

electronic comments to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, 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

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc)" dated May 2008. FDA is providing recommendations to establishments that collect human blood or blood components for a requalification method or process for the reentry of deferred donors into the donor pool based on a determination that previous tests that were repeatedly reactive for anti-HBc were falsely positive and that there is no evidence of infection with HBV. Due to the availability of this licensed HBV nucleic acid test and the improved specificity of anti-HBc assays, we are recommending a reentry algorithm for donors deferred due to a falsely positive repeatedly reactive test for anti-HBc in this guidance. Until now FDA has not recommended a requalification method or process for reentry of donors deferred due to reactive test results for hepatitis B core antigen (anti-HBc) due to the lack of licensed tests that could be recommended for use in a suitable algorithm for this purpose.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance.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 A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

III. Electronic Access

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

Dated: May 12, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-F-0290]

**Lubrizol Advanced Materials, Inc.;
Filing of Food Additive Petition**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Lubrizol Advanced Materials, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of cassia gum as a stabilizer in frozen dairy desserts, and to improve texture and water retention in cheeses, meat products, and poultry products.

FOR FURTHER INFORMATION CONTACT: Raphael A. Davy, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740-3835, 301-436-1272.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8A4772) has been filed by Lubrizol Advanced Materials, Inc., c/o Keller & Heckman LLP, 1001 G St., NW., suite 500 West, Washington, DC 20001.

The petition proposes to amend the food additive regulations in part 172, Food Additives Permitted for Direct Addition to Food for Human Consumption (21 CFR part 172) to provide for the safe use of cassia gum as a stabilizer in frozen dairy desserts, and to improve texture and water retention in cheeses, meat products, and poultry products.

The agency has determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: May 13, 2008.

Laura M. Tarantino,

*Director, Office of Food Additive Safety,
Center for Food Safety and Applied Nutrition.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

**Request for Public Comment: 60-Day
Proposed Information Collection:
Indian Health Service Loan Repayment
Program**

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, which requires 60 days for public comment on proposed information collection projects, the Indian Health Service (IHS) is publishing for comment a summary of a proposed information collection to be submitted to the Office of Management and Budget (OMB) for review.

Proposed Collection: Title: 0917-0014, "Indian Health Service Loan Repayment Program." *Type of Information Collection Request:* Extension, without revision, of currently approved information collection, 0917-0014, "Indian Health Service Loan Repayment Program." *Form(s):* The IHS Loan Repayment Program Information Booklet contains the instructions and the application formats. *Need and Use of Information Collection:* The IHS Loan Repayment Program (LRP) identifies health professionals with pre-existing financial obligations for education expenses that meet program criteria and who are qualified and willing to serve at, often remote, IHS health care facilities. Under the program, eligible health professionals sign a contract under which the IHS agrees to repay