DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@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, *Fax:* (202) 395–7285, *Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–28510 Filed 11–2–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0755]

Agency Information Collection Activities; Proposed Collection; Comment Request; Implementation of the Food and Drug Administration Amendments Act of 2007

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 the requirement established by Title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85) that device establishments must submit registration and listing information by electronic means, using FDA Form 3673, unless the Secretary of the Department of Health and Human Services (the Secretary) grants them a waiver from the electronic submission requirement.

DATES: Submit either written or electronic comments on the collection of information by January 3, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. 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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–5156, *Daniel.Gittleson@fda.hhs.gov.*

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.

Implementation of Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007 (OMB Control Number 0910–0625)—Extension

Sections 222, 223, and 224 of FDAAA, which were in effect on October 1, 2007, require that device establishment registrations and listings under section 510 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360), including the submission of updated information, be submitted to the Secretary by electronic means, unless the Secretary grants a request for waiver of the requirement because the use of electronic means is not reasonable for the person requesting the waiver. There are approximately 24,000 establishments that are electronically registered as of September 2011.

Section 222 of FDAAA amends sections 510(b) of the FD&C Act to require domestic establishments to register annually during the period beginning October 1 and ending December 31 of each year. Section 222 of FDAAA also amends section 510(i)(1) of the FD&C Act to require foreign establishments to register immediately upon first engaging in one of the covered device activities described under the statute, and in addition, they must also register annually during the time period beginning October 1 and ending December 31 of each year. Further, section 223 of FDAAA amends section 510(j)(2) of the FD&C Act to require establishments to list their devices with FDA annually, during the time period beginning October 1 and ending December 31 of each year.

Under FDAAA, device establishment owners and operators are required to keep their registration and device listing information up-to-date using the Agency's new electronic system. Owners and operators of new device establishments must use the electronic system to create new accounts, new registration records, and new device listings. Section 224 of FDAAA amends section 510(p) of the FD&C Act by allowing an affected person to request a waiver from the requirement to register electronically when the ''use of electronic means'' is not reasonable for the person.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDAAA Section of the 2007 Amendments	FDA Form No.	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
222 [3]	3673	21,254	1	21,254	0.75	15,941
222 [2]	3673	2,162	1	2,162	0.50	1,081
222 [3]	3673	8,067	1	8,067	1	8,067
222 [3]	3673	1,305	1	1,305	0.25	326
223 [3]	3673	17,750	1	17,750	1	17,750
224 (waiver request) [2]	3673	14	1	14	1	14
224 (waiver request) [3]	3673	1	1	1	2	2
Total						43,181

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One time burden.
[3] Annual recurring burden.

TABLE 2—ESTIMATED AVERAGE ANNUAL RECORDKEEPING BURDEN [1]

FDAAA Section of the 2007 Amendments	Number of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per record	Total hours
222 [2]	23,806	1	23,806	0.25	5,952
223 [2]	11,746	4	46,984	0.5	23,492
Total					29,444

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

The estimates in table 1 of this document are based on FDA's experience, data from the device registration and listing database, and our estimates of the time needed to complete the previously required forms. We estimate that the time needed to enter registration and listing information electronically using FDA Form 3673 will not differ significantly from the time needed to fill in the paper forms (FDA Forms 2891, 2891a, and 2892) that previously were used for this purpose because the information required is essentially identical.

In addition, under section 224 of FDAAA, device establishment owner/operators, for whom registering and listing by electronic means is not reasonable, may request a waiver from the Secretary. Because a device establishment's owner/operator is required to register and list, they would need only to have access to a computer, Internet, and an email address for registration and listing by electronic means, the Agency did not anticipate receipt of a large number of requests for waivers. From the October through December 2007 timeframe, FDA received fewer than 10 requests for waivers for the requirement to submit registration and listing information electronically. As data for more than 16,000 establishments were received electronically for the same period, these requests amount to less than 1 percent of the total number of establishments that have responded. The number of waiver requests received through fiscal year 2011 have remained consistently less than 1 percent.

Based on information taken from our databases, FDA estimates that there are 21,254 owner/operators who collectively register a total of 24,000 device establishments. The number of respondents listed for section 222 of FDAAA in table 1 of this document is 21,254, which corresponds to the number of owner/operators who annually register. In addition, FDA estimates that 3,504 owner/operators are initial importers who must register their establishments but who, under FDA's existing regulations, are not required to list their devices unless they initiate or develop the specifications for the devices or repackage or relabel the devices. The number of respondents included in table 1 of this document for section 223 of FDAAA is 17,750, which corresponds to the number of owner/operators who annually list one or more devices ($21,254 - 3,504 = 17,750$).

