the agency's functions; (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.

Type of Information Collection Request: Reinstatement, without change, of a previously approved collection for which approval has expired.

Title of Information Collection: Survey of Medicare Beneficiaries Who Involuntarily Disenroll from their Health Plan.

Form No.: CMS–10026 (OMB# 0938–0817).

Use: In January 2002, many managed care plans are expected to withdraw from Medicare or reduce their service area. This will continue a trend that began in January 1999. CMS wishes to survey approximately 3,600 affected beneficiaries in early 2002 to determine how they were impacted by the withdrawals and whether they received sufficient information about options for replacing their managed care coverage.

Frequency: Other: One-Time.

Affected Public: Individuals or Households.

Number of Respondents: 3,600.

Total Annual Responses: 3,600.

Total Annual Hours: 684.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access CMS's Web Site address at *http://www.hcfa.gov/regs/prdact95.htm,* or e-mail your request, including your address and phone number, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: September 25, 2001.

John P. Burke III,

CMS Reports Clearance Officer, CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 01–25688 Filed 10–11–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0048]

Agency Information Collection Activities; Announcement of OMB Approval; Current Good Manufacturing Practice Regulations for Type A Medicated Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Current Good Manufacturing Practice Regulations for Type A Medicated Articles,'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 15, 2001 (66 FR 32628), 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 0910–0154. The approval expires on September 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: October 5, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–25658 Filed 10–11–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0176]

Agency Information Collection Activities; Announcement of OMB Approval; Good Laboratory Practices (GLP) Regulations for Nonclinical Laboratory Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Good Laboratory Practices (GLP) Regulations for Nonclinical Laboratory Studies'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 20, 2001 (66 FR 37977), 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 0910–0119. The approval expires on September 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: October 5, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–25659 Filed 10–11–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0277]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by November 13, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Reports of Corrections and Removals—21 CFR Part 806 (OMB Control No. 0910–0359)—Extension

Section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(f)) directs FDA to issue regulations to require device manufacturers and importers to report promptly to FDA any correction or removal of a device undertaken by such manufacturers and importers if the correction or removal was undertaken to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health. Under 21 CFR 806.10 and 806.20(a), FDA requires that each device manufacturer and importer shall submit a written report to FDA of any action initiated to correct or remove a device to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health within 10 working days of initiating such correction or removal. In addition, each manufacturer and importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA shall keep a record of such correction or removal.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and to ensure that dangerous and defective devices are removed from the market, assuring that FDA has current and complete information regarding these corrections and removals and whether recall action is adequate. Failure to collect this information prevents FDA from receiving timely information about devices that may have a serious effect on the health of the users of the devices.

Respondents to this information collection are businesses or other for-profit manufacturers or importers of medical devices who must remove or correct medical devices that cause public health risk to the general public.

In the **Federal Register** of July 6, 2001 (66 FR 35644), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
806.10	880	1	880	10	8,800

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
806.20(a)	440	1	440	10	4,400

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

The following is an explanation of the burden estimate:

Reporting Burden

FDA estimates that it would take 10 staff hours to prepare and assemble a written report. For the estimated 880 reports, FDA estimates that respondents will spend 8,800 hours to prepare, assemble, and send the reports.

Recordkeeping Burden

FDA estimates that it would take 10 staff hours to prepare a written record. For the estimated 440 records, the total recordkeeping burden is estimated at 4,400 hours per recordkeeper.

Dated: October 5, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–25660 Filed 10–11–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Transmissible Spongiform Encephalopathies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Transmissible Spongiform Encephalopathies Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 25, 2001, from 8 a.m. to 3:30 p.m., and on October 26, 2001, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact: William Freas, or Sheila D. Langford, Center for Biologics