TITLE/TOPIC OF GUIDANCE	CONTACT
Personal Importation of and Use of Drug Products Not Approved in the United States	Do
Investigational Use of Marketed Drugs, Biologics, and Medical Devices	Do
Emergency Use: Exceptions From the Requirements for Institutional Review Board (IRB) Review and Informed Consent	Do
Emergency Use of an Investigational Drug or Biologic Under 21 CFR Part 312	Do
Expanded Access of Investigational Drugs	Do
Waiver of Institutional Review Board Requirements for Drug and Biologic Studies	Do
Drug Study Designs	Do
Evaluation of Gender Differences in Clinical Investigations	Do
Medical Devices 21 CFR Part 812	Do
Significant Risk and Nonsignificant Risk Medical Device Studies	Do
Emergency Use of Unapproved Medical Devices	Do
FDA Institutional Review Board Inspections	Do
Clinical Investigator Regulatory Sanctions	Do
Recordkeeping in Clinical Investigations	Do
Significant Differences in FDA's and the Department of Health and Human Services' Regulations	Do
A Self-Evaluation Checklist for Institutional Review Boards	Do
VII. OFFICE OF REGULATORY AFFAIRS (ORA)	
INSPECTION GUIDES	
Techniques for Detecting False Data During Bioresearch Monitoring Inspections	Gerald Miller, Division of Field Investigations (HFC–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5655
Guide to Inspections of Bulk Pharmaceutical Chemicals	Do
Guide to International Inspections and Travel	Rebecca Hackett, Division of Field Investigations, (HFC–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20857, 301–827–3777
Guide to Produce Farm Investigations	Ellen Morrison, Emergency Operations (HFC–160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5660

Dated: March 28, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–8262 Filed 4–3–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0093]

Small Entity Compliance Guide: ''Juice HACCP''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide (SECG) for a final rule published in the **Federal Register** of January 19, 2001, entitled ''Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice.'' This SECG, entitled ''Juice HACCP,'' is intended to set forth in plain language the requirements of that final rule and to help small businesses understand the regulation.

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

ADDRESSES: Submit written comments concerning this SECG 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.* Submit written requests for single copies of the SECG to Amy Green, Center for Food Safety and Applied Nutrition (CFSAN) (see **FOR FURTHER INFORMATION CONTACT**). Send one self-adhesive address label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Amy Green, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2025, FAX 301–436–2651.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 19, 2001 (66 FR 6138), FDA issued a final rule to ensure the safe and sanitary processing of fruit and vegetable juices. The regulations in part 120 (21 CFR part 120) mandate the application of HACCP principles to the processing of these foods. HACCP is a preventive system of hazard control. The effective dates of the final rule are staggered and based on the size of the business. For very small businesses (as defined in § 120.1(b)(1), the effective date is January 20, 2004. For small businesses, the effective date was January 21, 2003, and for all other size businesses the effective date was January 22, 2002.

FDA examined the economic implications of that final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–602). The agency determined that the final rule 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), FDA is making available this SECG stating in plain language the requirements of the juice HAACP regulations.

FDA is issuing this SECG as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the agency's current thinking on the subject. 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 (see **ADDRESSES**) written or electronic comments on the SECG entitled ''Juice HACCP.'' Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of SECG and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

The SECG also may be viewed on a personal computer with access to the Internet at *http://www.cfsan.fda.gov/guidance.html.*

Dated: March 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–8263 Filed 4–3–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1662]

''Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans'' dated April 2003. The document provides guidance on the production, testing, and evaluation of products intended for use in xenotransplantation. The guidance announced in this notice finalizes the draft guidance document of the same title dated February 2001.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written or electronic requests for single copies of this guidance to 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. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document 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.*

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans'' dated April 2003. The document provides guidance on the production, testing, and evaluation of products intended for use in xenotransplantation. The guidance document announced in this notice was revised based on public comments received on the draft guidance, and it finalizes the draft document of the same title dated February 2001 (66 FR 9348, February 7, 2001).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments to the Dockets Management Branch (see **ADDRESSES**) regarding this guidance document. Two copies of any mailed comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in