

## 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 Web site at [www.ffiec.gov/nic/](http://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 February 24, 2003.

**A. Federal Reserve Bank of Kansas City** (Susan Zubradt, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. *Sundance State Bank Profit Sharing ESOP and Trust*, Sundance Wyoming; to become a bank holding company by acquiring 28 percent of the voting shares of Sundance Bankshares, Inc., and Sundance State Bank, both of Sundance, Wyoming.

Board of Governors of the Federal Reserve System, January 24, 2003.

Jennifer J. Johnson,  
Secretary of the Board.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

#### Proposed Project

Mandatory Guidelines for Federal Workplace Drug Testing Programs (0930-0158, revision)—SAMHSA will request renewal of OMB approval for the Federal Drug Testing Custody and Control Form for Federal agency and federally regulated drug testing programs which must comply with the HHS Mandatory Guidelines for Federal

Workplace Drug Testing Programs (59 FR 29908) dated June 9, 1994, and for the information provided by laboratories for the National Laboratory Certification Program (NLCP).

The Federal Drug Testing Custody and Control Form is used by all Federal agencies and employers regulated by the Department of Transportation to document the collection and chain of custody of urine specimens at the collection site, for laboratories to report results, and for Medical Review Officers to make a determination. The Federal Drug Testing Custody and Control Form approved by OMB three years ago will be submitted for OMB approval without any revision.

Prior to an inspection, a laboratory is required to submit specific information regarding its laboratory procedures. A major change in the submitted information requires a laboratory to provide specific information on its specimen validity testing procedures. Since all certified laboratories are expected to have the capability to conduct specimen validity tests on regulated specimens, collecting this information prior to an inspection allows the inspectors to thoroughly review and understand the laboratory's specimen validity testing procedures before arriving at the laboratory.

The NLCP application form is being revised compared to the previous form. The major change in the NLCP application form includes, where appropriate in each section, a request for specific information on the applicant laboratory's ability to conduct specimen validity testing (*i.e.*, determining if a specimen is adulterated or substituted). Since all certified laboratories are expected to have the capability to conduct specimen validity tests on regulated specimens, it is necessary to ensure that each applicant laboratory has the same capability before being certified.

The annual total burden estimates for the Federal Drug Testing Custody and Control Form, the NLCP application, the NLCP inspection checklist, and NLCP recordkeeping requirements are shown in the following table.

Form/respondent	Burden/response (Hrs.)	Number of responses	Total annual burden (Hrs.)
Custody and Control Form:			
Donor .....	.08	7,096,000	567,680
Collector .....	.07	7,096,000	496,720
Laboratory .....	.05	7,096,000	354,800
Medical Review Officer .....	.05	7,096,000	354,800
Laboratory Application .....	3.00	3	9
Laboratory Inspection Checklist .....	3.00	110	330

Form/respondent	Burden/re- sponse (Hrs.)	Number of responses	Total annual burden (Hrs.)
Laboratory Recordkeeping .....	250.00	55	13,750
Total .....	.....	.....	1,788,089

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16-105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 23, 2003.

**Richard Kopanda,**

*Executive Officer, SAMHSA.*

[FR Doc. 03-2154 Filed 1-29-03; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 02P-0494]

#### Medical Devices; Exemptions From Premarket Notification; Class II Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that it has received a petition requesting exemption from the premarket notification requirements for a data acquisition unit for ceramic dental restoration systems. FDA is publishing this notice in order to obtain comments on this petition in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

**DATES:** Submit written or electronic comments by March 3, 2003.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (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:** Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act)

(21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), as amended by the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101-629), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification report containing information that allows FDA to determine whether the new device is "substantially equivalent" within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105-115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

##### II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in a guidance the agency issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff." That guidance can be obtained through the Internet on the CDRH home page at <http://www.fda.gov/cdrh> or by facsimile through CDRH Facts-on-Demand at 1-800-899-0381 or 301-827-0111. Specify "159" when prompted for the document shelf number.