

call to order by the Council Chair and approval of previous Council minutes. The AHRQ director will present her update on current research, programs, and initiatives. The agenda will include a discussion on Patient-centered Health Care and Cost Effective Health Care by the Council.

The final agenda will be available on the AHRQ Web site at <http://www.ahrq.gov> no later than November 3, 2008.

Dated: October 1, 2008.

**Carolyn M. Clancy,**

Director.

[FR Doc. E8-23732 Filed 10-8-08; 8:45 am]

**BILLING CODE 4160-90-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

**Proposed Projects**

*Title:* State Developmental Disabilities Council 5-Year State Plan.

*OMB No.:* 0980-0162.

*Description:* A Plan developed by the State Council on Developmental Disabilities is required by federal statute. Each State Council on Developmental Disabilities must develop the plan, provide for public

comments in the State, provide for approval by the State's Governor, and finally submit the plan on a five-year basis. On an annual basis, the Council must review the plan and make any amendments. The State Plan will be used (1) By the Council as a planning document; (2) by the citizenry of the State as a mechanism for commenting on the plans of the Council; and (3) by the Department as a stewardship tool, for ensuring compliance with the Developmental Disabilities Assistance and Bill of Rights Act, as one basis for providing technical assistance (e.g., during site visits), and as a support for management decision making.

*Respondents:* State Governments.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Developmental Disabilities Council 5-Year State Plan .....	55	1	367	20,185

*Estimated Total Annual Burden Hours:* 20,185.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded 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. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c)

the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: October 3, 2008.

**Janean Chambers,**

Reports Clearance Officer.

[FR Doc. E8-23881 Filed 10-8-08; 8:45 am]

**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

**Proposed Projects**

*Title:* Financial Status Reporting Form for State Councils on Developmental Disabilities Program.

*OMB No.:* 0980-0212.

*Description:* For the program of the State Councils on Developmental Disabilities, funds are awarded to State agencies contingent on fiscal requirements in subtitle B of the Developmental Disabilities Assistance and Bill of Rights Act. The SF-269, ordinarily mandated in the revised OMB Circular A-102, provides no accounting breakouts necessary for proper stewardship. Consequently, the proposed streamlined form will substitute for the SF-269 and will allow compliance monitoring and proactive compliance maintenance and technical assistance.

*Respondents:* State Councils and Designated State Agencies.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Financial Status Reporting Form for State Councils on Developmental Disabilities Program .....	55	3	5.10	841.50

*Estimated Total Annual Burden Hours:* 841.50.

In compliance with the requirements of section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded 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. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: October 3, 2008.

**Janean Chambers,**

*Reports Clearance Officer.*

[FR Doc. E8-23884 Filed 10-8-08; 8:45 am]

**BILLING CODE 4184-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-1999-D-0128] (formerly Docket No. 1999D-2013)

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry: Cooperative

Manufacturing Arrangements for Licensed Biologics" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:**

Jonna Capezzuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of November 19, 2007 (72 FR 65034), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0629. The approval expires on September 30, 2011. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: September 29, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-23907 Filed 10-8-08; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0314]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recall Regulations

**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 November 10, 2008.

**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, or e-mailed to

[baguilar@omb.eop.gov](mailto:baguilar@omb.eop.gov). All comments should be identified with the OMB control number 0910-0249. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Elizabeth Berbakos, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3792.

**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.

#### FDA Recall Regulations—21 CFR Part 7—(OMB Control Number 0910-0249—Extension)

Section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) and part 7, subpart C (21 CFR part 7, subpart C), set forth the recall regulations (guidelines) and provide guidance to manufacturers on recall responsibilities. The guidelines apply to all FDA regulated products (i.e., food, including animal feed; drugs, including animal drugs; medical devices, including in vitro diagnostic products; cosmetics; and biological products intended for human use). These responsibilities include: (1) developing a recall strategy that requires time by the firm to determine the actions or procedures required to manage the recall (§ 7.42); (2) providing FDA with complete details of the recall including reason(s) for the removal or correction, risk evaluation, quantity produced, distribution information, firm's recall strategy, a copy of any recall communication(s), and a contact official (§ 7.46); (3) notifying direct accounts of the recall, providing guidance regarding further distribution, giving instructions as to what to do with the product, providing recipients with a ready means of reporting to the recalling firm (§ 7.49); (4) submitting periodic status reports so that FDA may assess the progress of the recall (status report information may be determined by, among other things, evaluation return reply cards, effectiveness checks, and product returns) (§ 7.53); and (5) providing the opportunity for a firm to request in writing that FDA terminate the recall (§ 7.55).

A search of the FDA database was performed to determine the number of recalls that took place during fiscal year 2007. The resulting number of recalls from this database search (2,166) is used in estimating the current annual reporting burden for this report. FDA