

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.

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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.

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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