

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.

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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