V. Comments

Written comments regarding the agenda may be submitted and should be identified with the docket number found in brackets in the heading of this document. Comments should be annotated and organized to identify the specific issues to which they refer. These comments should be submitted by October 1, 2002, to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments may also be sent to the Dockets Management Branch via e-mail to fdadockets@oc.fda.gov or via the FDA Web site http://www.fda.gov.

Transcripts: An electronic transcript of this meeting will be prepared and may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20852, approximately 15 working days after the meeting at a cost of $18.25. The transcript of the meeting will also be available for public examination as soon as possible after the meeting, at the Dockets Management Branch (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA Office of Food Additive Safety Web site at http://www.cfsan.fda.gov/lrd/foodadd.html.

Dated: September 12, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–23690 Filed 9–17–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0402]

Guidance for Food and Drug Administration Field Offices on ''Regulatory Procedures Manual, Chapter 9, Subchapter, 'Import for Export'''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for FDA Field Offices entitled ''Regulatory Procedures Manual, Chapter 9, Subchapter, 'Import for Export'.'' This final guidance is a revision of the FDA Office of Regulatory Affairs' Regulatory Procedures Manual, Chapter 9, ''Import Operations/Actions,'' Subchapter, ''Import for Export,'' to provide guidance to the FDA Field Offices regarding the handling of products offered for import into the United States under section 801(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act). The revision is necessary because of the enactment of section 322 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107–188, signed into law on June 12, 2002. Section 322 amends section 801(d)(3) of the act and is effective September 9, 2002.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Import Operations and Policy (HFC–170), Office of Regulatory Affairs, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Joseph McCallion, Office of Regulatory Affairs (HFC–170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6553.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for FDA Field Offices entitled ''Regulatory Procedures Manual, Chapter 9, Subchapter, 'Import for Export'.''

Section 322 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107–188, signed into law on June 12, 2002, amended section 801(d)(3) of the act (21 U.S.C. 381). The amended provision requires submission of certain information when certain articles are offered for import into the United States. The amended provision is effective September 9, 2002.

The final guidance covers the scope of articles that can be offered under section 801(d)(3) of the act and the information required by the statutory provision to be submitted when certain articles are offered as ''import for export.'' The final guidance provides examples of documentation that will assist the FDA field offices in making a determination that the appropriate statements and information have been submitted and whether the entry should be allowed as an ''import for export'' or refused admission. The final guidance also provides information on the meaning of the terms ''further processing'' and ''incorporated'' to be used by the FDA field offices in making determinations on the entry of products. Direction on internal agency procedures for processing ''import for export'' entries is included in the final guidance.

This final guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). It is being implemented immediately without prior public comment, under § 10.115(g)(2), because of the agency's urgent need to provide guidance on the implementation of section 322 of the Bioterrorism Act, which is effective September 9, 2002, only 90 days after the statute's enactment. However, pursuant to GGPs, FDA requests comments on the guidance and will revise the document, if appropriate. The guidance represents the agency's current thinking on ''Regulatory Procedures Manual, Chapter 9, Subchapter, 'Import for Export''' and is intended to provide uniform procedures for handling such importations by all FDA Field Offices. 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 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 either http://www.fda.gov/ora/compliance_ref/rpm_new2/ or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: September 6, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–23759 Filed 9–13–02; 4:27 pm]

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