FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 17, 2003.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. Community State Bank Employee Stock ownership Plan & Trust, Union Grove, Wisconsin; to become a bank holding company through the retention of at least 29.59 percent, of the voting shares of Union Bancorporation, Inc., Union Grove, Wisconsin, and thereby indirectly acquire Community State Bank, Union Grove, Wisconsin.

Board of Governors of the Federal Reserve System, June 17, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–15730 Filed 6–20–03; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0222]

Agency Information Collection Activities; Proposed Collection; Comment Request; Product Jurisdiction; Assignment of Agency Component for Review of Premarket Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the procedure by which an applicant may obtain an assignment or designation determination.

DATES: Submit written or electronic comments on the collection of information by August 22, 2003.

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*. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Product Jurisdiction; Assignment of Agency Component for Review of Premarket Applications

This regulation relates to agency management and organization and has two purposes. The first is to implement section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)), as added by the Safe Medical Devices Act of 1990 (Public Law 101–629), and amended by the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), by specifying how FDA will determine the organizational component within FDA assigned to have primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of: (1) A drug and a device; (2) a device and a biological; (3) a biological and a drug; or (4) a drug, a device, and a biological. The second purpose of this regulation is to enhance the efficiency of agency management and operations by providing procedures for classifying and determining which agency component is designated to have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute.

The regulation establishes a procedure by which an applicant may obtain an assignment or designation determination. The regulation requires that the request include the identity of the applicant, a comprehensive description of the product and its proposed use, and the applicant's recommendation as to which agency component should have primary jurisdiction, with an accompanying statement of reasons. The information submitted would be used by FDA as one

of the bases for making the assignment or designation decision. Most information required by the proposed regulation is already required for premarket applications affecting drugs, devices, biological and combination products. The respondents will be businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3	28	1	28	24	672

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 16, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–15699 Filed 6–20–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0226]

Draft Guidance for Industry and FDA Staff; Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002—Identification of Manufacturer of Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled ''Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002—Identification of Manufacturer of Medical Devices.'' Section 301 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) requires that a device, or an attachment to the device, bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol that identifies the manufacturer. Section 301 becomes effective on April 26, 2004, for devices introduced or delivered for introduction into interstate commerce after that date. This draft guidance provides that the agency, in the exercise of enforcement discretion, does not intend to object if a manufacturer has not yet fully implemented the changes required by section 301 of MDUFMA for devices introduced or delivered for introduction into interstate commerce after April 26, 2004, for a period of up to 18 months after FDA issues final guidance on its interpretation and implementation of section 301. This draft guidance is neither final, nor is it in effect at this time.

DATES: Submit written or electronic comments by September 22, 2003.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002—Identification of Manufacturer of Medical Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), 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. Submit written comments concerning this draft 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.* See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Casper E. Uldriks, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4692, or Leonard Wilson, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–827–0799.

SUPPLEMENTARY INFORMATION:

I. Background

MDUFMA (Public Law 107–250) added a provision to the Federal Food, Drug, and Cosmetic Act that requires a device, or an attachment to the device, to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol that identifies the manufacturer. The requirement may be waived based on a determination that compliance is not feasible or would compromise the provision of reasonable assurance of safety and effectiveness for the device. Failure to comply with the new requirement misbrands the device (section 301 of MDUFMA (21 U.S.C. 352(u))). This provision is effective April 26, 2004, with respect to devices introduced or delivered for introduction into interstate commerce after that date.

This draft guidance provides that, in the exercise of enforcement discretion, FDA does not intend to object if a manufacturer has not yet fully implemented the changes required by section 301 of MDUFMA for devices introduced or delivered for introduction into interstate commerce after April 26, 2004, the effective date of the provision, for a period of up to 18 months after FDA issues final guidance on the implementation of section 301.

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, when finalized, will represent the agency's current thinking on the compliance with section 301 of MDUFMA. 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. Comments

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 brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.