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:* Conditions of Participation for Portable X-ray Suppliers and Supporting Regulations in 42 CFR, Sections 486.104, 486.106, and 486.110; *Use:* This information collection request contains the recordkeeping requirements contained in the above noted regulation sections. These requirements are designed to ensure that each supplier has a properly trained staff to provide the appropriate type and level of care, as well as a safe physical environment for patients. CMS uses these conditions to certify portable X-ray Suppliers wishing to participate in the Medicare program.; *Form Number:* CMS–R–43 (OMB#: 0938–0338); *Frequency:* Recordkeeping; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 602; *Total Annual Responses:* 602; *Total Annual Hours:* 1,505.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/regulations/pra/*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.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 CMS Paperwork Reduction Act Reports Clearance Officer designated at the address below: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Melissa Musotto, Room C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 3, 2005.

**John P. Burke, III,**

*CMS Paperwork Reduction Act Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group.*

[FR Doc. 05–2658 Filed 2–10–05; 8:45 am]

**BILLING CODE 4120–03–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier: CMS–10131]**

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), 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 function; (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:* New Collection; *Title of Information Collection:* Evaluation of Medicare Disease Management Demonstrations; *Form No.:* CMS–10131 (OMB# 0938–NEW); *Use:* CMS contracted with Mathematica Policy Research, Inc. for the evaluation of programs and disease management. The purpose of the patient survey is to assess the impact of disease management and prescription drug benefits (the latter in 3 of the sites) on patient's health and functioning status, care satisfaction, health behaviors and knowledge of condition. Data from the physician survey will be used to assess physician satisfaction with disease management services, their perceptions of the impact of disease management on patient outcomes, education, and service use, and on their own practice and office workload.; *Frequency:* On Occasion; *Affected Public:* Individuals or households, Business or other for-profit; *Number of Respondents:* 5000; *Total Annual Responses:* 2500; *Total Annual Hours:* 1625.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/regulations/pra/*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 3, 2005.

**John P. Burke, III,**

*CMS Paperwork Reduction Act Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group.*

[FR Doc. 05–2659 Filed 2–10–05; 8:45 am]

**BILLING CODE 4120–03–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 1998N–0046]**

### Annual Comprehensive List of Guidance Documents at the Food and Drug Administration; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of January 5, 2005 (70 FR 824). The document provided the agency's annual comprehensive list of guidance documents. The list provided information on current guidance documents and those that have been withdrawn. The document was published with some inadvertent errors. This document corrects those errors.

**FOR FURTHER INFORMATION CONTACT:** Joyce Strong, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 05–155, appearing on page 824 in the **Federal Register** of Wednesday, January 5, 2005, the following corrections are made:

1. On page 867, in the list, under the heading ''Guidance Documents Issued by CDRH—Continued,'' the entire entry is removed for the document entitled ''Review of 510(k)s for Computer Controlled Medical Devices (blue book

memo #K91–1)'' and for the document entitled ''FDA Policy for The Regulation of Computer Products; Draft.'' These two guidance documents were listed in error as both current and withdrawn. These guidances have been withdrawn by the agency.

2. On page 894, in the list, under the heading ''Guidance Documents Issued by CFSAN,'' the entire entry is removed for the document entitled ''Investigations Operations Manual'' and for the document entitled ''Regulatory Procedures Manual.'' These two guidance documents were listed as being issued by the Center for Food Safety and Applied Nutrition in error. They can be found in the list of guidance documents issued by the Office of Regulatory Affairs.

Dated: February 3, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05–2642 Filed 2–10–05; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003D–0474]**

### International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Final Guidance for Industry on Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI (VICH GL–36); Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry (#159) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI'' (VICH GL36). This guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document provides guidance for assessing the human food safety of residues from veterinary antimicrobial drugs with regard to effects on the human intestinal flora.

**DATES:** Submit written or electronic comments at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 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 guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** 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 International Conference on Harmonisation of Technical Requirements for Approval 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, 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.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/ New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

#### II. Guidance on Microbiological Acceptable Daily Intake

In the **Federal Register** of November 13, 2003 (68 FR 64354), FDA published the notice of availability of the VICH draft guidance, giving interested persons until December 15, 2003, to submit comments. After consideration of comments received, the draft guidance was changed in response to the comments and submitted to the VICH Steering Committee. At a meeting held on May 3, 2004, the VICH Steering Committee endorsed the final guidance for industry (VICH GL–36). This VICH guidance provides guidance for assessing the human food safety of residues from veterinary antimicrobial drugs with regard to effects on the human intestinal flora. The objectives of this guidance are: (1) To outline the recommended steps in determining the need for establishing a microbiological acceptable daily intake (ADI); (2) to recommend test systems and methods for determining no-observable adverse effect concentrations (NOAECs) and no-observable adverse effect levels (NOAELs) for the endpoints of health concern; and (3) to recommend a procedure to derive a microbiological ADI. It is recognized that different tests may be useful. The experience gained with the recommended tests may result in future modifications to this guidance and its recommendations. Information collection is covered under Office of