

Medicinal Products." This final guidance document is the annex and addresses the recommendations for stability testing of veterinary medicinal Type A medicated articles (referred to as medicated premix drug products in the final guidance) intended for submission for approval to the European Union, Japan, and the United States.

DATES: You may submit written comments at any time.

ADDRESSES: Copies of the final guidance document entitled "Stability Testing for Medicated Premixes (VICH GL8)" may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm/fda/mappgs/vich.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.

You may submit written comments at any time 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 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:

sthompson@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:

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.

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 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 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 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 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 Stability Testing

In the **Federal Register** of July 22, 1999 (64 FR 39515), FDA published the draft guidance entitled "Stability Testing for Medicated Premixes (VICH GL8)," 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 GL8, for industry.

VICH GL8 addresses the generation of acceptable stability information for submission in new animal drug applications (referred to as registration applications in the final guidance) for Type A medicated articles containing new molecular entities. This guidance will be implemented in May 2000.

This final guidance document represents the agency's current thinking on acceptable stability testing of Type A medicated articles. The document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternate approaches may be used if they satisfy the requirements of applicable statutes, regulations, or both.

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: March 3, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4567-N-01]

Notice of Proposed Information Collection: Comment Request; Customer Satisfaction Survey for Business Partners and Multiclass Program Participants

AGENCY: Office of the President of Government National Mortgage Association (Ginnie Mae), HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* May 15, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding

this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Sonya Suarez, Office of Policy, Planning and Risk Management, Department of Housing & Urban Development, 451—7th Street, SW, Room 6226, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT:

Sonya Suarez, Ginnie Mae, (202) 708-2772 (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Customer Satisfaction Survey for Business

Partners and Multiclass Program Participants.

OMB Control Number, if applicable:

Description of the need for the information and proposed use: The purpose of this information collection will be to evaluate existing Ginnie Mae services and programs. This request to conduct a Ginnie Mae Customer Satisfaction Survey is in response to Executive Order 12862 on setting customer driven standards. The survey will be used to evaluate what benefits would be needed to understand and satisfy Ginnie Mae customers, program participants, and business partners.

Agency form numbers, if applicable: Not applicable.

Members of affected public: For-profit business (mortgage industry trade associations, securities companies, accounting firms, law firms, service providers, etc.).

ESTIMATION OF THE TOTAL NUMBERS OF HOURS NEEDED TO PREPARE THE INFORMATION COLLECTION INCLUDING NUMBER OF RESPONDENTS, FREQUENCY OF RESPONSE, AND HOURS OF RESPONSE

	Respondents	Frequency of response	Hours of response
Business Partners	50	15	750 minutes or 12.5 hours.
Multiclass Securities Program Participants	100	15	1500 minutes or 25 hours.

Status of the proposed information collection: This is a new collection of information from Ginnie Mae's Business Partners and Multiclass Program participants.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: March 1, 2000.

George S. Anderson,

Executive Vice President, Ginnie Mae.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4561-N-12]

Notice of Submission of Proposed Information Collection to OMB; Tenant Assessment Subsystem (TASS) Computer Matching Income Verification

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork

Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* April 13, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT:

Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708-2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to

collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice Also Lists the Following Information

Title of Proposal: Tenant Assessment Subsystem (TASS) computer matching income verification.

OMB Approval Number: 2507-XXXX.
Form Numbers: HUD-50073, HUD-50074.

Description of the Need for the Information and Its Proposed Use: Real Estate Assessment Center (REAC) has developed the Tenant Assessment Subsystem (TASS) to identify potential income discrepancies between income