The undersigned approve the terms and conditions of this MOU and represent that they have the requisite authority to enter into it.

Douglas M. Browning, Deputy Commissioner
United States Customs and Border Protection
Department of Homeland Security

Date: 12/3/03

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs
Department of Health and Human Services

Date: Dec 3 2003

[FR Doc. 04–260 Filed 1–6–04; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0571]

Draft Guidance for Industry on Drug Substance; Chemistry, Manufacturing, and Controls Information; Availability

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Drug Substance: Chemistry, Manufacturing, and Controls Information.'' This draft guidance provides recommendations on the chemistry, manufacturing, and controls (CMC) information for drug substances that should be submitted to support original new drug applications (NDAs), abbreviated new drug applications (ANDAs), new animal drug applications (NADAs), and abbreviated new animal drug applications (ANADAs). The draft guidance is structured to facilitate the preparation of applications submitted in Common Technical Document (CTD) format.

DATES: Submit written or electronic comments on the draft guidance by July 5, 2004. 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:

Steve Miller, Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2392, or

Chris Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–435–5681, or

Dennis Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Drug Substance: Chemistry, Manufacturing, and Controls Information.'' This draft guidance provides recommendations on the drug substance information to be submitted in NDAs, ANDAs, NADAs, and ANADAs to ensure continued drug substance and drug product quality (i.e., the identity, strength, quality, purity, and potency). Recommendations are provided on the information that should be included for: (1) Nomenclature, structure, and general drug substance properties, (2) manufacture, (3) characterization, (4) control of drug substance, (5) reference standards or materials, (6) container closure system, and (7) stability. The draft guidance is structured to facilitate the preparation of applications submitted in CTD format. The draft guidance, when finalized, will replace the guidance entitled ''Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substance'' (February 1987).

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control numbers 0910–0001 and 0910–0032.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the

agency's current thinking on these topics. 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft 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 draft guidance and received comments are available for public examination in the Division of Dockets Management 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/ohrms/dockets/default.htm*.

Dated: December 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–259 Filed 1–6–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2002N–0276 and 2002N–0278]

Small Entity Compliance Guides on Registration of Food Facilities and Prior Notice of Imported Food; Correction.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of December 12, 2003 (68 FR 69408). This document is being republished in its entirety and will read as follows: The Food and Drug Administration (FDA) is announcing the availability of small entity compliance guides (SECGs) for the interim final rules on Registration of Food Facilities and Prior Notice of Imported Food issued under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). Both interim final rules published in the **Federal Register** of October 10, 2003. These SECGs are intended to help small businesses better understand the registration and prior notice regulations.

DATES: Submit written or electronic comments on the SECGs at any time.

ADDRESSES: Submit written comments concerning these SECGs to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the SECGs to *http://www.fda.gov/dockets/ecomments*.

Submit requests for single copies of one or both SECGs to the Prior Notice help desk by telephone at 1–800–216–7331 (within the United States) or 301–575–0156 (outside the United States), by FAX: 301–210–0247, or by e-mail: furls@fda.gov. See the **SUPPLEMENTARY INFORMATION** section for electronic access to these SECGs.

FOR FURTHER INFORMATION CONTACT: Questions Concerning Registration: Nina Adler, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0417, FAX 301–827–0482; or Judith Gushee, Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD, 20740, 301–436–2417.

Questions Concerning Prior Notice: Deborah Ralston, Office of Regulatory Affairs, Office of Regional Operations (HFC–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6230.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 10, 2003 (68 FR 58894 and 68 FR 58974), FDA issued two interim final rules to implement sections 305 (Registration of Food Facilities) and 307 (Prior Notice of Imported Food) of the Bioterrorism Act. The registration interim final rule requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. The prior notice interim final rule requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States beginning on December 12, 2003.

We examined the economic implications of these interim rules as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and determined that they would have a significant economic impact on a substantial number of small entities.

In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121), we are making available these SECGs that explain the requirements of these regulations.

FDA is issuing these SECGs as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). These SECGs restate, in simplified format and language, FDA's current requirements for Registration of Food Facilities and Prior Notice of Imported Food. As guidance, these documents are not binding on either FDA or the public. FDA notes, however, that the regulations that serve as the basis for these guidance documents establish requirements for all covered activities. For this reason, FDA strongly recommends that affected parties consult the regulations at 21 CFR part 1, subparts H and I, in addition to reading these SECGs.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding these SECGs. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the applicable docket number(s) found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain these SECGs at *http://www/cfsan.fda.gov/guidance.html*.

Dated: December 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–257 Filed 1–6–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Secretary's Advisory Committee on Xenotransplantation (SACX).