Location: Quality Suites, Potomac Ballroom, 3 Research Ct., Rockville, MD.

Contact Person: Nancy Chamberlin or Jaime Henriquez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, or e-mail: CHAMBERLINN@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539 and 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 17, 2000, the committees will discuss the current status of, and future plans for, the draft FDA guidance entitled ''A Guidance for Industry, Topical Dermatological Drug Product NDA's and ANDA's—In Vivo Bioavailability, Bioequivalence, In Vitro Release, and Associated Studies;'' see the FDA internet web address www.fda.gov/cder/guidance/2481dft.pdf under the heading of ''Biopharmaceutics Draft Guidances.'' A proposed research program for addressing scientific issues related to this guidance will also be discussed.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 6, 2000. Oral presentations from the public will be scheduled between approximately 11:15 a.m. to 12:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 6, 2000, 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.

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

Dated: October 11, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–26898 Filed 10–18–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1532]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidances for Industry on ''Effectiveness of Anthelmintics: Specific Recommendations for Equine'' (VICH GL15), ''Effectiveness of Anthelmintics: Specific Recommendations for Porcine'' (VICH GL16), and ''Effectiveness of Anthelmintics: Specific Recommendations for Canine'' (VICH GL19); 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 three draft guidances for industry (Nos. 109, 110, and 111, respectively) entitled: ''Effectiveness of Anthelmintics: Specific Recommendations for Equine'' (VICH GL15), ''Effectiveness of Anthelmintics: Specific Recommendations for Porcine'' (VICH GL16), and ''Effectiveness of Anthelmintics: Specific Recommendations for Canine'' (VICH GL19). These related draft guidance documents have been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). They are intended to standardize and simplify methods used in the evaluation of new anthelmintics submitted for approval to the European Union, Japan, and the United States.

DATES: Submit written comments on the draft guidances by December 18, 2000, 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 guidances entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Equine'' (VICH GL15), ''Effectiveness of Anthelmintics: Specific Recommendations for Porcine'' (VICH GL16), and ''Effectiveness of Anthelmintics: Specific Recommendations for Canine'' (VICH GL19) 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 guidances to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments 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 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 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 documents: Thomas Letonja, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7576, e-mail: tletonja@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 requirements for the development of pharmaceutical products. One of the goals of harmonization is to identify and then 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 (ICH) 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 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.

The VICH Steering Committee held a meeting on November 16 through 19, 1999, and agreed that the three draft guidances entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Equine'' (VICH GL15), ''Effectiveness of Anthelmintics: Specific Recommendations for Porcine'' (VICH GL16), and ''Effectiveness of Anthelmintics: Specific Recommendations for Canine'' (VICH GL19) should be made available for public comment.

The three draft guidances: VICH GL15, VICH GL16, and VICH GL19, should be read in conjunction with the ''Efficacy of Anthelmintics: General Recommendations (EAGR)'' announced in the **Federal Register** of July 16, 1999 (64 FR 38445). The draft guidances for equine, porcine, and canine are part of the EAGR, and the aim of these three draft guidances is to: (1) Be more specific for certain issues not discussed in the general guidance, (2) highlight differences with the EAGR on effectiveness data recommendations, and (3) give explanations for disparities with the EAGR. Comments about the draft guidances will be considered by the FDA and the VICH Anthelmintic Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidances and publish them as future guidances.

These draft guidances, developed under the VICH process, have been revised to conform to FDA's good guidance practices (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 ''requirement'' or ''acceptable'' have been replaced by ''recommendation'' or ''recommended'' as appropriate to the context.

These draft guidances represent current FDA thinking on effectiveness recommendations for certain veterinary anthelmintic medicinal products. These draft guidances do not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

II. Comments

These draft guidances are being distributed for comment purposes only, and they are not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft guidance documents by December 18, 2000. 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 guidances and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 6, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–26897 Filed 10–18–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–250 through HCFA–254]

Notice of Emergency Clearance and Public Meeting: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration, DHHS.

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.

We are, however, requesting an emergency review of the information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320. A disruption in this collection activity may cause public harm. This is due to the potential and unnecessary loss to the Medicare Trust Fund as the result of the non-identification of health insurance coverage that is primary to Medicare. Collection of this information allows HCFA to identify those Medicare beneficiaries who have other group health insurance that would pay before Medicare, resulting in savings to the Medicare Trust Fund. The annual savings from the Medicare Secondary Payer (MSP) program are more than $3 billion per year.

Emergency Clearance

HCFA is requesting OMB review and approval of this collection by November 24, 2000, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by November 23, 2000. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Request: Revision of a currently approved collection; *Title of Information Collection:* Medicare Secondary Payer Information Collection