proposing that the expiration date of the last lot sold must be reported to CMS once at the end of utilization of the NDC or when there are no sales for three consecutive quarters.

On November 21, 2005, we published an interim final rule (70 FR 70478) stating that, during the first three years of the Part B Drug Competitive Acquisition Program (CAP), sales and price concessions associated with units administered to a beneficiary by a participating CAP vendor are excluded from the ASP units and price. We propose to collect the number of CAP units excluded from the ASP calculation. *Frequency:* Recordkeeping and Reporting—Quarterly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 120; *Total Annual Responses:* 480; *Total Annual Hours:* 17,760.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Retiree Drug Subsidy (RDS) Payment Request and Instructions; *Form Number:* CMS–10170 (OMB #0938–0977); *Use:* Under section 1860D–22 of the Social Security Act (Act), added by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, plan sponsors (employers, unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28 percent tax-free subsidy for allowable drug costs. To receive the subsidy, plan sponsors must submit required prescription cost data. CMS has contracted with an outside vendor (ViPS) to assist in the administration of the retiree drug subsidy (RDS) program; this effort is called the RDS Center. Plan sponsors will request subsidy payments on-line by logging on to the RDS secure Web site. Cost data required for each payment request may be entered into the RDS secure Web site, or uploaded to the RDS Center mainframe. Once the plan sponsor submits the payment request, the RDS Center will process the request to determine if payment is due and the amount of the payment; *Frequency:* Recordkeeping and Reporting—Monthly, Quarterly and Annually; *Affected Public:* Not-for-profit institutions, Business or other for-profit, Federal Government, State, Local, or Tribal Government; *Number of Respondents:* 6,000; *Total Annual Responses:* 6,000; *Total Annual Hours:* 222,000.

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.

Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 23, 2006.

Michelle Shortt,

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

[FR Doc. 06–1920 Filed 3–2–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10185]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and 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 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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with an initiative of the Administration. CMS does not have sufficient time to complete the normal PRA clearance process. We request this Paperwork Reduction Act clearance under an emergency approval process to meet the statutorily-mandated reporting requirement under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and to accommodate the operational schedule for the bidding process for prospective and renewing Part D Sponsors. In order to uphold the MMA reporting requirement in conjunction with the bid deadline for contract year 2007, key preceding events must occur. If these events do not occur, prospective and renewing Part D Sponsors will be unable to adjust their bids to reflect compliance with these reporting requirements. Inaccuracies in Part D bids will cause many adverse consequences to Part D Sponsors, their enrolled Medicare beneficiaries, and CMS.

1. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Medicare Part D Reporting Requirements; *Use:* Data collected via Medicare Part D Reporting Requirements will be an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. Data will be validated, analyzed, and utilized for trend reporting by CMS. If outliers or other data anomalies are detected, CMS will work in collaboration with other CMS divisions for follow-up and resolution. *Form Number:* CMS–10185 (OMB #0938–New); *Frequency:* Reporting: Quarterly and Semi-annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 3,203; *Total Annual Responses:* 12,812; *Total Annual Hours:* 102,496.

CMS is requesting OMB review and approval of these collections by *April 14, 2006,* with a 180-day approval period. Written comments and recommendations will be considered from the public if received by the individuals designated below by *April 3, 2006.*

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.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed to the designees referenced below by *April 14, 2006:*

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: Bonnie L Harkless,

and,

OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 23, 2006.

Michelle Shortt,

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

[FR Doc. 06–1921 Filed 3–2–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0427]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Filing Objections and Requests for a Hearing on a Regulation or Order

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 April 3, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

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

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.

Filing Objections and Requests for a Hearing on a Regulation or Order —(OMB Control Number 0910–0184)—Extension

Under part 12 (21 CFR part 12), § 12.22, issued under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)(2)), sets forth the instructions for filing objections and requests for a hearing on a regulation or order under § 12.20(d). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection for which a hearing has been requested must be separately numbered and specify the provision of the regulation or the proposed order. In addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis to determine whether a hearing request is justified. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under § 12.24 and do not limit the evidence that may be presented if a hearing is granted.

Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

In the **Federal Register** of November 16, 2005 (70 FR 69577), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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
12.22	10	1	10	20	200

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

Dated: February 24, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–3020 Filed 3–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System Drugs 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). The meeting will be open to the public.

Name of Committee: Peripheral and Central Nervous System Drugs Advisory Committee.

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