for publishing ICH guidances. As of April 2000, FDA no longer includes the text of ICH guidances in the **Federal Register**. Instead, the agency publishes 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In the **Federal Register** of August 1, 2000 (65 FR 46936), FDA published a notice announcing the availability of the draft guidance entitled ''Q7A ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.'' The notice gave interested persons an opportunity to submit comments by October 2, 2000.

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 in November 2000.

The guidance describes CGMPs for the manufacturing of APIs. The guidance is intended to help ensure that all APIs meet the standards for quality and purity they purport or are represented to possess. The guidance is not intended to define registration or filing requirements or modify pharmacopeial requirements.

In the guidance, ''manufacturing'' includes all operations, and related controls, of receipt of materials, production, packaging, repackaging, labeling, relabeling, quality control, release, storage, and distribution of APIs. The guidance applies to the manufacture of APIs for use in human drug products, including sterile APIs up to the point immediately before the API is rendered sterile. The sterilization and aseptic processing of sterile APIs are not covered by this guidance. CGMP's described in the guidance should be applied to the API manufacturing process beginning with the use of API starting materials.

The guidance applies to APIs that are manufactured by chemical synthesis, extraction, cell culture/fermentation, recovery from natural sources, or any combination of these processes. APIs manufactured using blood or plasma as raw materials are also covered.

The guidance does not apply to vaccines, whole cells, whole blood and plasma, blood and plasma derivatives (plasma fractionation), and gene therapy APIs. The guidance does not apply to cell substrates, medical gases, bulk-packaged drug products, and manufacturing/control aspects specific to radiopharmaceuticals.

This guidance represents the agency's current thinking on CGMPs for manufacturing APIs. 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 may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft 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 either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/publications.htm.

Dated: September 18. 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–23980 Filed 9–24–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0361]

International Conference on Harmonisation; Draft Guidance on ICH Q1D Bracketing and Matrixing Designs for Stability Testing of Drug Substances and Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Q1D Bracketing and Matrixing Designs for Stability Testing of Drug Substances and Drug Products.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This draft guidance is an annex to an ICH draft guidance entitled ''Q1A(R) Stability Testing of New Drug Substances and Products,'' that published in the **Federal Register** of April 21, 2000 (65 FR 21446). ICH Q1D is intended to provide guidance on the application of reduced designs (i.e., bracketing and matrixing) for stability studies conducted in accordance with the principles outlined in ICH Q1A(R).

DATES: Submit written or electronic comments on the draft guidance by November 26, 2001.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), 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. Submit written comments on the draft 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 draft 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 European Union, 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, Labour, 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 procedure for publishing ICH guidances. As of April 2000, FDA no longer includes the text of ICH guidances in the **Federal Register**. Instead, the agency publishes a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance will be placed in the docket and can be obtained through regular agency sources (see the **ADDRESSES** section). Draft guidances will be left in the original ICH format. The final guidance will be reformatted to conform to the GGP style before publication.

In November 2000, the ICH Steering Committee agreed that an ICH draft guidance entitled ''Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Drug Products'' should be made available for public comment. The draft guidance is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

ICH Q1A(R) notes that, if justified, the use of two types of reduced stability study designs (i.e., bracketing and matrixing) can be applied to the testing of new drug substances and products, but ICH Q1A(R) provides no further guidance on the subject. This draft guidance (ICH Q1D) describes the principles for applying bracketing or matrixing in situations where further justification is or is not important. Design factors and other considerations are presented, and potential risks of using reduced designs are discussed. Sample designs are provided as illustrations.

This draft guidance represents the agency's current thinking on reduced 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 comments on the draft guidance by November 26, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft 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 http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/publications.htm.

Dated: September 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–23981 Filed 9–24–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0418]

Solvay Pharmaceuticals, Inc.; Withdrawal of Approval of Two New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two new drug applications (NDAs) held by Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062. In 1997, the agency informed Solvay of its intention to assess the validity of data and information in all of Solvay's pending and approved applications. However, Solvay does not intend to conduct validity assessments of the two NDAs named in this notice because the products are no longer marketed. Solvay has agreed to permit FDA to withdraw approval of the applications, thereby waiving its opportunity for a hearing.

DATES: Effective September 25, 2001.

FOR FURTHER INFORMATION CONTACT: David Read, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: Recently, FDA determined that Solvay submitted untrue statements of material fact in several applications filed with the agency. These findings, along with other information submitted to the agency by Solvay, provided sufficient justification to question the reliability of data in all of Solvay's applications filed with the agency. Solvay was notified in writing of the agency's determinations and its intention to assess the validity of the data and information in all of Solvay's pending and approved applications. The agency offered Solvay the opportunity to permit FDA to withdraw approval, under § 314.150(d) (21 CFR 314.150(d)), of any application not undergoing a validity assessment.

Subsequently, in letters dated February 29, 2000, Solvay requested withdrawal under § 314.150(d) of the following NDAs held by Solvay:

NDA 16–782; Lithonate (lithium carbonate tablets USP) 300 milligrams (mg); and

NDA 16–980; Lithotabs (lithium carbonate tablets USP) 300 mg.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority