II. Comments

Interested persons may, at any time, submit written or electronic comments regarding the draft guidance. Written comments should be submitted to the Dockets Management Branch (address above). 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. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Comments may also be submitted electronically on the Internet at http://www.fda.gov/dockets/ecomments. Once on this Internet site, select the relevant ''docket number'' and follow the directions. Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm.

Dated: May 7, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–12179 Filed 5–14–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2406]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Final Guidance for Industry entitled ''Good Clinical Practice'' (VICH GL9); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (No. 85) entitled ''Good Clinical Practice'' (VICH GL9). This guidance document has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The final VICH guidance is intended to provide a unified standard for designing, conducting, monitoring, recording, and reporting studies used in registration applications for approval of veterinary products submitted to the European Union, Japan, and the United States.

DATES: Submit written comments at any time. This guidance will be implemented July 1, 2001.

ADDRESSES: Submit written requests for a single copy of the final guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance document.

Submit written comments at any time on the final guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852,— e-mail: *fdadockets@oc.fda.gov*.

FOR FURTHER INFORMATION CONTACT: Herman M. Schoenemann (HFV–120), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0220, e-mail: *3hschoene@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 recommendations. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical recommendations for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce the differences in technical recommendations for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for several years to develop harmonized technical recommendations 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 recommendations 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; the European Medicines Evaluation Agency; the European Federation of Animal Health; 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.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand and one representative from the industry in Australia/New Zealand. 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 Good Clinical Practice

In the **Federal Register** of August 3, 1999 (64 FR 42135), FDA published the notice of availability of the draft guidance entitled ''Good Clinical Practices'' (VICH GL9), giving interested persons until September 2, 1999 to submit comments. After considering the comments received, FDA made principally editorial changes. The final guidance was submitted to the VICH Steering Committee. At a meeting held on June 14 through 16, 2000, the VICH Steering Committee endorsed the final guidance for industry, VICH GL9.

The guidance is intended to be an international ethical and scientific quality standard for designing, conducting, monitoring, recording, auditing, analyzing, and reporting clinical studies evaluating veterinary products. This final guidance document is intended to be consistent with the laws of the European Union, Japan, and the United States.

VICH GL9 is a revision of and will replace CVM guidance No. 58 entitled ''Good Target Animal Studies Practices: Investigators and Monitors.'' In addition, there are some minor conflicts between this guidance and recent CVM guidance No. 56 entitled ''Protocol Development Guideline for Clinical Effectiveness and Target Animal Safety Trials,'' and No. 104 entitled ''Guidance for Industry: Content and Format of Effectiveness and Target Animal Safety Technical Sections and Final Study Reports for Submission to the Division of Therapeutic Drugs for Non-Food Animals.'' Until the center revises these guidances, sponsors should follow the

recommendations in VICH GL9 when differences among the guidances occur.

This Level 1 final guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents FDA's current thinking on design and conduct of all clinical studies of veterinary products in the target species. 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 method may be used as long as it satisfies the requirements of applicable statutes and regulations.

Information collected is covered under OMB control number 0910–0032.

III. Electronic Access

Copies of the final guidance documents entitled ''Good Clinical Practice'' (VICH GL9) may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm. Comments may also be submitted electronically on the Internet at http://www.fda.gov/dockets/ecomments. Once on this Internet site, select ''99D–2406 Good Clinical Practice'' and follow the directions.

IV. Comments

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

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

Dated: May 7, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–12092 Filed 5–14–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–R–235]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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, 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: Revision of a currently approved collection;

Title of Information Collection: Data Use Agreement and Information Collection Requirements, model language, and Supporting Regulations in 45 CFR, part 5b;

Form No.: HCFA–R–235 (OMB# 0938–0734);

Use: This agreement is used as a binding agreement stating conditions under which HCFA will disclose and user will maintain HCFA data that are protected by the Privacy Act.;

Frequency: On occasion;

Affected Public: Not-for-profit institutions;

Number of Respondents: 1,500;

Total Annual Responses: 1,500;

Total Annual Hours: 750.

To obtain copies of the supporting statement and any related forms 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, phone number, OMB number, and HCFA 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 HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, HCFA–R–235, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 24, 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. 01–12203 Filed 5–14–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Special Projects of National Significance; Targeted HIV Outreach and Intervention Model Development; Evaluation and Program Support Center

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Correction.

In the **Federal Register** of April 13, 2001, appearing on page 19180, second column, line 21 is an incorrect website to locate the guidance. The correct HRSA web site for the guidance should read, *www.hab.hrsa.gov/grants.html.*

Dated: May 9, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–12180 Filed 5–14–01; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of June 2001.

Name: Maternal and Child Health Research Grants Review Committee.

Date and Time: June 20–22, 2001; 8 am–5 pm.