EXHIBIT 3. ANNUAL COSTS FOR THE ESTIMATE OF THE NUMBER OF PERSONS WHO CAN ACCESS THEIR MEDICATION INFORMATION ONLINE—Continued

	Annual cost
Interviewer training, sample purchase, survey administration, data entry, toll calls	30,274
Other direct costs:	
Computer charge, telephone/fax/teleconference, printing and duplication, travel	28,418
Indirect costs:	
Regular overhead, 46.5%; G&A	101,775
Contract Fee	25,602
Total	$310,067

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research, quality improvement and information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: September 9, 2008.

Carolyn M. Clancy,

Director.

[FR Doc. E8–21824 Filed 9–18–08; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–8003]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Home and Community Based Waiver Requests and Supporting Regulations in 42 CFR 440.180 and 441.300–310; *Use*: Under a Secretarial waiver, States may offer a wide array of home and community-based services to individuals who would otherwise require institutionalization. States requesting a waiver must provide certain assurances, documentation and cost and utilization estimates which are reviewed, approved and maintained for the purpose of identifying/verifying States' compliance with such statutory and regulatory requirements. *Form Number*: CMS–8003 (OMB# 0938–0449); *Frequency:* Occasionally; *Affected Public*: State, Local or Tribal Governments; *Number of Respondents*: 50; *Total Annual Responses*: 136; *Total Annual Hours*: 8,010.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *October 20, 2008*.

OMB, Office of Information and Regulatory Affairs, *Attention*: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, *Fax Number*: (202) 395–6974.

Dated: September 11, 2008.

Michelle Shortt,

Director, Regulations Development Group. Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E8–21906 Filed 9–18–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Structured Product Labeling Content of Labeling and Electronic Drug Establishment Registration and Drug Listing for the Biologics Industry; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Structured Product Labeling (SPL) Content of Labeling and Electronic Drug Establishment Registration and Drug Listing for the Biologics Industry.'' The purpose of the public workshop is to provide the biologics industry with guidance on submitting to FDA content of labeling in SPL format, present an overview of FDA's voluntary pilot program for electronic submission of drug establishment registration and drug

listing information under the regulations, and exhibit vendor SPL authoring tools that may be used in the creation and manipulation of SPL content of labeling.

Date and Time: The public workshop will be held on November 17, 2008, from 8:30 a.m. to 4 p.m.

Location: The public workshop will be held at the Universities at Shady Grove, Multipurpose Room, Building II, 9630 Gudelsky Dr., Rockville, MD 20850.

Contact Person: Donna Lipscomb, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079; e-mail: *spl@fda.hhs.gov* (Subject line: CBER SPL Public Workshop).

Registration: Mail, FAX, or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by October 30, 2008. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space-available basis beginning at 8 a.m.

Vendor Registration: Vendors wishing to exhibit their SPL authoring tools at this public workshop must register and submit their registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by October 30, 2008, via e-mail to *spl@fda.hhs.gov*.

If you need special accommodations due to a disability, please contact Donna Lipscomb (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop to provide the biologics industry with guidance on submitting to FDA content of labeling in SPL format and to present an overview of FDA's voluntary pilot program for electronic submission of drug establishment registration and drug listing information under the regulations in part 207 (21 CFR part 207).

FDA's Center for Biologics Evaluation and Research (CBER) has stated in a memorandum, posted on July 11, 2008, to Docket No. FDA–1992–S–0039 (formerly 1992S–0251), that beginning October 15, 2008, SPL in XML (extensible markup language) is the acceptable presentation in electronic format for the submission of content of labeling that CBER can process, review, and archive. This applies to the content of labeling with original submissions, supplements, and annual reports. Individuals may electronically access CBER's notification on the submission of SPL content of labeling at *http://www.fda.gov/oc/datacouncil/spl.html*.

In the **Federal Register** of July 11, 2008 (73 FR 39964), FDA announced the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing.'' This draft guidance established a pilot program for industry to voluntarily submit drug establishment registration and drug listing information in SPL format. The draft guidance only applies to drug establishments that currently register their establishments and list their products under the regulations in part 207 and explains how to transition from submitting the required information on paper to submitting the required information using the SPL standard. The draft guidance also describes how to voluntarily submit additional useful, but not required, information that currently is often included by industry in their registration and listing paper submissions. FDA plans to complete the voluntary pilot program and begin receiving drug establishment and drug listing information only electronically and only in SPL format (including labeling) beginning June 1, 2009, unless a waiver is granted.

This public workshop will feature presentations by FDA experts on SPL content of labeling and electronic drug establishment registration and drug listing. In addition, registrants will have access to a vendor exhibition of SPL authoring tools.

Dated: September 15, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–21968 Filed 9–18–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0457]

Draft Guidance for Industry and Food and Drug Administration Staff; Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence.'' This draft guidance document describes FDA's proposed recommendations for clinical investigations of medical devices indicated for the treatment of urinary incontinence. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by December 18, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence'' 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 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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

FOR FURTHER INFORMATION CONTACT: John Baxley, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4130.

SUPPLEMENTARY INFORMATION:

I. Background

Urinary incontinence is defined as the involuntary loss of urine. This draft guidance is intended to assist device manufacturers who plan to conduct clinical investigations of devices intended to treat urinary incontinence in support of premarket approval (PMA) applications or premarket notification (510(k)) submissions. The draft guidance describes FDA's proposed recommendations for human clinical trials that involve the use of any type of urinary incontinence device, including, but not limited to, urological clamp for males; nonimplanted, peripheral and