

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 August 3, 2001.

A. Federal Reserve Bank of Minneapolis (JoAnne F. Lewellen, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. *Douglas County Bancshares, Inc.*, Alexandria, Minnesota; to become a bank holding company by acquiring 100 percent of the voting shares of Neighborhood National Bank, Alexandria, Minnesota.

Board of Governors of the Federal Reserve System, July 5, 2001.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 01-17263 Filed 7-10-01; 8:45 am]

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FEDERAL RESERVE SYSTEM

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

This notice corrects a notice (FR Doc. 01-15731) published on page 33543 of the issue for Friday, June 22, 2001.

Under the Federal Reserve Bank of Minneapolis heading, the entry for First Western Bancorp., Inc., Huron, South Dakota, is revised to read as follows:

A. Federal Reserve Bank of Minneapolis (JoAnne F. Lewellen, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. *First Western Bancorp, Inc.*, Huron, South Dakota; to acquire 74.8 percent of the voting shares American Bank Shares, Inc., Rapid City, South Dakota, and thereby indirectly acquire American State Bank of Rapid City, Rapid City, South Dakota.

Comments on this application must be received by July 19, 2001.

Board of Governors of the Federal Reserve System, July 5, 2001.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 01-17264 Filed 7-10-01; 8:45 am]

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GENERAL ACCOUNTING OFFICE

Commercial Activities Panel Hearings

AGENCY: General Accounting Office.

ACTION: Notice of public hearings.

SUMMARY: Section 832 of the National Defense Authorization Act for Fiscal Year 2001 requires the Comptroller General of the United States to convene a panel of experts to study the transfer of commercial activities currently performed by government employees to federal contractors, a procedure commonly known as "contracting out" or "outsourcing." This notice announces two public hearings to be held by the Commercial Activities Panel ("the Panel").

DATES: The Commercial Activities Panel will hold a public hearing in Indianapolis, Indiana, on August 8, 2001, beginning at 8:30 a.m. in the University Place Conference Center and Hotel at Indiana University-Purdue University Indianapolis. Another hearing will be held on August 15 beginning at 8:30 a.m. in the Fiesta Ballroom of the Lackland Gateway Club at Lackland Air Force Base in San Antonio, Texas. Individuals or groups wishing to attend or participate in either of the hearings should notify the Panel and submit written summaries of their statements by July 25 for the Indianapolis hearing and by August 1 for the San Antonio hearing.

ADDRESSES: Submit requests to attend or participate in the hearings, written summaries of oral statements, and any other relevant materials via E-mail to A76panel@gao.gov.

FOR FURTHER INFORMATION CONTACT:

Debra McKinney at (202) 512-8517 or McKinneyD@gao.gov regarding the Indianapolis, Indiana, hearing; and Marilyn Wasleski at (202) 512-8436 or WasleskiM@gao.gov regarding the San Antonio, Texas, hearing.

SUPPLEMENTARY INFORMATION: Section 832 of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001, Public Law 106-398, Oct. 30, 2000, directs the Comptroller General of the United States to convene a panel of experts to study the policies and procedures governing the transfer of commercial activities for the federal government from government personnel to a federal contractor. The Panel's study is to include a review of: (1) Procedures for determining whether functions should continue to be performed by government personnel; (2) procedures for comparing the costs of performing functions by government personnel with the costs of performing

those functions by federal contractors; (3) implementation by the Department of Defense of the Federal Activities Inventory Reform (FAIR) Act of 1998 (Pub. L. 105-270, 112 Stat. 2382, 31 U.S.C. 501 note); and (4) procedures of the Department of Defense for public-private competitions under Office of Management and Budget (OMB) Circular A-76. Formation of the Panel was announced in the **Federal Register** on April 17, 2001 (66 FR 19786). By May 1, 2002, the Comptroller General must submit to Congress a report of the Panel on the results of the study, including recommended changes with regard to implementing policies and enactment of legislation.

