fdadockets@oc.fda.gov. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: David N. Heller, Center for Veterinary Medicine (HFV–510), Food and Drug Administration, 8401 Muirkirk Rd., Laurel, MD 20708, 301–827–8156, e-mail: dheller@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) requires FDA to determine whether each new animal drug proposed for use in food-producing animals is safe and effective. In some cases, the new animal drugs used in food-producing animals have the potential to adversely affect the health of the humans who consume food derived from these animals. The sponsor of the new animal drug is responsible for establishing the safety of each new animal drug through appropriate tests.

To determine human food safety of new animal drugs, FDA evaluates the information/data, identifies and characterizes potential hazards, assesses exposure levels and characterizes the overall risk. Through this process, FDA establishes an allowable daily intake and tolerances (the amount of drug residue allowed in tissues) for each drug. Drug sponsors submit to FDA analytical methods that are designed to measure the concentration of the proposed drug in the edible tissues at the drug's tolerances. Analytical methods are used to monitor the tolerances set by FDA. FDA reviews the analytical methods during its review of new animal drug applications (21 CFR 514.1(b)(7)).

Analytical methods may also be used to monitor safe levels as established by the agency. Under section 512(a)(4)(B) of the act and 21 CFR 530.22, the agency may establish a safe level for extra-label use of a drug when the agency finds that there is a reasonable probability that an extra-label use may result in drug residues in edible tissue of the treated animals at a level that may present a risk to the public health if it was above the safe level. Under the same provisions, FDA may require the development of an acceptable analytical method for the quantification of residues above any safe level.

FDA issues guidance recommending methods of analysis to potential sponsors to foster timely and objective review of proposed new animal drugs, including the review of analytical methods. In the **Federal Register** of December 31, 1987 (52 FR 49589), FDA announced the availability of a set of eight guidance documents entitled ''General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals'' (52 FR 49589); revisions to one of the guidances were announced in the **Federal Register** of July 22, 1994 (59 FR 37499). These guidances were designed to inform sponsors of the scientific data that FDA believes will provide an acceptable basis for determining the safety of such compounds, and for designing analytical methods.

Part V in the above-mentioned set of guidances, entitled ''Guideline for Approval of a Method of Analysis for Residues,'' recommended that sponsors develop rugged methods of analysis designed to exceed rather than meet the minimal standards of acceptability. This serves two purposes: (1) To lower the number of method of analysis submissions that pass desk review but fail interlaboratory studies designed to test their effectiveness, and (2) to increase the precision and specificity of safety determination by ensuring a higher quality assay. The guidance then explained the evaluation criteria and data needed for approval of a method of analysis.

The draft guidance entitled ''Guidance for Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues'' is designed to complement part V of ''General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals.'' The purpose of this document is to facilitate and expedite coordination between FDA's Center for Veterinary Medicine (CVM) and sponsors so the development, evaluation, and application of qualitative mass spectrometric methods will be completed in a consistent and timely manner.

This draft document is intended for technical professionals familiar with mass spectrometry. A glossary at the end of the draft guidance defines key terms used throughout the document.

This draft guidance should be used in the development of new methods, the review of methods submitted to CVM, and in the laboratory trial of methods submitted to CVM. The document also should help in making decisions about appropriate methodology in various regulatory situations and ensuring consistency in work done for CVM's purposes.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance describes the basic principles the agency recommends for development, evaluation, or application of qualitative mass spectrometric methods for confirming the identity of new animal drug residues. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Information collection provisions described in this guidance have been approved under OMB control numbers 0910–0032 and 0910–0325.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by September 11, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Comments on the draft guidance may be electronically submitted at http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm. Electronic copies of the draft guidance and other guidances discussed in this notice may be obtained at http://www.fda.gov/cvm.

Dated: May 30, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–14813 Filed 6–12–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–297]

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

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested

persons are invited to send comments regarding the 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: Existing collection in use without an OMB control number; *Title of Information Collection:* Request for Employment Information; *Form No.:* HCFA–R–297 (OMB# 0938–0787); *Use:* This form is needed to determine whether a beneficiary can enroll in Part B Medicare and/or qualify for premium reduction. This form is used by the Social Security Administration to obtain information from employers regarding whether a Medicare beneficiary's coverage under a group health plan is based on current employment.; *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 5,000; *Total Annual Responses:* 5,000; *Total Annual Hours:* 750.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA'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: June 5, 2001.

John P. Burke, III,

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

[FR Doc. 01–14884 Filed 6–12–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited 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) ways to enhance 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.

Proposed Project: The National Health Service Corps (NHSC) and Native Hawaiian Health (NHH) Scholarship Programs Data Collection Worksheets (OMB No. 0915–0226)—Extension

The NHSC and NHH Scholarship Programs were established to assure an adequate supply of trained primary care health professionals to the neediest communities in the Health Professional Shortage Areas (HPSAs) of the United States. Under these programs, allopathic physicians, osteopathic physicians, dentists, nurse practitioners, nurse midwives, physician assistants, and, if needed by the NHSC or NHH program, students of other health professions are offered the opportunity to enter into a contractual agreement with the Secretary under which the Public Health Service agrees to pay the total school tuition, required fees, other reasonable costs (ORC) and a stipend for living expenses. In exchange, the scholarship recipients agrees to provide full-time clinical services at a site in a federally designated HPSA.

In order to accurately determine the amount of scholarship support that students will need during their academic training the Bureau of Primary Health Care must contact each scholars's school for an estimate of tuition, fees, and ORC. The Data Collection Worksheet collects these itemized costs for both resident and nonresident students.

Estimated Burden Hours

HRSA form	Number of respondents	Responses per respondent	Total responses	Hours per responses	Total burden hours
Worksheet	600	1	600	.50	300

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: June 6, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–14866 Filed 6–12–01; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Meeting.