SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 16, 2002 (67 FR 63931), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0428. The approval expires on December 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: January 9, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–905 Filed 1–15–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1528]

Delfina Hernandez; Rescission of Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is rescinding an order issued under the Federal Food, Drug, and Cosmetic Act (the act) debarring Ms. Delfina Hernandez for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA is issuing this rescission because service of a notice proposing to debar Ms. Hernandez and offering her an opportunity for a hearing on the proposal was sent to the wrong person.

DATES: This notice is effective November 6, 2002.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 6, 2002 (67 FR 67629), FDA issued an order debarring Ms. Delfina Hernandez for 5 years from providing services in any capacity to a person that has an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (see sections 306(c)(1)(B) and (c)(2)(A)(iii) and 201(dd) of the act (21 U.S.C. 321(dd))).

The debarment order stated that FDA had served Ms. Hernandez by certified mail on May 13, 2002, a notice proposing to debar her and offering her an opportunity for a hearing on the proposal. The debarment order further stated that Ms. Hernandez had failed to request a hearing and thereby waived her opportunity for a hearing and waived any contentions concerning her debarment.

FDA has learned that the notice proposing to debar Ms. Hernandez and offering her an opportunity for a hearing was sent to an incorrect address and was apparently signed for by a person with the same name as Ms. Hernandez, but who was not the intended subject of the notice. Accordingly, FDA is rescinding the November 6, 2002, order.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (section 306 (21 U.S.C. 335a)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.34).

Dated: January 2, 2003.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 03–1020 Filed 1–15–03; 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; Guidance on Q1D Bracketing and Matrixing Designs for 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 guidance entitled ''Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This guidance is an annex to an ICH guidance entitled ''Q1A(R) Stability Testing of New Drug Substances and Products'' (66 FR 56332, November 7, 2001). It 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: The guidance is effective January 16, 2003. 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), Food and Drug Administration, 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance 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*. Requests and comments should be identified with the docket number found in brackets in the heading of this 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, Rockville, MD 20852–1448, 301–402–4635.

Regarding the ICH: Janet Showalter, Office of International Programs (HFG–1), 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, Health Canada's Health Products and Food 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, we 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 **ADDRESSES**). Draft guidances are left in the original ICH format. The final guidance is reformatted to conform to the GGP style before publication.

In the **Federal Register** of September 25, 2001 (66 FR 49029), FDA published a draft tripartite guidance entitled ''Q1D Bracketing and Matrixing Designs for Stability Testing of Drug Substances and Drug Products.'' The notice gave interested persons an opportunity to submit comments by November 26, 2001. 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 regulatory agencies on February 7, 2002.

This guidance is an annex to an ICH guidance entitled ''Q1A(R) Stability Testing of New Drug Substances and Products'' (66 FR 56332). It is intended to provide guidance on the application of bracketing and matrixing for stability studies conducted in accordance with the principles outlined in Q1A(R).

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 ICH Q1D guidance is intended to provide guidance on bracketing and matrixing designs. Specific principles are defined in this guidance for situations in which bracketing or matrixing can be applied and where bracketing or matrixing can be applied if additional justification is provided. Design factors and other considerations are presented, and potential risks of using reduced designs are discussed. Sample designs are also provided for illustrative purposes.

This 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 statues and regulations.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (see **ADDRESSES**) written comments on the guidance. 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 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*, *http://www.fda.gov/cber/publications.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: January 8, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–904 Filed 1–15–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0492]

Draft Guidance for Industry and Reviewers on Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and reviewers entitled ''Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers.'' This draft guidance outlines a common process (algorithm) and terminology for deriving a maximum recommended starting dose for ''first in human'' clinical trials of new molecular entities in adult healthy volunteers. Described in the guidance is a method for using nonclinical data to select a maximum starting dose in adult humans that is not expected to result in significant toxicity. The goal is to ensure the safety of adult human volunteers in initial clinical trials.

DATES: Submit written or electronic comments on the draft guidance by March 17, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft 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. Send two self-addressed adhesive labels to assist that 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.