati see *Location*) through November 7, 2005, or until the SoCRA room block is full.

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 Marie Falcone at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The ''FDA Clinical Trials Statutory and Regulatory Requirements'' workshop 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. FDA has made education of the research community a high priority to assure the quality of clinical data and protect research subjects.

The workshop helps to implement the objectives of section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

The following topics will be discussed at the workshop:

- FDA and confidence in the conduct of clinical research;
- Medical device, drug, and biological product aspects of clinical research;
- Investigator initiated research;
- Pre-investigational new drug application (IND) meetings and FDA meeting process;
- Informed consent requirements;
- Ethics in subject enrollment;
- FDA regulation of Institutional Review Boards;
- Electronic records requirements;
- Adverse event reporting;
- How FDA conducts bioresearch inspections; and
- What happens after the FDA inspection.

Dated: September 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18654 Filed 9–19–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0337]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Oral Rinse to Reduce the Adhesion of Dental Plaque; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Class II Special Controls Guidance Document: Oral Rinse to Reduce the Adhesion of Dental Plaque.'' This guidance document describes a means by which oral rinse to reduce the adhesion of dental plaque may comply with the requirements of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify oral rinse to reduce the adhesion of dental plaque into class II (special controls). This guidance document is immediately in effect as the special control for the oral rinse to reduce the adhesion of dental plaque, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs). General comments on agency guidance documents are welcomed at any time.

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

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Oral Rinse to Reduce the Adhesion of Dental Plaque'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Robert Betz, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, ext. 125.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying the oral rinse to reduce the adhesion of dental plaque device into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for the generic device oral rinse to reduce the adhesion of dental plaque. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (§ 10.115). The guidance represents the agency's current thinking on oral rinse to reduce the adhesion of dental plaque. 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 statute and regulations.

III. Electronic Access

To receive ''Class II Special Controls Guidance Document: Oral Rinse to Reduce the Adhesion of Dental Plaque'' by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1559) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic