DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0522]

Draft Guidance for Industry and Food and Drug Administration Staff; Premarket Submissions and Labeling Recommendations for Drugs of Abuse Screening Tests; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Draft Guidance for Industry and FDA Staff; Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests.'' This draft guidance is intended to assist industry in preparing premarket notification submissions for drugs of abuse screening tests. The draft guidance also provides recommendations regarding the labeling of these tests. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this guidance by March 1, 2004.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Draft Guidance for Industry and FDA Staff; Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jean Cooper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850 301–594–1243

SUPPLEMENTARY INFORMATION:

I. Background

On November 14, 2000, FDA issued two draft guidance documents entitled ''Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications'' and ''Guidance for Prescription Use Drugs of Abuse Assays Premarket Notifications'' (docket nos. 1999D–1020 and 2000D–1587). This draft guidance replaces those documents and is intended to address concerns about those documents, including concerns regarding a recommendation that the cost of confirmatory testing be bundled with the cost of screening tests. Among other changes, the draft guidance FDA is issuing today recognizes that measures other than bundling the cost of confirmatory testing may help mitigate the risk of inaccurate results. The new draft guidance also clarifies that premarket submissions for drugs of abuse screening tests used in workplace and other repetitive testing sites may not require the same types of data as submissions for screening tests that are intended for sale directly to untrained users. The draft guidance is intended to assist manufacturers in preparing premarket submissions for drugs of abuse tests used in any setting, including hospital, workplace, sports, insurance, and home settings. The draft guidance also provides recommendations on labeling drugs of abuse screening tests.

II. Significance of Guidance

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 premarket submissions and labeling of drugs of abuse screening tests. 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 statute and regulations.

III. Electronic Access

To receive ''Draft Guidance for Industry and FDA Staff; Premarket Submissions and Labeling Recommendations for Drugs of Abuse Screening Tests'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (152) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

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 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E) (OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document at any time. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed comments, 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. Comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 13, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–29855 Filed 12–01–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999N–1168]

Listeria Monocytogenes Risk Management Action Plan; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) is announcing the availability of a *Listeria monocytogenes* risk management action plan. The action plan identifies activities planned by FDA and the Centers for Disease Control and Prevention (CDC) that are targeted to reduce *L. monocytogenes* associated with illnesses; these activities are intended to help achieve the Healthy People 2010 goal of reducing listeriosis by 50 percent by the year 2005.

ADDRESSES: Submit written requests for single copies of the risk management action plan entitled ''Reducing the Risk of *Listeria Monocytogenes* FDA/CDC 2003 Update of the Listeria Action Plan'' to John Kvenberg, Center for Food Safety and Applied Nutrition (CFSAN) (see **FOR FURTHER INFORMATION CONTACT**). Send one self-adhesive label with your address to assist that office in processing your request. You also may request a copy of the risk management action plan by faxing your name and mailing address with the name of the document you are requesting to the CFSAN Outreach and Information Center at 1–877–366–3322. See the **SUPPLEMENTARY INFORMATION** section for electronic access to these documents.

FOR FURTHER INFORMATION CONTACT: John Kvenberg, Center for Food Safety and Applied Nutrition (HFS–600), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD, 20740, 301–436–2359.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 19, 2001 (67 FR 5515), FDA, in cooperation with the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture and in consultation with CDC of HHS, announced the availability of two documents on these topics: (1) A draft risk assessment on the relationship between foodborne *L. monocytogenes* and human health that considers categories of ready-to-eat food and (2) a proposed risk management action plan that considered the draft *L. monocytogenes* risk assessment. The action plan articulated how FDA, FSIS, and CDC intended to achieve the Healthy People 2010 goal of reducing *L. monocytogenes* illness by 50 percent. FDA, FSIS, and CDC held a public meeting on March 19, 2001 (66 FR 13544), to receive comments on the technical aspects of the draft risk assessment and the draft action plan. Interested persons were given until March 20, 2001, with extensions to May 21, 2001, and to July 18, 2001, to comment on the documents. The risk assessment has been revised in response to the public comments, newly available data, and updated modeling techniques; and it was made available to the public on October 24, 2003 (68 FR 61006).

II. Risk Management Action Plan

The updated risk management action plan outlines the actions that FDA and CDC plan to undertake to reduce *L. monocytogenes* illness from ready-to-eat foods. These planned actions are structured according to the food categories used in the risk assessment as either warranting additional measures to reduce *L. monocytogenes* contamination or warranting collection of additional data.

The action plan contains these six action areas:

- Guidance for processors, retailers, food service operations, and institutional establishments;
- Training and technical assistance;
- Consumer and health care provider information and education;
- Enforcement and regulatory strategies;
- Disease surveillance and outbreak response; and
- Research needs.

A public meeting to present the revised risk assessment and the action plan has been scheduled for December 4, 2003, from 8:30 a.m. to 5 p.m. (see 68 FR 63108 for details). The meeting will be held at the FDA/CFSAN Harvey W. Wiley Building, 5100 Paint Branch Pkwy., College Park, MD 20740.

III. Review of Document

The risk management action plan may be reviewed at the FDA Division of Dockets Management (Docket No. 1999N–1168), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

The risk management action plan is available electronically at *http://www.cfsan.fda.gov* and *www.foodsafety.gov.*

Dated: November 26, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–30025 Filed 11–28–03; 9:19 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Statement of Organization, Functions, and Delegations of Authority

Part M of the Substance Abuse and Mental Health Services Administration (SAMHSA) Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services as amended most recently at 68 FR 45264, August 1, 2003, is amended to: revise the functional statements for the Office of the Administrator (OA); and the Office of Policy, Planning and Budget (OPPB) within the Office of the Administrator, and reflect changes in the Division structure within OPPB; and to also revise the functional statements for the Office of Program Services (OPS), and reflect changes in the Division structure within OPS. These organizational changes will more effectively align budget, planning, and administrative functions; achieve further delayering by restructuring certain divisions, abolishing subordinate branch structures, and reducing the number of supervisory positions; and allow SAMHSA to more effectively use its resources and deploy additional positions to mission support activities. The changes are as follows:

Section M.20, Functions is amended as follows:

(A) The functional statements for the Office of the Administrator (MA), the Office of Policy, Planning and Budget (MAC) and the prior Division of Policy Coordination (MAC–1) and Division of Planning and Budget (MAC–2) are replaced with the following:

Office of the Administrator (MA)

The Administrator is responsible to the Secretary for managing and directing SAMHSA. The office functions are as follows: (1) Provides leadership in the development of agency policies and programs; (2) maintains liaison with the Office of the Secretary on matters related to program and other activities;