To calculate the burden estimate for waiver requests under section 224 of FDAAA, we assume as stated previously, that less than 1 percent of the 24,000 total device establishments would request waivers from FDA. This means the total number of waiver requests would probably not exceed 14 requests ($24,000 \times 0.0006$). We also estimate that the one-time burden on these establishments would be an hour of time for a mid-level manager to draft, approve, and mail a letter. In addition, FDA estimates the total number of establishments will increase by 2,162 new establishments each year. Of the 2,162 new registrants each year, we assume that less than 1 percent (*i.e.,* 1) of these will also request waivers each year. The total, therefore, is 14 waiver requests, which could increase by only one additional request each year.

Based on the number of owner operators of foreign establishments reflected in our current database, approximately 8,067 owner operators will spend an hour annually identifying the name, address, telephone and fax numbers, email address, and registration number, if any has been assigned, of any importer of the establishment's devices that is known to the foreign establishment.

Also based on the current number of owner/operators in the FDA database, we estimate that approximately 1,305 owner operators will spend .25 hours each year to identify changes in their U.S. agent's name, address, or phone number to FDA.

The burden estimate for recordkeeping requirements under section 222 of FDAAA in table 2 of this document, complies with the requirement that owners or operators keep a list of officers, directors, and partners for each establishment. Owners or operators will need to provide this information only upon request from

FDA. However, it is assumed that some effort will need to be expended for keeping such lists current.

The burden estimate for the recordkeeping requirements under section 223 of FDAAA in table 2 of this document reflect other recordkeeping requirements for devices listed with FDA and the requirement to provide these records upon request from FDA. These estimates are based on FDA experience.

Dated: October 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–28476 Filed 11–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0547]

Clinical Development Programs for Sedation Products; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration's (FDA), Center for Drug Evaluation and Research (CDER) is announcing a scientific workshop to solicit information on a variety of issues related to the clinical development and use of sedation products in adult and pediatric age groups. FDA intends to take into account the information provided from this workshop as we develop FDA guidance on clinical development programs for sedation products. FDA issued a notice in the **Federal Register** of November 29, 2010, inviting an interested party, or parties, to facilitate an evaluation of the critical fundamentals of the science related to sedation products and to plan and conduct one or more public meetings to bring together experts in the field, including from academia, patient organizations, and industry, to discuss these issues. FDA has since determined that it will facilitate the evaluation itself, and as a first step, is announcing this workshop.

Date and Time: The public workshop will be held on May 3, 2012, from 8:30 a.m. to 5 p.m.

Location: The workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002.

Contact Person: Mary C. Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, (301) 796–3519, email: *mary.gross@fda.hhs.gov;* or Diana Walker, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, (301) 796–4029, email: *Diana.Walker@fda.hhs.gov.*

Registration to Participate in Scientific Panels: If you wish to participate as part of a scientific panel, please email your request to *CDER_Sedation_Workshop@FDA.HHS.gov* by December 2, 2011. As part of your request, please describe your area of expertise and interest based on the questions identified below. If selected, a subset of panel representatives may be asked to provide formal presentations and/or participate in panel discussions.

Registration to Attend the Workshop and Requests to Participate in Open Public Hearing: If you wish to attend or testify at the open public hearing, please email your registration to *CDER_Sedation_Workshop@FDA.HHS.gov* by April 2, 2012. Those without email access may register by contacting one of the persons listed in the Contact Person section of the document. Please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the meeting will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop at: *http://www.fda.gov/Drugs/NewsEvents/ucm221185.htm.*

An open public hearing will be held between 1:30 p.m. to 2:30 p.m. on May 3, 2012, during which speaker testimony will be accepted. We will try to accommodate all persons who wish to testify, however, the duration of each speaker's testimony during this open public hearing may be limited by time constraints.

Comments: Submit either electronic or written comments by July 3, 2012. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

If you need special accommodations due to a disability, contact Mary Gross or Diana Walker (see Contact Person) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of November 29, 2010 (75 FR 73104), FDA indicated that it was seeking information on a variety of issues related to the clinical development and use of sedation products in adult and pediatric age groups. In the notice, FDA invited any interested party to take on the role of facilitating an evaluation of these issues and as a first step, plan or hold one or more public meetings to discuss these issues. FDA was going to take into account the information provided by these activities in the development of guidance on clinical development programs for sedation products. FDA has now determined that it will conduct the evaluation itself, and is announcing this workshop to further understand the physiology of sedation and clinical trial design issues related to the development of sedation products.

FDA will explore the following topics during this public workshop:

1. For clinical trials of sedation drug products, which surgical and diagnostic procedures would provide the most relevant efficacy and safety data, while still allowing for a reasonable level of feasibility and efficiency?

2. What patient subgroups, other than pediatric, geriatric, and patients with hepatic or renal impairment, would require specific evaluation in clinical trials involving sedation drug products?

3. What is the most appropriate primary efficacy endpoint to assess in a clinical trial of a sedation drug product?

a. Which measurement scales have been adequately studied and validated for use in assessing the endpoint measure recommended previously.

b. Is there a clinically meaningful effect size that should be considered as a minimal requirement for a determination of efficacy?

c. How do the responses to the previous questions differ, if at all, for the pediatric population, in particular, the youngest of these patients who have no or limited communication skills.