

M/S e-28, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 498-0622.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and NCEH/ATSDR.

Dated: May 12, 2006.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-262 and CMS 10196]

Agency Information Collection Activities: Proposed Collection; 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) 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.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Plan Benefit Package (PBP) and Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDPs); *Use:* Under the Medicare Modernization Act (MMA), Medicare Advantage (MA) and Prescription Drug Plan (PDP) organizations are required to submit plan benefit packages for all Medicare beneficiaries residing in their service area. CMS requires that MA and PDP organizations submit a completed

formulary and PBP as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to CMS for review and approval; *Form Number:* CMS-R-262 (OMB#: 0938-0763); *Frequency:* On occasion, Annually, and Other: As required by new legislation; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 553; *Total Annual Responses:* 5,807; *Total Annual Hours:* 13,272.

2. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Medicare Part C Audit Guide, Version 4.0 and Supporting Regulation contained in 42 CFR 423.502; *Use:* The Medicare Modernization Act provides CMS the regulatory authority to audit, evaluate, or inspect any Part C sponsors' performance related to the law in the areas including enrollment & disenrollment, marketing, benefits and beneficiary protections, quality assurance, provider relations and contracts. The information collected will be an integral resource for oversight, monitoring, compliance, and auditing activities necessary to ensure quality provision of the Part C Medicare Advantage benefit to beneficiaries. *Form Number:* CMS-10196 (OMB#: 0938-New); *Frequency:* Recordkeeping and Reporting—Annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 393; *Total Annual Responses:* 393; *Total Annual Hours:* 12,576.

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 at the address below, no later than 5 p.m. on July 18, 2006.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—C, Attention: Bonnie L. Harkless, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: May 10, 2006.

Michelle Shortt,

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

[FR Doc. E6-7510 Filed 5-18-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-718BP, 719BP, 720BP, 721BP, SUM, STAFFING, SC1 and SC2]

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:* Business Proposal Forms for Quality Improvement Organizations (QIOs); *Use:* The submission of proposal information by current QIOs and other bidders, on the appropriate forms, will satisfy CMS's need for meaningful, consistent, and verifiable data with which to evaluate contract proposals. The Government will be able to compare the costs reported by the QIOs on the cost reports to the proposed costs noted on the business proposal forms. Subsequent contract and modification negotiations will be based on historic cost data. The business proposal forms will be one element of the historical cost data from which we can analyze future

proposed costs. In addition, the business proposal format will standardize the cost proposing and pricing process among all QIOs. With well-defined cost centers and line items, proposals can be compared among QIOs for reasonableness and appropriateness; *Form Number*: CMS-718BP, 719BP, 720BP, 721BP, SUM, STAFFING, SC1 and SC2 (OMB#: 0938-0579); *Frequency*: Reporting—Triennially; *Affected Public*: Not-for-profit institutions, Business or other for-profit; *Number of Respondents*: 20; *Total Annual Responses*: 20; *Total Annual Hours*: 455.

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 or faxed 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. Fax Number: (202) 395-6974.

Dated: May 9, 2006.

Michelle Shortt,

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

[FR Doc. E6-7511 Filed 5-18-06; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0180]

Agency Information Collection Activities; Proposed Collection; Comment Request; Records and Reports Concerning Experience With Approved New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the

PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements for recordkeeping and reports concerning experience with approved new animal drugs. The information contained in the reports required by this regulation enables FDA to monitor the use of new animal drugs after approval and to ensure their continued safety and efficacy.

DATES: Submit written or electronic comments on the collection of information by July 18, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's

estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Records and Reports Concerning Experience With Approved New Animal Drugs—21 CFR 514.80—(OMB Control Number 0910-0284)—Extension

Implementation of section 512(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) and 21 CFR 514.80 requires applicants of approved new animal drug applications and abbreviated new animal drug applications (NADAs) to submit product/manufacturing defects, initial and followup reports for adverse drug experiences and lack of effectiveness of new animal drugs, increased frequency 15-day alert reports, periodic drug experience reports (annually or semiannually in a specific format), and other reports (special drug experience reports, advertisement and promotional material submissions, and distributor statements.)

This continuous monitoring of approved NADAs affords the primary means by which FDA obtains information regarding potential problems in safety and effectiveness of marketed animal drugs and potential manufacturing problems. Current data on file with FDA is not adequate because animal drug effects can change over time, and less apparent effects may take years to manifest themselves.

Adverse reaction reports are required to be submitted by the drug manufacturer on FDA Forms 1932 or 1932a (voluntary reporting form), following complaints from animal owners or veterinarians. Also, product defects and lack of effectiveness complaints are submitted to FDA by the drug manufacturer following their own detection of a problem or complaints from product users or their veterinarians using FDA Forms 1932 and 1932a. Form FDA 2301 is used to submit the required transmittal of periodic reports and promotional material for new animal drugs. The reporting and recordkeeping burden estimates are based on the submission of reports to the Division of Surveillance, Center for Veterinary Medicine. The total annual responses are also based on the submission of reports to the Division of Surveillance, Center for Veterinary Medicine. The