

Dated: January 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-1576 Filed 1-31-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

University of Arkansas/Food and Drug Administration Food Labeling Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs, Southwest Regional Small Business Representative (SWR SBR) Program, in collaboration with The University of Arkansas (UA), is announcing a public workshop entitled "UA/FDA Food Labeling Workshop." This public workshop is intended to

provide information about FDA food labeling regulations and other related subjects to the regulated industry, particularly small businesses and startups.

Date and Time: This public workshop will be held on April 10, 2007, from 8 a.m. to 5 p.m., and on April 11, 2007, from 8 a.m. to 4 p.m.

Location: The public workshop will be held at the Continuing Education Center, 2 East Center St., Fayetteville, AR (located downtown).

Contact: David Arvelo, Small Business Representative, Food and Drug Administration, Southwest Regional Office, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214-253-4952, FAX: 214-253-4970, or e-mail: david.arvelo@fda.hhs.gov.

For information on accommodation options, contact Steven C. Seideman, 2650 North Young Ave., Institute of Food Science & Engineering, University of Arkansas, Fayetteville, AR 72704, 479-575-4221, FAX: 479-575-2165, or e-mail: seideman@uark.edu.

Registration: You are encouraged to register by March 23, 2007. The

University of Arkansas has a \$150 registration fee to cover the cost of facilities, materials, speakers, and breaks. Seats are limited; please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is \$200 payable to: "The University of Arkansas." If you need special accommodations due to a disability, please contact Steven C. Seideman (see *Contact*) at least 7 days in advance.

Registration Form Instructions: To register, please complete the following form and submit along with a check or money order for \$150 payable to the "The University of Arkansas." Mail to: Institute of Food Science & Engineering, University of Arkansas, 2650 North Young Ave., Fayetteville, AR 72704.

UNIVERSITY OF ARKANSAS/FOOD AND DRUG ADMINISTRATION FOOD LABELING WORKSHOP REGISTRATION FORM

Name: _____

Affiliation: _____

Mailing Address: _____

City/State/Zip Code: _____

Phone: _____

Fax: _____

E-mail: _____

Special Accommodations Required: _____

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested at cost through the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: This public workshop is being held in response to the large volume of food labeling inquiries from small food manufacturers and startups originating

from the area covered by the FDA Dallas District Office. The SWR SBR presents these workshops to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is consistent with the purposes of the SBR Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses,

with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), as outreach activities by government agencies to small businesses.

The goal of this public workshop is to present information that will enable manufacturers and regulated industry to better comply with labeling requirements, especially in light of growing concerns about obesity and food allergens. Information presented will be based on agency position as

articulated through regulation, compliance policy guides, and information previously made available to the public. Topics to be discussed at the workshop include: (1) Mandatory label elements, (2) nutrition labeling requirements, (3) health and nutrition claims, (4) the Food Allergen Labeling and Consumer Protection Act of 2004, and (5) special labeling issues such as exemptions. FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the regulatory and policy perspectives on food labeling and increase voluntary compliance.

Dated: January 25, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0025]

Guidance for Industry; Class II Special Controls Guidance Document: Cord Blood Processing System and Storage Container; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Class II Special Controls Guidance Document: Cord Blood Processing System and Storage Container." The guidance document describes a means by which a cord blood processing system and storage container may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying a cord blood processing system and storage container into class II (special controls). This guidance document is immediately in effect as the special control for this device, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written 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, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the 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>.

FOR FURTHER INFORMATION CONTACT:

Denise Sanchez, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying a cord blood processing system and storage container into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This notice announces the availability of the guidance document that will serve as the special control for this device.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device into class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device.

Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such a classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible or appropriate to allow for public participation before issuing this guidance as a final guidance document. Thus, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect.

FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of the Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the agency's current thinking on a cord blood processing system and storage container. 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E (regulations governing premarket notification submissions) have been approved under OMB Control No. 0910-0120.

IV. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments 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 the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: January 24, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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