DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0017]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Guidance on Validation of Analytical Procedures: Definition and Terminology; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a final guidance for industry entitled ''Validation of Analytical Procedures: Definition and Terminology.'' This guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from an identically titled guidance adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and published in the **Federal Register** of March l, 1995 (60 FR 11260). The document provides guidance on characteristics that should be considered during the validation of analytical procedures included as part of registration applications for approval of veterinary medicinal products submitted to the European Union, Japan, and the United States.

DATES: Submit written comments at any time.

ADDRESSES: Copies of the final guidance document entitled ''Validation of Analytical Procedures: Definition and Terminology'' may be obtained on the Internet within 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 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 document 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 the guidance: William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6966, e-mail ''wmarnane@cvm.fda.gov''.

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''.

SUPPLEMENTARY INFORMATION: 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 seeking scientifically based harmonized technical procedures 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.

FDA has actively participated in the ICH for several years to develop harmonized technical requirements for the approval of human pharmaceutical products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary pharmaceutical products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary pharmaceutical 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 U.S. Food and Drug Administration; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; 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 MERCOSUR (Argentina, Brazil, Uruguay, and Paraguay), and one representative from Federacion Latino–Americana de la Industria para la Salud Animal. 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.

In the **Federal Register** of January 27, 1998 (63 FR 3907), FDA published this guidance in draft form, giving interested persons until March 30, 1998, to submit comments. After consideration of comments received, a final draft guidance was submitted to the VICH steering committee.

At a meeting held from October 20 through 22, 1998, the VICH Steering Committee endorsed the draft guidance entitled ''Validation of Analytical Procedures: Definition and Terminology.'' This guidance discusses the characteristics that should be considered during the validation of the analytical procedures included in an application for registration of veterinary medicinal products in the European Union, Japan, and the United States. It is not intended to cover testing requirements or procedures, rather it is to serve as a collection of terms and definitions. These common definitions such as ''analytical procedures,'' ''specificity,'' ''precision,'' ''accuracy,'' etc., are meant to bridge the differences that often exist among various compendia and requirements of the European Union, Japan, and the United States. The final guidance will be implemented in October of 1999.

The final guidance represents the agency's current thinking on characteristics for consideration during the validation of the analytical procedures included as part of applications. It does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternate approach may be used if it satisfies the requirements of applicable statutes, regulations, or both.

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: July 21, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–19194 Filed 7–27–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0273]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

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:* Community Mental Health Center Site Visit Assessment Tool and Supporting Regulations in 42 CFR 410.2; *Form No.:* HCFA–R–0273 (OMB# 0938–0770); *Use:* This information collection tool is essential for the Health Care Financing Administration (HCFA) to ensure that existing Community Mental Health Centers (CMHC), as well as CMHC applicants to the Medicare program are incompliance with Medicare provider requirements, as well as all applicable Federal and State requirements. The collection tool will be completed and used by HCFA and or its contractors to collect patient records, other CMHC operational information, and to verify CMHC compliance as determined by the HCFA regional office. CMHCs will be required to sign the completed form, provide medical records, and other operational information to be copied by the HCFA contractor representative on-site at the CMHC during the site visit.; *Frequency:* Upon initial application or re-enrollment into the Medicare program; *Affected Public:* Business or other for profit, Not for profit institutions, and State, Local, or Tribal Government; *Number of Respondents:* 850; *Total Annual Responses:* 850; *Total Annual Hours:* 3,400.

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

Dated: July 19, 1999.

John P. Burke III,

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

[FR Doc. 99–19210 Filed 7–27–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

2000 National Household Survey on Drug Abuse—(0930–0110, Revision)

The National Household Survey on Drug Abuse (NHSDA) is a survey of the civilian, noninstitutionalized population of the United States 12 years old and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

For the 2000 NHSDA, additional questions in the following substantive areas are planned: mental health; mental health service utilization; industry and occupation; youth access to tobacco products and the cost of the last cigarettes purchased for adults as well as youth; and, substance abuse and treatment need. The remaining modular components of the NHSDA questionnaire will remain essentially unchanged except for minor modifications to wording and selective elimination of sufficient questions to allow for the additional burden of the questions and modules listed above.

As in 1999, the sample size of the survey for 2000 will be sufficient to permit prevalence estimates for each of the fifty states and the District of Columbia. The total annual burden estimate is 81,626 hours as shown below:

	Number of Respondents	Responses per respondent	Average burden per response (hrs.)	Total burden hours
Household Screener	210,000	1	0.050	10,500
NHSDA Questionnaire and interview verification	70,000	1	1.016	71,126
Total				81,626