

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/](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 October 4, 2000.

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

1. *Dinsdale Brothers, Inc.*, Palmer, Nebraska; to acquire 12.78 percent of the voting shares of Pinnacle Bank—Wyoming, Torrington, Wyoming.

Board of Governors of the Federal Reserve System, September 14, 2000.

**Jennifer J. Johnson,**

*Secretary of the Board.*

[FR Doc. 00-24029 Filed 9-18-00; 8:45 am]

**BILLING CODE 6210-01-P**

## 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 13, 2000.

**A. Federal Reserve Bank of St. Louis** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166-2034:

1. *Allegiant Bancorp, Inc.*, St. Louis, Missouri; to acquire Equality Bancorp, Inc., St. Louis, Missouri, thereby indirectly acquiring its wholly owned thrift subsidiary, Equality Savings Bank, St. Louis, Missouri, and thereby engage in owning and operating a savings association, pursuant to § 225.28(b)(4)(ii) of Regulation Y. Comments regarding this application must be received not later than October 13, 2000.

**B. Federal Reserve Bank of San Francisco** (Maria Villanueva, Consumer Regulation Group) 101 Market Street, San Francisco, California 94105-1579:

1. *BYL Bancorp*, Orange, California; to engage *de novo* through its subsidiary, CNL Commercial Finance, Inc., Mission Viejo, California, in extending credit and servicing loans, pursuant to § 225.28(b)(1) of Regulation Y, and activities related to the extension of credit, pursuant to § 225.28(b)(2) of Regulation Y.

Board of Governors of the Federal Reserve System, September 13, 2000.

**Jennifer J. Johnson,**

*Secretary of the Board.*

[FR Doc. 00-23968 Filed 9-18-00; 8:45 am]

**BILLING CODE 6210-01-P**

## GENERAL SERVICES ADMINISTRATION

### Office of Communications; Cancellation of an Optional Form by Department of State

**AGENCY:** General Services Administration.

**ACTION:** Notice.

**SUMMARY:** The Department of State is cancelling the following Optional Form because of low usage:

OF 167, Evidence Which May Be Present To Meet The Public Charge Provisions Of The Law  
This form will become a Department of State form.

**DATES:** Effective September 19, 2000.

**FOR FURTHER INFORMATION CONTACT:** Mr. Charles Cunningham, Department of State, (202) 647-0596.

Dated: August 24, 2000.

**Barbara M. Williams,**

*Deputy Standard and Optional Forms Management Officer.*

[FR Doc. 00-23973 Filed 9-18-00; 8:45 am]

**BILLING CODE 6820-34-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-1501]

### Agency Information Collection Activities: Proposed Collection; Comment Request; Extension; Threshold of Regulation for Substances Used in Food-Contact 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 (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 requests for exemption from the food additive listing regulation requirements.

**DATES:** Submit written or electronic comments on the collection of information by November 20, 2000.

**ADDRESSES:** Submit electronic comments on the collection of information via the Internet at: <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/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, including each proposed extension 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.

**Threshold of Regulation for Substances used in Food-Contact Articles—21 CFR 170.39 (OMB Control Number 0910–0298)—Extension**

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless: (1) It conforms to an exemption for investigational use under 409(j); (2) it conforms to the terms of a regulation prescribing its use; or (3) in the case of a food additive which meets the definition of a food-contact substance in section 409(h)(6), there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B).

In the **Federal Register** of July 17, 1995 (60 FR 36582), § 170.39 (21 CFR 170.39) established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification. The agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 parts per billion. The second exempts regulated direct food

additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

In order to determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes: (1) The chemical composition of the substance for which the request is made; (2) detailed information on the conditions of use of the substance; (3) a clear statement of the basis for the request for exemption from regulation as a food additive; (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance; (5) results of a literature search for toxicological data on the substance and its impurities; and (6) information on the environmental impact that would result from the proposed use.

FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves.

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

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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.39	6	1	6	48	288

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

The above annual reporting estimate is based on information received from representatives of the food packaging and processing industries and on agency records. In the past, FDA has typically received 60 threshold of regulation exemption requests per year. However, it is estimated that up to 90 percent of the requests that would have previously been submitted under § 170.39 will now be submitted under the premarket notification process for food-contact substances established by section 409(h) of the act.

Dated: September 12, 2000.  
**William K. Hubbard,**  
*Senior Associate Commissioner for Policy, Planning, and Legislation.*  
[FR Doc. 00–23884 Filed 9–18–00; 8:45 am]  
**BILLING CODE 4160–01–F**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 00N–1503]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Orphan Drugs**

**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 orphan drugs.

**DATES:** Submit written or electronic comments on the collection of information by November 20, 2000.