80202–1129. All data and other information with respect to the variances and exemptions issued by the State of Colorado are located at the Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, Denver, Colorado 80246–1530.

FOR FURTHER INFORMATION CONTACT: Jack Theis at 303–312–6347 or *Theis.Jack @epa.gov*.

SUPPLEMENTARY INFORMATION: Colorado has an EPA approved program for assuming primary enforcement authority for the PWSS program, pursuant to section 1413 of the Safe Drinking Water Act (SDWA), 42 U.S.C. 300g–2 and 40 CFR Part 142.

A. Why do States issue variances and exemptions?

States with primary enforcement authority are authorized to grant variances and exemptions from National Primary Drinking Water Regulations due to particular situations with specific public water systems providing these variances and exemptions meet the requirements of the SWDA Section 1415 and 1416 and are protective of public health.

B. Why is a review of the variances and exemption necessary?

Colorado is authorized to grant variances and exemptions to drinking water systems in accordance with the SDWA. The SDWA requires that EPA periodically review State issued variances and exemptions to determine compliance with the Statute. 42 U.S.C. 300g–4(e)(8); 42 U.S.C.300g–5(d).

Dated: September 14, 2007.

Kerrigan G. Clough,

Deputy Regional Administrator, Region 8.

[FR Doc. E7–18843 Filed 9–24–07; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK OF THE UNITED STATES

Economic Impact Policy

This notice is to inform the public that the Export-Import Bank of the United States has received an application to guarantee $19 million in commercial bank financing for the U.S. export of approximately $31 million worth of photovoltaic module manufacturing equipment and services for the construction of a new thin film photovoltaic production facility in Germany. The U.S. exports will enable the German company to produce approximately 21.5 megawatts (MW) worth of amorphous silicon thin film photovoltaic modules per year on average during the 8-year repayment term of the loan. Available information indicates that all of this new German production will be consumed in Germany. Interested parties may submit comments on this transaction by e-mail to *economic.impact@exim.gov* or by mail to 811 Vermont Avenue, NW., Room 1238, Washington, DC 20571, within 14 days of the date this notice appears in the **Federal Register**.

Helene S. Walsh,

Director, Policy Oversight and Review.

[FR Doc. E7–18888 Filed 9–24–07; 8:45 am]

BILLING CODE 6690–01–P

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 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 October 19, 2007.

A. Federal Reserve Bank of Cleveland (Douglas A. Banks, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101–2566:

1. Fifth Third Bancorp, and Fifth Third Financial Corporation, both of Cincinnati, Ohio; to merge with First Charter Corporation, and thereby indirectly acquire First Charter Bank, both of Charlotte, North Carolina.

B. Federal Reserve Bank of Atlanta (David Tatum, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. City Savings Bancshares, Inc., Deridder, Louisiana; to merge with Louisiana Community Bancshares, Inc., Kaplan, Louisiana, and thereby indirectly acquire Kaplan State Bank, Kaplan, Louisiana, and Teche Bank & Trust Co., Saint Martinville, Louisiana.

Board of Governors of the Federal Reserve System, September 20, 2007.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E7–18833 Filed 9–24–07; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0202]

Draft Guidance for Industry: Microbiological Considerations for Antimicrobial Food Additive Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Guidance for Industry: Microbiological Considerations for Antimicrobial Food Additive Submissions.'' The draft guidance explains, using a question and answer format, FDA's current thinking on a number of microbiological issues unique to the preparation of premarket submissions for antimicrobial food additives.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by November 26, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and

Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1071.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration (FDA) is responsible for prescribing the conditions of safe use of food additives under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348). To evaluate the safety of food additives and determine their conditions of safe use, the agency uses various premarket approval processes (food additive petition process (21 CFR 171.1), premarket notification process for food contact substances (21 CFR 170.100), and threshold of regulation process for substances used in food contact articles that migrate or may be expected to migrate into food (21 CFR 170.39)). This guidance provides answers to common questions arising during the preparation of premarket submissions that seek FDA approval of new antimicrobial food additives. This guidance will assist petitioners and notifiers in designing studies to determine whether an antimicrobial food additive achieves its intended technical effect. In addition, this guidance discusses microbiological data that may demonstrate that an antimicrobial agent will be safe for the intended use. This guidance applies to all premarket approval submissions for food additives that are intended to control microbes in or on food, including sources of radiation for treating food.

The agency has adopted good guidance practices (GGPs) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115). This draft guidance is being issued as a Level 1 guidance document consistent with the GGPs. The draft guidance represents the agency's current thinking on microbiological considerations for antimicrobial food additive submissions. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see **FOR FURTHER INFORMATION CONTACT**).

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 70.25, 71.1, 170.35, and 171.1 have been approved under OMB control number 0910–0016; the collection of information in 21 CFR 170.39 has been approved under OMB control number 0190–0298; and the collections of information in 21 CFR 170.101 and 170.106 have been approved under OMB control number 0190–0495.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. If you base your comments on scientific evidence or data, please submit copies of the specific information along with your comments. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.cfsan.fda.gov/guidance.html*.

Dated: September 18, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–18816 Filed 9–24–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (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: The Division of Independent Review Grant Reviewer Recruitment Form (OMB No. 0915–0295): Extension

HRSA's Division of Independent Review (DIR) is responsible for carrying out the independent and objective review of all eligible applications submitted to HRSA. DIR ensures that the independent review process is efficient, effective, economical, and complies with statutes, regulations, and policies. The review of applications is performed by people knowledgeable in the field of endeavor for which support is requested and is advisory to individuals in HRSA responsible for making award decisions.

To streamline the selection and assignment of grant reviewers to objective review committees, HRSA utilizes a Web-based data collection form to gather critical reviewer information. The Grant Reviewer Form standardizes pertinent categories of reviewer information, such as: Areas of