

holding company by acquiring 100 percent of the voting shares of First Bancorp in Davidson, Inc., Davidson, Oklahoma, and thereby indirectly acquire voting shares of First State Bank in Davidson, Davidson, Oklahoma.

Board of Governors of the Federal Reserve System, October 9, 2001.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 01-25834 Filed 10-12-01; 8:45 am]

**BILLING CODE 6210-01-S**

## FEDERAL RESERVE SYSTEM

### Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at [www.ffiec.gov/nic/](http://www.ffiec.gov/nic/).

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 29, 2001.

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

1. *M.S. Investment Company*, Milwaukee, Wisconsin, and its subsidiary, Mitchell Bank Holding Corporation, Milwaukee, Wisconsin, to continue to engage in extending credit and servicing loans, pursuant to § 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, October 10, 2001.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 01-25899 Filed 10-12-01; 8:45 am]

**BILLING CODE 6210-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Advisory Committee on Childhood Lead Poisoning Prevention: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the Advisory Committee on Childhood Lead Poisoning Prevention, Centers for Disease Control and Prevention, of the Department of Health and Human Services, has been renewed for a 2-year period through October 31, 2003.

For information, contact Gary P. Noonan, Executive Secretary, Advisory Committee on Childhood Lead Poisoning Prevention, Centers for Disease Control and Prevention, of the Department of Health and Human Services, 1600 Clifton Road, NE, M/S E-25, Atlanta, Georgia 30333, telephone 404-498-1442 or fax 404-498-1444.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: October 4, 2001.

**Carolyn J. Russell,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 01-25851 Filed 10-12-01; 8:45 am]

**BILLING CODE 4163-19-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0046]

#### Agency Information Collection Activities; Announcement of OMB Approval; 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 that a collection of information entitled "Current Good Manufacturing Practice Regulations for Medicated Feeds" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**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:** In the **Federal Register** of June 15, 2001 (66 FR 32629), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0152. The approval expires on September 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 5, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01-25763 Filed 10-12-01; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0132]

#### Agency Information Collection Activities; Announcement of OMB Approval; Protection of Human Subjects, Recordkeeping and Reporting Requirements for Institutional Review Boards

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Protection of Human Subjects, Recordkeeping and Reporting Requirements for Institutional Review Boards," has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of March 30, 2001 (66 FR 17427), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0130. The approval expires on September 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 5, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01-25764 Filed 10-12-01; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0114]

#### Agency Information Collection Activities; Announcement of OMB Approval; Patent Term Restoration, Due Diligence Petitions, Filing, and Content of Petitions

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of March 23, 2001 (66 FR 16249), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An

agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0233. The approval expires on September 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 5, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01-25837 Filed 10-12-01; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 80N-0042]

RIN 0910-AA01

#### Anticaries Drug Products for Over-the-Counter Human Use; Use of Intraoral Appliance Models for Compliance With Biological Testing Requirements; Request for Information and Comments

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting information and comments on the use of intraoral appliance (IOA) models as a substitute for the animal caries reduction ("rat caries models") biological test required by the monograph for over-the-counter (OTC) anticaries drug products to demonstrate the availability of fluoride in OTC dentifrice formulations. This notice is part of the ongoing review of OTC drug products conducted by FDA.

**DATES:** Submit written or electronic comments by January 14, 2002.

**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:** Robert L. Sherman, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

**SUPPLEMENTARY INFORMATION:**

## I. Background

The testing procedures for fluoride dentifrice drug products in 21 CFR 355.70 of the final monograph for OTC anticaries drug products (60 FR 52474, October 6, 1995), include both in vitro and biological testing to demonstrate the effectiveness of OTC anticaries dentifrices. The two in vitro tests (fluoride enamel uptake and enamel solubility reduction) demonstrate that fluoride is chemically available. The biological testing (animal caries reduction) assures that the fluoride is also bioavailable to alter tooth structure and make the tooth resistant to caries.

In the preamble to the final monograph for OTC anticaries drug products, FDA encouraged the development of additional testing procedures, such as remineralization tests. The agency noted that sufficient data were not available to correlate these tests specifically with clinical studies that demonstrate the effectiveness of fluoride dentifrices (60 FR 52474 at 52499). The agency stated that it would consider such tests as a substitute for the animal caries reduction test if adequate data were submitted demonstrating that an alternative testing procedure provides results of equivalent accuracy.

In 1996, FDA granted a petition (Refs. 1 and 2) that included the results of a study conducted in humans wearing an IOA with attached enamel chips as a substitute for the animal caries reduction test. Although the agency had initial concerns about the design and results of this IOA test, the data were considered sufficient to accept the test as an alternative to the animal caries model to demonstrate the effectiveness of the tested dentifrice formulation.

The petition also requested that the results of the IOA test be accepted as evidence of the effectiveness of the petitioner's other formulations. However, because these formulations contain different abrasives and flavorings, the agency determined that all other formulations must be tested individually (Ref. 2). The agency also recommended that protocols for any further IOA tests be submitted for review prior to conducting the tests.

IOA models employ small pieces of tooth enamel, mounted in the acrylic flanges of dentures worn by subjects that have been randomized to the various treatments to be investigated. The enamel chips are examined for demineralization or remineralization using various test methods. Proponents of the IOA model argue that, when compared with the animal caries reduction test, the IOA test is more