Respondents	No. of respondents	No. of responses/ respondents	Avg. burden per response (in hours)
Workers (Data Collection #1)	1000	1	20/60
Workers (Data Collection #2)	3000	1	15/60

Dated: September 12, 2002.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 02–23681 Filed 9–17–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0403]

Premarket Notification for Food Contact Substances; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting entitled ''FDA Workshop on the Notification Process for Food Contact Substances.'' The purpose of the meeting is to discuss the food contact notification (FCN) process so that notifiers and/or their representatives, consumer interest groups, and other interested members of the general public can have a better understanding of the FCN process, the information requirements of an FCN, and the common deficiencies to be avoided.

Date and Time: The meeting will be held on Tuesday, October 15, 2002, from 8 a.m. to 5 p.m.

Location: The meeting will be held on the campus of the National Institutes of Health (NIH) in the Lister Hill Center Auditorium, Bldg. 38A, National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894. The NIH campus is accessible by the Washington, DC area Metrorail system using the Medical Center station. Attendees must bring photo identification to gain admittance.

Contact: William J. Trotter, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3088, FAX 202–418–3131, or e-mail: wjt@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In November 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA) of 1997. Section 309 of FDAMA amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to establish a notification process for food contact substances (FCSs). An FCS is defined as any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in such food (21 U.S.C. 348(h)(6)). Congress intended the notification process to be the primary route for authorizing the use of FCSs (21 U.S.C. 348(h)(3)(A)).

Under section 409(h) of the act, the notification process requires a manufacturer or supplier of an FCS to notify FDA at least 120 days prior to marketing an FCS for a new use. If FDA does not object to the notification within 120 days, the notification becomes effective (21 U.S.C. 348(h)(2)(A)) and the substance may be legally marketed for the requested use by the notifier (21 U.S.C. 348(a)(3)(B)).

In the **Federal Register** of May 21, 2002 (67 FR 35724), FDA published a final rule amending the food additive regulations regarding the premarket notification process for FCSs. The rule became effective on June 20, 2002, and required that a notification for an FCS must contain sufficient scientific information to demonstrate that the FCS that is the subject of the notification is safe for the intended use (21 U.S.C. 348(h)(1)). Since the inception of the FCN process in 1999, FDA has observed that FCNs frequently have deficiencies such that the FCNs are not complete. FDA is having this public meeting to discuss the data requirements for an FCN and the commonly observed deficiencies, and to assist notifiers and/or their representatives in submitting adequate and complete FCNs.

II. Registration and Written Questions

Persons interested in attending the October 15, 2002, meeting should send their registration information (including name, title, business affiliation, address, and telephone and fax numbers) and any questions they wish to have answered at the meeting to the contact person. To expedite processing, fax registration information to 202–418–3131 or e-mail: wjt@cfsan.fda.gov. There will be no registration charges for attending the meeting.

If you need special accommodations due to disability, please notify the contact person by October 1, 2002.

III. Availability of Guidance Documents for FCNs

Administrative, chemistry, and toxicology guidance documents for FCNs are available at http://www.cfsan.fda.gov/dms/opa-notf.html.

IV. Agenda and Goals

FDA will present what information the agency requires in an FCN to make it adequate and complete. Topics to be presented will be broadly divided among the general categories of administrative, chemical, toxicological, and environmental. There will also be workshops in which questions from the audience will be encouraged. The issues to be discussed include the following:

1. Administrative: Guidance document, number of copies of the FCN to submit and where to submit the FCN, common FCN deficiencies, Form 3480, confidentiality, one FCS per FCN, and conditions under which a food additive petition should be submitted;

2. Chemical: Guidance document, common FCN deficiencies, approaches for determining migrant levels in food, estimated daily intake, and cumulative estimated daily intake;

3. Toxicological: Guidance document, common FCN deficiencies, acceptable daily intake, risk assessments, structure activity relationships, and genetic toxicology; and

4. Environmental: Guidance document, common FCN deficiencies, the National Environmental Policy Act as applied to the notification process, categorical exclusions, and requirements for an environmental assessment.

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]

BILLING CODE 4160–01–S