geriatric patients (aged 65 and over). The information collection burden imposed by this regulation is necessary to facilitate the safe and effective use of prescription drugs in older populations. The geriatric use subsection enables physicians to more effectively access geriatric information in physician prescription drug labeling.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents per Response	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.57(f)(10)—new drug applications	83	1.49	124	8	992
201.57(f)(10)—abbreviated new drug applications	117	3.96	464	2	928
Total					1,920

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In the **Federal Register** of January 5, 2001 (66 FR 1142), the agency requested comments on the proposed collections of information. No significant comments were received.

Dated: April 6, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–9119 Filed 4–12–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4070]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Final Guidance for Industry Entitled ''Stability Testing of New Biotechnological/Biological Veterinary Medicinal Products'' (VICH GL17); 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 (No. 99) entitled ''Stability Testing of New Biotechnological/Biological Veterinary Medicinal Products'' (VICH GL17). This guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal (VICH) from similarly titled guidance regarding pharmaceuticals for human use, which was adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This final VICH document is intended to provide guidance to applicants regarding the stability studies that should be conducted and the stability data that should be provided in support of new animal drug applications (NADA's) (referred to as marketing applications in the final guidance) for veterinary biotechnological/biological products that are regulated by FDA and for which the NADA's are submitted to the European Union, Japan, and the United States.

DATES: Submit written comments at any time.

ADDRESSES: 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance document.

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

FOR FURTHER INFORMATION CONTACT: William G. Marnane (HFV–140), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6966, e-mail: wmarnane@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 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; the European Medicines Evaluation Agency; the European Federation of Animal Health; 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 industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Guidance on Stability Testing of New Biotechnological/Biological Veterinary Medicinal Products

This final guidance entitled ''Stability Testing of New Biotechnological/

Biological Veterinary Medicinal Products'' (VICH GL17) has been adapted for veterinary use by the VICH from a guidance regarding pharmaceuticals for human use, which was adopted by the ICH and published in the **Federal Register** of July 10, 1996 (61 FR 36466).

In the **Federal Register** of October 12, 1999 (64 FR 55294), FDA published the VICH draft guidance, giving interested persons until November 12, 1999, to submit comments. FDA shared the comments it received with the appropriate VICH Expert Working Group and after considering the comments, the work group submitted the final guidance to the VICH Steering Committee. No changes were made in response to the comments. At a meeting held on June 14 through 16, 2000, the VICH Steering Committee endorsed the final guidance for industry, VICH GL17.

Biotechnological/biological products have distinguishing characteristics to which consideration should be given in any well-defined testing program designed to confirm their stability during the intended storage period. For such products, in which the active components are typically proteins and/or polypeptides, maintenance of molecular conformation and biological activity is dependent on noncovalent as well as covalent forces. The products are particularly sensitive to environmental factors such as temperature changes, oxidation, light, ionic content, and shear. In order to ensure maintenance of biological activity and to avoid degradation, stringent conditions for their storage are usually necessary. The evaluation of stability may require complex analytical methodologies. With these concerns in mind, applicants should develop proper supporting stability data for new products of this type.

This final guidance document is intended to provide guidance to applicants regarding the type of stability studies that should be conducted and the stability data that should be provided in support of NADA's for veterinary biotechnological/biological products that are regulated by FDA. It is intended to supplement the tripartite VICH GL3 guidance entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products'' (a copy of this final guidance document may be obtained on the Internet from the CVM home page at www.fda.gov/cvm).

This Level 1 final guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115; 65 FR 56468, September 19, 2000). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

Information collected is covered under OMB control number 0910–0117.

III. Electronic Access

Copies of the final guidance document entitled ''Stability Testing of New Biotechnological/Biological Veterinary Medicinal Products'' (VICH GL17) may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm.

IV. 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 final guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend this final guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this final guidance document at any time. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the final 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: April 6, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–9259 Filed 4–12–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3068–N]

Medicare Program; Educational Symposium To Discuss the Use of Evidence-Based Medicine in the Medicare Coverage Decision Process—May 3, 2001

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

ACTION: Notice of meeting.

SUMMARY: This document announces an educational symposium open to all interested parties at which presenters will describe evidence-based medicine and its role in the decision making process for Medicare coverage issues. This meeting represents one aspect of the evolving process for making the Medicare coverage process more open and comprehensible to the public.

DATES: *The Meeting:* The meeting will be held on May 3, 2001, from 8 a.m. until 12 noon, E.D.T.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify the **FOR FURTHER INFORMATION CONTACT** person by April 20, 2001.

ADDRESSES: The meeting will be held at the HCFA headquarters MultiPurpose Room, 7500 Security Boulevard, Baltimore, Maryland 21244. Seating in the MultiPurpose Room is limited to 150 persons, and is available on a first come, first served basis.

FOR FURTHER INFORMATION CONTACT: Janet Anderson at 410–786–2700, email *JAnderson@hcfa.gov*, or Janet Anderson, Coverage and Analysis Group, 7500 Security Blvd, mailstop S3–02–01, Baltimore, MD 21244.

SUPPLEMENTARY INFORMATION:

I. Background

On April 27, 1999, we published a general notice in the **Federal Register** (64 FR 22619) that announced the process we use to make national coverage decisions under the Medicare program. In the notice, we explained that these coverage decisions are prospective, population-based policies that apply to a clinical subset or class of Medicare beneficiaries. We described the clinical circumstances and setting under which an item or service is available (or not available). We included information and approaches we are considering for making coverage decisions. One approach is the use of the principles of evidence-based medicine in evaluating the effectiveness of health services. We also clarified that the notice was not intended to address individual medical necessity determinations and claims adjudication by our contractors and other adjudicators, nor was it intended to address changes in current Medicare payment policies.

On August 13, 1999, we published a notice in the **Federal Register** (64 FR 44231) to describe the Medicare Coverage Advisory Committee (MCAC), which provides advice and recommendations to us about clinical issues. The MCAC is charged with providing recommendations on a variety