technical guidance in the European Union, Japan, and the United States for approval of therapeutic antimicrobial veterinary medicinal products intended for use in food-producing animals with regard to characterization of antimicrobial resistance selection in bacteria of human health concern.

This guidance document outlines the types of studies and data that may be used to characterize the potential for resistance to develop in the target animal when an antimicrobial drug product is used under the proposed conditions. This includes information which describes the drug substance, drug product, nature of the resistance, and potential exposure of gut flora in the target animal species. This information may be used as part of an overall assessment of the potential impact of the product on human health. Information collection is covered under the Office of Management and Budget control number 0910–0032.

III. Significance of Guidance

This guidance document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline.'' Because guidance documents are not binding, mandatory words such as ''must,'' ''shall,'' and ''will'' in the original VICH document have been substituted with ''should'' or ''recommend.''

This VICH guidance document is consistent with the agency's current thinking, on the type of pre-approval information that should be considered for new veterinary medicinal products for food-producing animals with regard to characterization of antimicrobial resistance selection in bacteria of human health concern. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically review the comments in the docket and where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit written comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance document and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with Internet access may obtain a copy of the guidance document entitled ''Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals with Respect to Antimicrobial Resistance'' (VICH GL–27) may be obtained on the Internet from the CVM Home Page at *http://www.fda.gov/cvm*.

Dated: April 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–9836 Filed 4–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Health Care Infrastructure Forms for Funding Opportunities—NEW

HRSA Safety Net programs, including the Consolidated Health Center (CHC) Program and the Healthy Communities Access Program (HCAP), are administered by HRSA's Bureau of Primary Health Care (BPHC). HRSA/BPHC is committed to assisting communities in the development of integrated and comprehensive health care delivery systems which will improve the effectiveness, efficiency, and coordination of services for uninsured and underinsured individuals, resulting in higher quality care for these populations at less cost.

Grant funding opportunities are provided to health centers to support: The integration and coordination of primary, hospital, and specialty care; the enhancement of the network and the health centers ability to compete in the marketplace; and the strategic alignment of health center information systems and technology infrastructure to integrate uniform clinical information with business systems.

BPHC will assist in achieving this new health center infrastructure through various funding opportunities. Application forms are used by new and current health centers through (1) Health Center Network Planning and Development which includes the Integrated Service Development Initiative (ISDI), Shared Integrated Management Information System (SIMIS), Integrated Information and Communication Technology (ICT), (2) Healthy Communities Access Program (HCAP), and (3) Operational Health Center Networks (OHCN) which include the ISDI and Pharmacy Networks.

The burden estimate of for this activity is as follows:

Type of application	Number of respondents	Hours per response	Total burden hours
Healthy Communities Access Program	242	45	10,890
Health Center Network Planning and Development:			
Integrated Service Development Initiative	7	45	315
Shared Integrated Management Information System	7	45	315
Integrated Information and Communication Technology	9	45	405
Pharmacy Networks	12	45	540
Operational Health Center Networks:			
Pharmacy Networks	20	45	900

Type of application	Number of respondents	Hours per response	Total burden hours
Integrated Service Development Initiative	17	45	765
Total	314		14,130

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Desk Officer, Health Resources and Services Administration, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: April 23, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–9802 Filed 4–29–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Smallpox Vaccine Injury Compensation Program (OMB No. 0915–0282)—Extension

The Smallpox Emergency Personnel Protection Act (SEPPA) authorized the Secretary of Health and Human Services to establish The Smallpox Vaccine Injury Compensation Program, which is designed to provide benefits and/or compensation to certain persons harmed as a direct result of receiving smallpox covered countermeasures, including the smallpox vaccine, or as a direct result of contracting vaccinia through certain accidental exposures.

The benefits available under the Program include compensation for medical care, lost employment income, and survivor death benefits. To be considered for Program benefits, requesters (*i.e.*, smallpox vaccine recipients, vaccinia contacts, survivors, or the representatives of the estates of deceased smallpox vaccine recipients or vaccinia contacts), or persons filing on their behalf as their representatives, must file a Request Form and the documentation required under this regulation to show that they are eligible.

Requesters must submit appropriate documentation to allow the Secretary to determine if the requesters are eligible for Program benefits. This documentation will vary somewhat depending on whether the requester is filing as a smallpox vaccine recipient, a vaccinia contact, a survivor, or a representative of an estate.

All requesters must submit medical records sufficient to demonstrate that a covered injury was sustained by a smallpox vaccine recipient or a vaccinia contact.

The burden estimate is as follows:

Form	Number of respondents	Responses per respondent	Hourly response	Total burden hours
Request Form	1,250	1	5	6,250
Certification	1,250	1	1	1,250
Total	2,500	.....	.....	7,500

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Desk Officer, Health Resources and Services Administration, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: April 23, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–9803 Filed 4–29–04; 8:45 am]

BILLING CODE 4165–15–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, Public Law 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.