b. The accuracy of the agencies' estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or start up costs and costs of operation, maintenance, and purchase of services to provide information.

Comments submitted in response to this notice will be shared among the agencies. All comments will become a matter of public record.

Proposal To Extend for Three Years, Without Revision, the Following Currently Approved Collection of Information

Report Title: Country Exposure Report for U.S. Branches and Agencies of Foreign Banks.

Form Number: FFIEC 019.

OMB Number: 7100–0213.

Frequency of Response: Quarterly.

Affected Public: U.S. branches and agencies of foreign banks.

Estimated Number of Respondents: 168.

Estimated Average Time per Response: 10 hours.

Estimated Total Annual Burden: 6,720 hours.

General Description of Report: This information collection is mandatory: 12 U.S.C. 3906 for all agencies; 12 U.S.C. 3105 and 3108 for the Board; sections 7 and 10 of the Federal Deposit Insurance Act (12 U.S.C. 1817, 1820) for the FDIC; and the National Bank Act (12 U.S.C. 161) for the OCC. This information collection is given confidential treatment under the Freedom of Information Act (5 U.S.C. 552(b)(8)).

Abstract: All individual U.S. branches and agencies of foreign banks that have more than $30 million in direct claims on residents of foreign countries must file the FFIEC 019 report quarterly. Currently, all respondents report adjusted exposure amounts to the five largest countries having at least $20 million in total adjusted exposure. The agencies collect this data to monitor the extent to which such branches and agencies are pursuing prudent country risk diversification policies and limiting potential liquidity pressures. No changes are proposed to the FFIEC 019 reporting form or instructions.

Board of Governors of the Federal Reserve System, July 31, 2012.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2012–19059 Filed 8–3–12; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 21, 2012.

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

1. *Opportunity Fund, LLC; Bank Opportunity Advisors LLC; and Bank Acquisitions LLC,* all in Washington, DC; to acquire voting shares of Middlefield Banc Corp., and thereby indirectly acquire voting shares of The Middlefield Banking Company, both in Middlefield, Ohio, and Emerald Bank, Dublin; Ohio.

B. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street NE., Atlanta, Georgia 30309:

1. *Moishe Gubin,* Hillside, Illinois; to acquire voting shares of OptimumBank Holdings, Inc., Ft. Lauderdale, Florida, and thereby indirectly acquire voting shares of OptimumBank, Plantation, Florida.

Board of Governors of the Federal Reserve System, August 1, 2012.

Michael J. Lewandowski,

Assistant Secretary of the Board.

[FR Doc. 2012–19092 Filed 8–3–12; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Extension to HS Transportation Requirement.

OMB No.: 0970–0260.

Description: The Office of Head Start is proposing to renew authority to collect information regarding the Head Start transportation requirement without changes. The transportation requirement provides the requirement that each child be seated in a child restraint system while the vehicle is in motion, and the requirement that each bus have at least one bus monitor on board at all times. Waivers would be granted when the Head Start or Early Head Start grantee demonstrates that compliance with the requirement(s) for which the waiver is being sought will result in a significant disruption to the Head Start program or the Early Head Start program and that waiving the requirement(s) is in the best interest of the children involved.

Respondents: Head Start and Early Head Start program grants recipients.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average Burden Hours per Response	Total Burden Hours
Form	275	1	1	275

Estimated Total Annual Burden Hours: 275.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington,

DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–19141 Filed 8–3–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0724]

Documents to Support Submission of an Electronic Common Technical Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the following final versions of documents that support making regulatory submissions in electronic format using the electronic Common Technical Document (eCTD) specifications: ''The eCTD Backbone Files Specification for Module 1, version 2.0'' (which includes the U.S. regional document type definition (DTD), version 3.0) and ''Comprehensive Table of Contents Headings and Hierarchy, version 2.0.'' Supporting technical files are also being made available on the Agency Web site. These documents represent FDA's major updates to Module 1 of the eCTD, which contains regional information. FDA is not prepared at present to accept submissions utilizing this new version because eCTD software vendors need time to update their software to accommodate this information and because its use will require software upgrades within the Agency. FDA estimates it will be able to receive submissions utilizing Module 1 Specifications 2.0 by September 2013, but this is not a firm date and we will give 30 days advance notice to industry.

ADDRESSES: Submit written requests for single copies of the documents to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm 2201, Silver Spring, MD 20993–0002; or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the documents.

FOR FURTHER INFORMATION CONTACT: Virginia Hussong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm 1161, Silver Spring, MD 20993, email: *Esub@fda.hhs.gov*; or Mary Padgett, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–0373, email: *mary.padgett@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The eCTD is an International Conference on Harmonisation (ICH) standard based on specifications developed by ICH and its member parties. FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) have been receiving submissions in the eCTD format since 2003, and the eCTD has been the standard for electronic submissions to CDER and CBER since January 1, 2008. The majority of new electronic submissions are now received in eCTD format. Since adoption of the eCTD standard, it has become necessary to update the administrative portion of the eCTD (Module 1) to reflect regulatory changes, to provide clarification of business rules for submission processing and review, to refine the characterization of promotional marketing and advertising material, and to facilitate automated processing of submissions. In preparation for the Module 1 update, FDA made available draft technical documentation for public comment in a **Federal Register** notice dated October 26, 2011 (Docket No. FDA–2011–N–0724). After considering comments submitted, FDA revised the draft documentation and is making available final versions of the following documents:

- ''The eCTD Backbone Files Specification for Module 1, version 2.0,'' which provides specifications for creating the eCTD backbone file for Module 1 for submission to CDER and CBER. It should be used in conjunction with the guidance for industry ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications,'' which can be found online (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072349.pdf*), and which will be revised as part of the implementation of the updated eCTD backbone files specification.
- ''Comprehensive Table of Contents Headings and Hierarchy, version 2.0,'' which reflects updated headings that are specified in the draft document entitled ''The eCTD Backbone Files Specification for Module 1, version 2.0,'' as well as mappings to regulations and legislation.

Supporting technical files are also being made available on the Agency Web site. The documents include changes that:

- Allow submission of promotional label and advertising materials to CDER in eCTD format;
- Provide for processing of grouped submissions (e.g., a supplement that can be applied to more than one new drug application or biologics license application);
- Provide detailed contact information so that companies can specify points of contact to discuss technical matters that may arise with a submission;
- Clarify headings;
- Use attributes in place of certain headings to provide flexibility for future changes without revising the specification itself.

FDA is not prepared at present to accept submissions utilizing this new version because eCTD software vendors need time to update their software to accommodate this information and because its use will require software upgrades within the Agency. FDA estimates it will be able to receive submissions utilizing Module 1 Specifications 2.0 by September 2013, but this is not a firm date and we will give 30 days advance notice to industry.