During the course of its work, the Panel will hold several public hearings. Interested parties are invited to attend these hearings to provide their perspectives on sourcing issues. On June 11, 2001, the GAO held its first public hearing, which focused on the principles and policies underlying outsourcing. The second public hearing will be held on August 8, 2001, beginning at 8:30 a.m. in the University Place Conference Center and Hotel on the Indiana University-Purdue University Indianapolis Campus, 850 West Michigan Street, Indianapolis, Indiana. The focus of this hearing will be on alternatives to the current outsourcing processes. The third hearing will be held on August 15 beginning at 8:30 a.m. in the Fiesta Ballroom of the Lackland Gateway Club, Building 2490, on Kenly Avenue at Lackland Air Force Base, San Antonio, Texas. This hearing will address current processes, such as OMB Circular A-76, public-private competitions, and the FAIR Act.

Any party who would like to attend either of the August hearings or make a presentation should contact the following E-mail address: A76panel@gao.gov. Those who wish to make presentations at either hearing should submit written summaries of their oral statements via the same E-mail address. These summaries must be received in our Office by July 25, 2001, for the Indianapolis hearing and by August 1, 2001, for the San Antonio hearing. The Panel will attempt to accommodate all interested parties who respond before these deadlines. Presenters must be prepared to limit their oral statements to 3 to 5 minutes. Interested parties who would like to make electronic presentations during the hearings must indicate their desire to do so by the July 25 deadline for the Indianapolis hearing and by the August 1 deadline for the San Antonio hearing. If time permits, individuals with no

prepared statements will be given the opportunity to speak, but the Panel may not be able to accommodate all such requests. Any individual who would like to attend the hearing at Lackland Air Force Base must present at any of its gates on the hearing date: (1) A picture identification (such as a driver's license), and (2) proof of automobile insurance, if driving a vehicle. The gate located closest to the Lackland Gateway Club is the Luke East Gate on Military Drive, which intersects U.S. Highway 90. More detailed guidance on hearing procedures will be provided to presenters by E-mail in advance of the hearings. Any interested party may submit full statements for inclusion in the hearing records by 5:30 p.m. on August 22. The hearings will be transcribed.

Further information, including hearing transcripts and copies of statements by all presenters, will be available on the GAO website, www.gao.gov, by clicking on "Commercial Activities Panel."

Jack L. Brock, Jr.,

Managing Director, Acquisition and Sourcing Management, General Accounting Office.

[FR Doc. 01-17270 Filed 7-10-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0267]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Labeling Regulations

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 certain general medical device labeling provisions.

DATES: Submit written or electronic comments on the collection of information by September 10, 2001.

ADDRESSES: Submit electronic comments on the collection of

information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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.

Medical Device Labeling—21 CFR Parts 800, 801, and 809

Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352), among other things, establishes requirements that the label or labeling of a medical device must meet so that it is not misbranded and subject to regulatory action. Certain of the

provisions of section 502 of the act require that manufacturers, importers, and distributors of medical devices disclose information about themselves or their devices on the labels or labeling of the devices. Section 502(b) of the act requires that, if the device is in a package, the label must contain the name and place of business of the manufacturer, packer, or distributor and an accurate statement of the quantity of the contents. Section 502(f) of the act provides that the labeling of a device must contain adequate directions for use. FDA may grant an exemption from the adequate directions for use requirement, if FDA determines that adequate directions for use are not necessary for the protection of the public health.

FDA regulations in parts 800, 801, and 809 (21 CFR parts 800, 801, and 809) require manufacturers, importers, and distributors of medical devices to disclose to health professionals and consumers specific information about themselves or their devices on the label or labeling of their devices. FDA issued these regulations under the authority of sections 201, 301, 502, and 701 of the act (21 U.S.C. 321, 331, 352, and 371). Most of the regulations in parts 800, 801, and 809 derive from the requirements of section 502 of the act, which provides, in part, that a device shall be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the device, is false or misleading in any particular, or fails to contain adequate directions for use.

Sections 800.10(a)(3) and 800.12(c) require that the label of contact lens cleaning solutions contain a prominent statement alerting consumers to the tamper-resistant feature required by § 800.12.

Section 800.10(b)(2) requires that the labeling of liquid ophthalmic preparations packed in multiple-dose containers include information as to duration of use and necessary warnings to afford adequate protection from contamination during use.

Section 801.1 requires that the label of a device in package form contain the name and place of business of the manufacturer, packer, or distributor.

Section 801.5 requires that the labeling of devices include directions under which the layman can use a device safely and for the purposes for which it is intended. Section 801.4 defines intended use. Where necessary, the labeling should include: (1) Statements of all conditions, purposes, or uses for which the device is intended, unless the device is a prescription device subject to the requirements of