| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| Only federal time limit is binding | | | | |
| First call | 13 | 1 | .25 | 3.25 |
| Written survey | 13 | 1 | 21 | 273 |
| Second call | 13 | 1 | 1 | 13 |
| Federal and state time limits are binding. | | | | |
| First call | 4 | 1 | .25 | 1 |
| Written survey | 4 | 1 | 23 | 92 |
| Second call | 4 | 1 | 1.5 | 6 |
| Estimated Total Annual Hours: | | | | 825.75 |

*Additional Information:* Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, *Attn:* Desk Officer for ACF.

Dated: November 1, 2001.

**Bob Sargis,**

*Reports Clearance Officer.*

[FR Doc. 01–27980 Filed 11–6–01; 8:45 am]

**BILLING CODE 4184–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 93D–0139]**

### International Conference on Harmonisation; Guidance on Q1A Stability Testing of New Drug Substances and Products; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a revised guidance entitled ''Q1A(R) Stability Testing of New Drug Substances and Products.'' The revised guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance sets forth recommendations on the information to be submitted in the stability data package for a new drug substance or drug product for a registration application within the three regions of the European Union (EU), Japan, and the United States. The purpose of the revision is to add information to certain sections and to provide clarification to other sections of the guidance.

**DATES:** This guidance is effective November 7, 2001. Submit written or electronic comments at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Regarding the guidance: Chi-wan Chen, Center for Drug Evaluation and Research (HFD–830), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2001, or Andrew Shrake, Center for Biologics Evaluation and Research (HFM–345), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–402–4635.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The EU, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health, Labor and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedures for publishing ICH guidances. As of April 2000, FDA no longer include the text of ICH guidances in the **Federal Register**. Instead, we publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance is placed in the docket and can be obtained through regular agency sources (see the **ADDRESSES** section). Draft ICH guidances are left in the original ICH format. Final guidances are reformatted to conform to the GGP style before publication.

In the **Federal Register** of April 21, 2000 (65 FR 21446), FDA published a draft revised tripartite guidance entitled ''Q1A(R) Stability Testing of New Drug Substances and Products.'' The notice gave interested persons an opportunity to submit comments by June 5, 2000. The draft revised guidance was a revision of an ICH guidance on the same topic published in the **Federal Register** of September 22, 1994 (59 FR 48754).

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies on November 9, 2000.

ICH Q1A provides guidance on the information to be submitted in the stability data package for a new drug substance or drug product for a registration application within the three regions: The EU, Japan, and the United States. The purpose of the ICH Q1A revision is to add information to certain sections and to provide clarification to other sections of the guidance. The following sections are the most important sections that have been revised:

- The section on stress testing of the active substance has been moved from the glossary to the main text.
- The text on test procedures has been brought in line with the ICH Q6A guidance. Relevant cross-references to other ICH guidances have been introduced.
- The text on testing frequency has been amended for accelerated testing conditions.
- Storage conditions have been described in more detail. Testing at low temperature and testing of aqueous liquids in semipermeable containers have been specifically addressed.
- The postapproval commitment is now clearly described.

The guidance has also been revised to remove several editorial inconsistencies, including some revision of the glossary.

This guidance represents the agency's current thinking on stability testing of new drug substances and products. 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.

## II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the guidance at any time. Two copies of any comments are to be submitted, except that individuals can submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the document at eitherhttp://www.fda.gov/ohrms/dockets/default.htm, http://www.fda.gov/cder/guidance/index.htm, or http://www.fda.gov/cber/publications.htm.

Dated: October 30, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01–27958 Filed 11–6–01; 8:45 am]

BILLING CODE 4160–01–S

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization Functions and Delegations of Authority of the Department of Health and Human Services (DHHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995 as last amended at 66 FR 52421–29, dated October 15, 2001).

This notice announces the title change only for the Division of Health Careers Development (RPD) in the Bureau of Health Professions (BHPr), the functions remain the same. Make the following change in the title:

**Division of Health Careers Diversity and Development (RPD)**

Serves as the focal point for the Health Professions and Nursing Student Loan and Scholarship Programs, the Exceptional Financial Need Scholarship Program, the Federal Assistance to Disadvantaged Health Professions Scholarship Program, the Health Educational Assistance Loan Program, the Health Professions and Nursing Educational Loan Repayment and Loan Cancellation Programs by providing leadership to assure equity in access to health resources and health careers for diverse and disadvantaged populations. Specifically: (1) Provides technical assistance to groups that represent and seek to improve the health status of diverse and disadvantaged populations, and facilitates the access of such groups to Bureau and other Federal programs and resources; (2) provides leadership and direction for the development and implementation of Bureau objectives as they relate to diverse and disadvantaged populations; (3) develops and recommends health resources and health career opportunities for diverse and disadvantaged populations; (4) initiates, stimulates, supports, coordinates, and evaluates Bureau programs for improving the availability and accessibility of health careers for diverse and disadvantaged populations; (5) initiates, stimulates, supports, coordinates, and evaluates in conjunction with other Bureau units, comprehensive data systems and analyses on requirements, resources, accessibility, and accountability of the health delivery system for diverse and disadvantaged populations; (6) conducts special studies and collects baseline data to identify specific factors contributing to the health and health-related problems of diverse and disadvantaged populations, and to develop strategies for improving health services and career opportunities for diverse and disadvantaged populations; (7) conducts extramural programs, including the use of grants and contracts, specifically designed to promote equity in access to health careers; (8) assures contract compliance and implementation of the Policy Statement on Civil Rights in the Bureau; (9) in coordination with the Bureau's