DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 170

[Docket No. 2001N–0234]

Food Additives: Food Contact Substance Notification System; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of our advance notice of proposed rulemaking (ANPRM) published in the **Federal Register** of May 21, 2002 (67 FR 35764). The ANPRM requested input on whether the agency should establish regulations permitting the licensing of the rights to manufacture and market a food contact substance (FCS) for a use that is the subject of an effective food contact notification (FCN). FDA is withdrawing the ANPRM based upon comments indicating that such a regulation would not be necessary.

DATES: The advance notice of proposed rulemaking is withdrawn September 30, 2004.

FOR FURTHER INFORMATION CONTACT: Kenneth McAdams, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3392, e-mail: *kenneth.mcadams@cfsan.fda.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 21, 2002 (67 FR 35764), FDA published an ANPRM requesting input on whether the agency should establish regulations permitting the licensing of the rights to manufacture and market an FCS for a use that is the subject of an effective FCN. We received five comments on the ANPRM. Three of the comments, from individuals, concerned unrelated issues and did not address the ANPRM. The other two comments, from the American Plastics Council and the Society of the Plastics Industry, stated that a procedure to transfer or license the rights to an FCN is not needed because of the speed and efficiency of the current FCN system. Both comments also stated that if regulations for such a procedure are issued, they should be kept simple, requiring only notification that the transfer has occurred.

After careful consideration of these comments, FDA has concluded that a procedural regulation for transferring or licensing the rights to an FCN is not needed. Therefore, FDA is withdrawing our ANPRM.

Dated: September 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2003P–0564]

Microbiology Devices; Reclassification of Hepatitis A Virus (HAV) Serological Assays (IgM Antibody, IgG Antibody and Total Antibodies (IgM and IgG))

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify hepatitis A virus (HAV) serological assays from Class III (premarket approval) to class II (special controls). These devices are used for testing specimens from individuals who have signs and symptoms consistent with acute hepatitis A or for determining if an individual has been previously infected with HAV. The detection of these antibodies aids in the clinical laboratory diagnosis of an acute or past infection by HAV in conjunction with other clinical laboratory findings. FDA is proposing this action after reviewing a reclassification petition submitted by Beckman Coulter, Inc. The agency is taking this action under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a class II special controls draft guidance entitled ''Class II Special Controls Guidance Document: Hepatitis A Serological Assays for the Clinical Laboratory Diagnosis of Hepatitis A Virus.''

DATES: Submit written or electronic comments by December 29, 2004. See section VIII of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: Submit written comments 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: Sally Hojvat, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–2096.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The act, as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629), and FDAMA (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices generally remain in class III until the device is reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a legally marketed device. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without