

from the National Information Center website 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 March 8, 2001.

**A. Federal Reserve Bank of Richmond** (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. *BB&T Corporation, Winston-Salem, North Carolina*; to merge with Century South Banks, Inc., Alpharetta, Georgia, and Independent Bancorp, Inc., Oxford, Alabama, and thereby indirectly acquire Century South Bank of Alabama, Oxford, Alabama; Century South Bank of Central Georgia, National Association, Macon, Georgia; Century South Bank of Dahlonega, Dahlonega, Georgia; Century South Bank of Danielsville, Danielsville, Georgia; Century South Bank of Dawsonville, Dawsonville, Georgia; Century South Bank of Ellijay, Ellijay, Georgia; Century South Bank of Fannin County, National Association, Blue Ridge, Georgia; Century South Bank of Lavonia, Lavonia, Georgia; Century South Bank of Northeast Georgia, National Association; Gainesville, Georgia; Century South Bank of Polk County, Copperhill, Tennessee; and Century South Bank of the Coastal Region, National Association, Savannah, Georgia.

In connection with this application, Applicant also has applied to acquire HBI Acquisition Corp., Waynesboro, North Carolina, and thereby indirectly acquire Century South Bank of the Carolinas, FSB, Waynesville, North Carolina, and thereby engage in operating a savings association, pursuant to § 225.28(b)(4)(ii) of Regulation Y.

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

1. *Native American Bancorporation, Co., Denver, Colorado*; to become a bank holding company by acquiring 100 percent of the voting shares of Blackfeet National Bank, Browning, Montana.

**C. Federal Reserve Bank of Kansas City** (D. Michael Manies, Assistant Vice President), 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. *American State Bancshares, Inc., Great Bend, Kansas*; to become a bank holding company by acquiring 100 percent of the voting shares of American State Bank & Trust Company, NA, Great Bend, Kansas.

Board of Governors of the Federal Reserve System, February 6, 2001.

**Robert deV. Frierson,**  
*Associate Secretary of the Board.*

[FR Doc. 01-3393 Filed 2-8-01; 8:45 am]

**BILLING CODE 6210-01-U**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0048]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Type A Medicated Articles

**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 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the recordkeeping requirements for manufacturers of Type A medicated articles.

**DATES:** Submit written or electronic comments on the collection of information by April 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:** Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**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, including each proposed reinstatement of an existing 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.

#### Current Good Manufacturing Practice Regulations for Type A Medicated Articles—21 CFR 226 (OMB Control No. 0910-0154)—Extension

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351), FDA has the statutory authority to issue current good manufacturing practice (CGMP) regulations for drugs, including Type A medicated articles. A Type A medicated article is a feed product containing a concentrated drug diluted with a feed carrier substance. A Type A medicated article is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or for growth promotion and feed efficiency.

Statutory requirements for CGMP's for Type A medicated articles have been codified in part 226 (21 CFR part 226). Type A medicated articles that are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the act. Under part 226, a manufacturer is

required to establish, maintain, and retain records for Type A medicated articles, including records to document procedures required under the manufacturing process to assure that proper quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (i.e., batch and stability testing), and product distribution. This information is needed so that FDA can monitor drug usage and possible

misformulation of Type A medicated articles. The information could also prove useful to FDA in investigating product defects when a drug is recalled. In addition, FDA will use the CGMP criteria in part 226 to determine whether or not the systems used by manufacturers of Type A medicated articles are adequate to assure that their medicated articles meet the requirements of the act as to safety and also meet the articles, claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the act as to

safety and also meet the articles, claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the act.

The respondents for Type A medicated articles are pharmaceutical firms that manufacture both human and veterinary drugs, those firms that produce only veterinary drugs and commercial feed mills.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
226.42	115	260	29,900	0.75	22,425
226.58	115	260	29,900	1.75	52,325
226.80	115	260	29,900	0.75	52,325
226.102	115	260	29,900	1.75	52,325
226.110	115	260	29,900	0.25	7,475
226.115	115	10	1,150	0.5	575
Total					187,450

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the time required for record preparation and maintenance is based on agency communications with industry. Other information needed to calculate the total burden hours (i.e., manufacturing sites, number of Type A medicated articles being manufactured, etc.) are derived from agency records and experience.

Dated: February 2, 2001.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 01-3348 Filed 2-8-01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0046]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Medicated Feeds

**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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the recordkeeping requirements for manufacturers of medicated animal feeds.

**DATES:** Submit written or electronic comments on the collection of information by April 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:** Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1462.

**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 including each proposed reinstatement of an existing 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.