

provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the

use of automated collection techniques, when appropriate, and other forms of information technology.

Voluntary Registration of Cosmetic Product Establishments—21 CFR Part 710 (OMB Control Number 0910-0027)—Extension

Under the Federal Food, Drug, and Cosmetic Act (the act), cosmetic products that are adulterated under section 601 of the act (21 U.S.C. 361) or misbranded under section 602 of the act (21 U.S.C. 362) may not be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, FDA requests that establishments that manufacture or package cosmetic products register with the agency on Form FDA 2511 entitled "Registration of Cosmetic Product Establishment." Regulations providing procedures for the voluntary registration of cosmetic product establishments are found in 21 CFR part 710.

Since mandatory registration of cosmetic establishments is not authorized by statute, voluntary registration provides FDA with the best

information available about the location, business trade names used, and the type of activity (manufacturing or packaging) of cosmetic product establishments that participate in this program. In addition, the registration information is an essential part of planning onsite inspections to determine the scope and extent of noncompliance with applicable provisions of the act. The registration information is used to estimate the size of the cosmetic industry regulated. Registration is permanent, although FDA requests that firms submit an amended registration on Form FDA 2511 if any of the information originally submitted changes.

FDA uses registration information as input for a computer data base of cosmetic product establishments. This data base is used for mailing lists to distribute regulatory information or to invite firms to participate in workshops on topics in which they may be interested.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
710	FDA 2511	50	1	50	0.4	20

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

The burden estimates are based on past experience and on discussions with registrants during routine communications. FDA receives an average of 50 registration submissions annually. There has been no change over the past 16 years in the number of submissions of Form FDA 2511 or in the time it takes to complete this form.

Dated: April 6, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1674]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of "Geriatric Use" Subsection in the Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments on the collection of information by May 14, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of "Geriatric Use" Subsection in the Labeling (OMB Control No. 0910-0370)—Extension

Section 201.57(f)(10) (21 CFR 201.57(f)(10)) requires that the "Precautions" section of prescription drug labeling must include a subsection on the use of the drug in elderly or

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 BURDEN¹

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.

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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/