before the committee. Written submissions may be made to the contact person by May 19, 2004. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 19, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kimberly Littleton Topper at 301–827–7001, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 22, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–9801 Filed 4–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0051]

International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products; Guidance for Industry on Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals With Respect to Antimicrobial Resistance (VICH GL27); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#144) entitled ''Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals With Respect to Antimicrobial Resistance'' (VICH GL27). This guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document is an initial step in developing harmonized 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. The guidance outlines the types of studies and data which are recommended for assessing the potential for resistance to develop in association with the use of antimicrobial drugs in food-producing animals.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic or written comments at any time on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified by the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–2), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4514, e-mail: *wflynn@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH steering committee: One representative from the Government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the Government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Guidance on Antimicrobial Resistance

In the **Federal Register** of June 12, 2003 (68 FR 35234), FDA published the notice of availability of the VICH draft guidance, giving interested persons until July 14, 2003, to submit comments. After consideration of comments received, the draft guidance was changed in response to the comments and submitted to the VICH Steering Committee. At a meeting held on October 7 and 8, 2003, the VICH Steering Committee endorsed the guidance for industry, VICH GL27.

The VICH guidance document is an initial step in developing harmonized

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]

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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