approved collection; *Title of Information Collection:* State Health Insurance Assistance Program (SHIP) Client Contact Form, Public and Media Activity Form, and Resource Report; *Form No.:* CMS–10028A, B, C (OMB# 0938–0850); *Use:* The State Health Insurance Assistance Program (SHIP) Client Contract form will be completed by SHIP counselors at each counseling event in order to collection SHIP performance data. This data will then be accumulated and analyzed to measure SHIP performance; *Frequency:* Semi-annually and annually; *Affected Public:* State, Local, or Tribal Government, not-for-profit institutions, and Federal Government; *Number of Respondents:* 53; *Total Annual Responses:* 265; *Total Annual Hours:* 159.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, 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 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Melissa Musotto, Room C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 12, 2003.

Julie Brown,

CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–23913 Filed 9–18–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10079]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

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) (formerly known as the Health Care Financing Administration (HCFA), 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.

Type of Information Collection Request: New collection: *Title of Information Collection:* Hospital Wage Index Occupational Mix Survey and Supporting Regulations in 42 CFR 412.230, 412.304 and 413.65; *Form No.:* CMS–10079 (OMB# 0938–NEW); *Use:* In the May 4, 2001 Proposed Rule (66 FR 22674), CMS proposed to conduct a special survey to collect data from a sample of occupational categories that provide a valid measure of wage rates within a geographical area. In the August 1, 2001 Final Rule (66 FR 39860), we responded to comments from the Proposed Rule and stated that, CMS will conduct a special survey of all short-term acute-care hospitals that are required to report wage data to collect these data. Section 304 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 requires CMS to collect wage data on hospital employees by occupational category. The collection is to be completed by September 30, 2003 and to be used to adjust the wage index by October 1, 2004.; *Frequency:* Other: once every three years; *Affected Public:* Business or other for-profit, and not-for-profit institutions; *Number of Respondents:* 4,500; *Total Annual Responses:* 4,500; *Total Annual Hours:* 720,000.

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://cms.hhs.gov/regulations/pra/default.asp,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, 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: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: September 12, 2003.

Julie Brown,

CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–23914 Filed 9–18–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0424]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substantial Evidence of Effectiveness of 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 for an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for meeting the substantial evidence standards necessary for demonstrating the safety and effectiveness of a new animal drug.

DATES: Submit written or electronic comments on the collection of information by November 18, 2003.

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.

Substantial Evidence of Effectiveness of New Animal Drugs—21 CFR Part 514 (OMB Control Number 0910–0356)—Extension

Description: Congress enacted the Animal Drug Availability Act of 1996 (ADAA) (Public Law 104–250) on October 9, 1996. As directed by the ADAA, FDA published a regulation, § 514.4(a) (21 CFR 514.4(a)), to further define substantial evidence in a manner that encourages the submission of NADA's and supplemental NADA's and encourages dose range labeling. Under the ADAA, substantial evidence is the standard that a sponsor must meet to demonstrate the effectiveness of a new animal drug for its intended use under the conditions suggested in its proposed labeling. Section 514.4(a) gives FDA greater flexibility to make case-specific scientific determinations regarding the number and types of adequate and well-controlled studies that will provide, in an efficient manner, substantial evidence that a new animal drug is effective. FDA believes this regulation will address the following issues: (1) Reduce the number of adequate and well-controlled studies necessary to demonstrate the effectiveness of certain combination new animal drugs; (2) eliminate the need for an adequate and well-controlled dose titration study; and may, in limited instances, (3) reduce or eliminate the number of adequate and well-controlled field investigations necessary to demonstrate by substantial evidence the effectiveness of a new animal drug. Table 1 of this document represents the estimated burden of meeting the substantial evidence standard.

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
514.4(a)	190	4.5	860	632.6	544,036

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

Dated: September 15, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–23940 Filed 9–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–1146]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concerns

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 (the PRA).

DATES: Fax written comments on the collection of information by October 20, 2003.

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, or e-mail comments to *Fumie_Yokota@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B–41, Rockville, MD 20857, 301–827–1472.

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.

Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concerns

This guidance document discusses a recommended approach for assessing the antimicrobial resistance concerns as part of the overall preapproval safety evaluation of new animal drugs, focusing on the microbiological effects on bacteria of human health concern. In particular, the guidance describes a methodology sponsors of antimicrobial new animal drug applications for food-producing animals may use to complete a qualitative antimicrobial resistance risk assessment. This risk assessment