ADDRESSES: Copies of the final guidance document entitled ''Impurities in New Veterinary Medicinal Products'' (VICH GL11) may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm. Persons without Internet access may 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.

Submit written comments on the final guidance document to the Policy and Regulations Team (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT:

Regarding VICH: Sharon R. Thompson, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798, e-mail: sthompso@cvm.fda.gov, or Robert C. Livingston, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–5903, e-mail: rlivings@cvm.fda.gov.

Regarding the guidance document: Kevin J. Greenlees, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6977, e-mail: kgreenle@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities, industry associations, and individual sponsors 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 requirements for the development of pharmaceutical products. One of the goals of harmonization is to identify and reduce the differences in technical requirements 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 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 meetings are held under the auspices of the Office International des Epizooties (OIE). During the initial phase of the VICH, an OIE representative chairs the VICH Steering Committee. 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 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.

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 Confederation Mondiale de L'Industrie de la Sante Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Guidance on Impurities in New Veterinary Medicinal Products

In the **Federal Register** of July 22, 1999 (64 FR 39514), FDA published the draft guidance entitled ''Impurities in New Veterinary Medicinal Products'' (VICH GL11) giving interested persons until August 23, 1999, to submit comments. After consideration of comments received, the final draft guidance was submitted to the VICH steering committee. At a meeting held on November 16 through 19, 1999, the VICH Steering Committee endorsed the final draft guidance, VICH GL11, for industry.

This document is intended to provide guidance for new animal drug applications (referred to as registration applications or marketing authorization in the final guidance) on the content and qualification of impurities in new drug substances intended to be used for new veterinary medicinal products produced by chemical syntheses and not previously registered in a region or member State. (Information collected is covered under OMB Control No. 0910–0032.)

This final guidance document represents current FDA thinking on impurities in new veterinary medicinal products and does not create or confer any rights for or on any person and does not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of applicable statutes and regulations.

III. 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 guidance. The comments in the docket will be periodically reviewed, and, where appropriate, the guidance will be amended. The public will be notified of any such amendments through a notice in the **Federal Register**.

Dated: June 29, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–17200 Filed 7–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2215]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Final Guidance on ''Impurities in New Veterinary Drug Substances'' (VICH GL10); 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 (#92) entitled ''Impurities in New Veterinary Drug Substances'' (VICH GL10). This guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The guidance is intended to assist in developing registration applications for approval of veterinary medicinal products submitted to the European Union, Japan, and the United States.

DATES: Submit written comments at any time.

ADDRESSES: Copies of the final guidance entitled ''Impurities in New Veterinary Drug Substances'' (VICH GL10) may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm. Persons without Internet access may 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.

Submit written comments on the final guidance to the Policy and Regulations Team (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT:

Regarding VICH: Sharon R. Thompson, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798, e-mail: sthompso@cvm.fda.gov, or Robert C. Livingston, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–5903, e-mail: rlivings@cvm.fda.gov.

Regarding the guidance document: Kevin J. Greenlees, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6977, e-mail: kgreenle@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities, industry associations, and individual sponsors 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 requirements for the development of pharmaceutical products. One of the goals of harmonization is to identify and reduce the differences in technical requirements for drug development among regulatory agencies in different countries.

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The VICH meetings are held under the auspices of the Office International des Epizooties (OIE). During the initial phase of the VICH, an OIE representative chairs the VICH Steering Committee. 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 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.

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 Confederation Mondiale de L'Industrie de la Sante Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Guidance on Impurities in New Veterinary Drug Substances

In the **Federal Register** of July 22, 1999 (64 FR 39516), FDA published the draft guidance entitled ''Impurities in New Veterinary Drug Substances'' (VICH GL10) giving interested persons until August 23, 1999, to submit comments. After consideration of comments received, the final draft guidance was submitted to the VICH steering committee. At a meeting held on November 16 through 19, 1999, the VICH Steering Committee endorsed the final draft guidance, VICH GL10, for industry.

This document is intended to provide guidance for new animal drug applications (referred to as registration applications or marketing authorization in the final guidance) on the content and qualification of impurities in new drug substances intended to be used for new veterinary medicinal products, produced by chemical syntheses and not previously registered in a region or member State. (Information collected is covered under OMB Control No. 0910–0032.)

This final guidance document represents current FDA thinking on impurities in new veterinary drug substances and does not create or confer any rights for or on any person and does not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of applicable statutes and regulations.

III. 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 guidance. The comments in the docket will be periodically reviewed, and, where appropriate, the guidance will be amended. The public will be notified of any such amendments through a notice in the **Federal Register**.

Dated: June 29, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–17201 Filed 7–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–77]

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