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.

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 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

minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Limitation on Liability and Information Collection Requirements Referenced in 42 CFR 411.404, 411.406, and 411.408;

Form No.: HCFA–R–77 (OMB# 0938–0465);

Use: The Medicare program requires to provide written notification of noncovered services to beneficiaries by the providers, practitioners, and suppliers. The notification gives the beneficiary, provider, practitioner, or supplier knowledge that Medicare will not pay for items or services mentioned in the notification. After this notification, any future claim for the same or similar services will not be paid by the program and the affected parties will be liable for the noncovered services.

Frequency: Other; as needed;

Affected Public: Individuals or Households;

Number of Respondents: 890,826;

Total Annual Responses: 3,563,304;

Total Annual Hours: 296,942.

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, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 28, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–17214 Filed 7–6–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1140–N]

Medicare Program; Question and Answer Session on July 24, 2000 To Discuss Remaining Concerns About the Implementation of the Hospital Outpatient Prospective Payment System (PPS)

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting to provide an opportunity for hospital administrators, hospital industry representatives, hospital professionals, community mental health centers, home health agencies, comprehensive outpatient rehabilitation facilities, beneficiary advocates and other interested parties, to have pre-submitted questions and issues answered regarding remaining concerns they may have about the August, 2000 implementation of the hospital outpatient prospective payment system. Appropriate HCFA staff will be present to ensure that those questions and concerns will be answered.

DATES: The meeting is scheduled for July 24, 2000 from 9:30 a.m. until 4 p.m., E.D.T. The morning session (9:30 a.m. until 12) will be for hospital providers and the afternoon session (1:30 p.m. until 4 p.m.) will be for other providers; that is, community mental health centers (CMHCs, home health agencies (HHAs), and comprehensive outpatient rehabilitation facilities (CORFs).

ADDRESSES: The meeting will be held in the HCFA Central Office Main Auditorium, 7500 Security Boulevard, Baltimore, MD 21244.

FOR FURTHER INFORMATION CONTACT: Judy Hunt, (410) 786–7874 or Mary Loane, (410) 786–1405 (for registration information and pre-submitted questions).

SUPPLEMENTARY INFORMATION:

Background

On April 7, 2000 a final rule with comment period on the hospital outpatient prospective payment system (PPS) was published. This new PPS will go into effect for hospital outpatient services designated by the Secretary, certain Part B services furnished to hospital inpatients who have no Part A coverage, and partial hospitalization services furnished by community mental health centers. This outpatient PPS was enacted as part of the Balanced Budget Act of 1997. This meeting will provide a forum, for outpatient facilities, to receive answers to their pre-submitted questions and issues concerning the August, 2000, implementation of hospital outpatient PPS.

The format of the meeting will be a question and answer session. Appropriate HCFA staff will be present to ensure that questions and concerns will be answered.

During this session, major provider organizations are invited to give a brief pre-scheduled statement on the coming implementation of the outpatient PPS. Those organizations wishing to take advantage of this opportunity should submit their statement in writing to HCFA not less than 3 working days prior to this meeting and make copies available to attendees on the day of the conference.

While the meeting is open to the public, attendance is limited to space available. Individuals must register in advance as described below.

Registration

Individuals may register by following the directions soon to be posted on the HCFA website, www.hcfa.gov. Once individuals are on this website, they will need to highlight the red bullet, in the lower right hand corner, titled ''Events, Meetings, and Workgroups.'' Individuals should also submit questions they would like to have answered, no later than July 14, 2000, by following the directions soon to be posted on the same HCFA website, www.hcfa.gov. The registration site will link you to the site for submission of questions.

Each participant will be provided with a meeting agenda at the time of the meeting.

If individuals have questions regarding registration; would like to register by phone; or would like to submit questions regarding hospital outpatient PPS issue, they should contact Judy Hunt (410) 786–7874 or Mary Loane (410) 786–1405.

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 30, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 00–17136 Filed 7–6–00; 8:45 am]

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