National Institute for Occupational Safety and Health, 1600 Clifton Road, NE, Atlanta, Georgia 30333. Phone 404/639–3342, e-mail bbk1@cdc.gov.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: December 11, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention CDC.

[FR Doc. 00–32102 Filed 12–15–00; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1631]

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on ''Safety Studies for Veterinary Drug Residues in Human Food: Genotoxicity Studies'' (VICH GL23); Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance document for industry (No. 116) entitled ''Safety Studies for Veterinary Drug Residues in Human Food: Genotoxicity Studies'' (VICH GL23). This draft guidance document has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a guidance regarding pharmaceuticals for human use, which was adopted by the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use (ICH). This draft VICH guidance document recommends a basic battery of tests that can be used to evaluate the genotoxicity of veterinary drug residues in human food in the European Union, Japan, and the United States.

DATES: Submit written comments on the draft guidance document by January 17, 2001, to ensure their adequate consideration in preparation of the final guidance document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance document entitled ''Safety Studies for Veterinary Drug Residues in Human Food: Genotoxicity Studies'' (VICH GL23) may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm/fda/TOCs/guideline.html. Persons without Internet access may submit written requests for single copies of the draft guidance document 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.

You may submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the VICH: Sharon 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 Carole R. Andres, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6524, e-mail: candres1@cvm.fda.gov.

Regarding the draft guidance document: Louis T. Mulligan, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6984, e-mail: lmulliga@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 ICH 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; U.S. FDA; U.S. Department of Agriculture; Animal Health Institute; Japanese Veterinary Pharmaceutical Association; Japanese Association of Veterinary Biologics; and 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. Draft Guidance on Genotoxicity Studies

The VICH Steering Committee held a meeting on June 14 through 16, 2000, and agreed that the draft guidance document entitled ''Safety Studies for Veterinary Drug Residues in Human Food: Genotoxicity Studies'' (VICH GL23) should be made available for public comment. This draft guidance document has been adapted for veterinary use by the VICH from guidances regarding pharmaceuticals for human use which were adopted by the ICH and published in the **Federal Register** of April 24, 1996 (61 FR 18197), and November 21, 1997 (62 FR 62471). This draft guidance document is one of a series of VICH guidances developed to facilitate the mutual acceptance of safety data necessary for the establishment of acceptable daily intakes for veterinary drug residues in human food by the relevant regulatory

authorities. The guidance on the overall strategy for the evaluation of veterinary drug residues in human food (VICH Guidance on General Testing Approach) will be made available at a later time. This guidance was developed after consideration of the existing ICH guidances for pharmaceuticals for human use: ''Genotoxicity: A Standard Battery of Genotoxicity Testing of Pharmaceuticals'' and ''Guidance on Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals.'' Account was also taken of the Organisation for Economic Cooperation and Development methodological guidances and of the current practices for evaluating the safety of veterinary drug residues in human food in the European Union, Japan, the U.S.A., Australia, and New Zealand.

Comments about the draft guidance documents will be considered by the FDA and the VICH Safety Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidances and publish them as future guidance. (Information collection is covered under OMB No. 0910–0117. Information collection also could be covered by OMB No. 0910–0032.)

III. Significance of Guidance

This draft guidance document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (65 FR 56468, September 19, 2000). For example, the documents have been designated ''guidance'' rather than ''guideline.'' Because guidance documents are not binding, unless specifically supported by statute or regulation, mandatory words such as ''must,'' ''shall,'' and ''will'' in the original VICH documents have been substituted with ''should.'' Similarly, words such as ''require'' or ''requirement'' have been replaced by ''recommendation'' or ''recommended'' as appropriate to the context.

The draft guidance document represents the agency's current thinking on genotoxicity safety studies for veterinary drug residues in human food. This guidance document 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

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments by January 17, 2001, to ensure adequate consideration in preparation of the final guidance. 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 document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 8, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–32113 Filed 12–15–00; 8:45 am]

BILLING CODE: 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Prescription Drug User Fee Rates for Fiscal Year 2001

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2001. The Prescription Drug User Fee Act of 1992 (the PDUFA), as amended by the Food and Drug Administration Modernization Act of 1997 (the FDAMA), authorizes FDA to collect user fees for certain applications for approval of drug and biological products, on establishments where the products are made, and on such products. Fees for applications for FY 2001 were set by the PDUFA, as amended, subject to adjustment for inflation. Total application fee revenues fluctuate with the number of fee-paying applications FDA receives. Fees for establishments and products are calculated so that total revenues from each category will approximate FDA's estimate of the revenues to be derived from applications.

FOR FURTHER INFORMATION CONTACT: Frank P. Claunts, Office of Management and Systems (HF–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION:

I. Background

The PDUFA (Public Law 102–571), as amended by the FDAMA (Public Law 105–115), referred to as the PDUFA II in this document, establishes three different kinds of user fees. Fees are assessed on: (1) Certain types of applications and supplements for approval of drug and biological products, (2) certain establishments where such products are made, and (3) certain products (21 U.S.C. 379h(a)). When certain conditions are met, FDA may waive or reduce fees (21 U.S.C. 379h(d)).

For FY 1998 through 2002, under the PDUFA II, the application fee rates are set in the statute, but are to be adjusted annually for cumulative inflation since FY 1997. Total application fee revenues are structured to increase or decrease each year as the number of fee-paying applications submitted to FDA increases or decreases.

Each year from FY 1998 through 2002, FDA is required to set establishment fees and product fees so that the estimated total fee revenue from each of these two categories will equal the total revenue FDA expects to collect from application fees that year. This procedure continues the arrangement under which one-third of the total user fee revenue is projected to come from each of the three types of fees: Application fees, establishment fees, and product fees.

This notice establishes fee rates for FY 2001 for application, establishment, and product fees. These fees are retroactive to October 1, 2000, and will remain in effect through September 30, 2001. For fees already paid on applications and supplements submitted on or after October 1, 2000, FDA will bill applicants for the difference between fees paid and fees due under the new fee schedule. For applications and supplements submitted after December 31, 2000, the new fee schedule must be used. Invoices for establishment and product fees for FY 2001 will be issued in December 2000, using the new fee schedule.

II. Inflation and Workload Adjustment Process

The PDUFA II provides that fee rates for each FY shall be adjusted by notice in the **Federal Register**. The adjustment must reflect the greater of: (1) The total percentage change that occurred during the preceding FY in the Consumer Price Index (CPI) (all items; U.S. city average), or (2) the total percentage pay change for that FY for Federal employees stationed in the Washington, DC, metropolitan area. The PDUFA II provides for this annual adjustment to be cumulative and compounded annually after 1997 (see 21 U.S.C. 379h(c)(1)).