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