which protects from disclosure ''trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential.''

Current actions: On April 17, 2019, the Board published a notice in the **Federal Register** (84 FR 16015) requesting public comment for 60 days on the extension, without revision, of the FR 2436. The comment period for this notice expired on June 17, 2019. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, July 15, 2019.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2019–15312 Filed 7–17–19; 8:45 am]

BILLING CODE 6210–01–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 applications will also 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.

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 August 12, 2019.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Senior Vice President) 33 Liberty Street, New York, New York 10045–0001. Comments can also be sent electronically to *Comments.applications@ny.frb.org:*

1. *Banco Bradesco, S.A., Lecce Holdings S.A., Fundação Bradesco, BBD Participações S.A., Nova Cidade de Deus Participações S.A., and Cidade de Deus Cia. Comercial de Participações, all of Osasco, São Paulo, Brazil;* to become bank holding companies by acquiring substantially all of the shares of BAC Florida Bank, Coral Gables, Florida.

B. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Brodhead Bancshares, Inc., Brodhead, Wisconsin;* to acquire 100 percent of the voting shares of Farmers and Merchants Bank of Orfordville, Orfordville, Wisconsin.

Board of Governors of the Federal Reserve System, July 12, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–15250 Filed 7–17–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; ORR Data Collection for the Annual Survey of Refugees (OMB #0907–0033)

AGENCY: Office of Refugee Resettlement; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) within the U.S. Department of Health and Human Services (HHS) seeks an update to the existing data collection for the Annual Survey of Refugees. The Annual Survey of Refugees is a yearly sample survey of refugee households entering the U.S. in the previous five fiscal years. The requested update is based upon results of a multi-year effort in instrument redesign and field testing. ACF estimates the proposed changes will increase response burden from 30 to 45 minutes per respondent.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *OPREinfocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Data from the Annual Survey of Refugees are used to meet the Office of Refugee Resettlement's Congressional reporting requirements, as set forth in the Refugee Act of 1980 (Section 413(a) of the Immigration and Nationality Act). The Office of Refugee Resettlement makes survey findings available to the general public and uses findings for the purposes of program planning, policy-making, and budgeting.

The requested update reflects changes to the survey instrument to: Enhance ORR's understanding of refugees' resettlement experiences; streamline the collection of household-level information; and improve data reliability and validity.

Respondents: The Annual Survey of Refugees secures a nationally representative sample of refugee households arriving in the United States in the previous five fiscal years.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
ORR–9 (Annual Survey of Refugees)	6000	2000	1	.75	1500
Pre-Survey Information Form	6000	2000	1	.05	100

Estimated Total Annual Burden Hours: 1,600

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Sec. 413. [8 U.S.C. 1523]

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–15274 Filed 7–17–19; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0976]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance: Emergency Use Authorization of Medical Products and Related Authorities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 19, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0595. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867 *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance: Emergency Use Authorization of Medical Products and Related Authorities

OMB Control Number 0910–0595—Extension

The guidance describes the Agency's policies applicable to the authorization of the emergency use of certain medical products under sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3, 360bbb–3a, and 360bbb–3b), as amended or added by the Project BioShield Act of 2004 (Pub. L. 108–276), the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5), 21st Century Cures Act (Pub. L. 114–255), and Public Law 115–92 (2017). The FD&C Act permits the FDA Commissioner (the Commissioner) to authorize the use of unapproved medical products or unapproved uses of approved medical products during an emergency declared under section 564 of the FD&C Act. The data to support issuance of an emergency use authorization (EUA) must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb–3(c)). Although the exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency and the nature of the candidate product, FDA recommends that a request for consideration for an EUA include scientific evidence evaluating the product's safety and effectiveness, including the adverse event profile for diagnosis, treatment, or prevention of the serious or life-threatening disease or condition, as well as data and other information on safety, effectiveness, risks and benefits, and (to the extent available) alternatives.

Under section 564 of the FD&C Act, the Commissioner may establish conditions on the authorization. Section 564(e) requires the Commissioner (to the extent practicable given the circumstances of the emergency) to establish certain conditions on an authorization that the Commissioner finds necessary or appropriate to protect the public health and permits the Commissioner to establish other conditions that he or she finds necessary or appropriate to protect the public health. Conditions authorized by section 564(e) of the FD&C Act include, for example: Requirements for information dissemination to healthcare providers or authorized dispensers and product recipients; adverse event monitoring and reporting; data collection and analysis; recordkeeping and records access; restrictions on product advertising, distribution, and administration; and limitations on good manufacturing practices requirements. Some conditions, the statute specifies, are mandatory to the extent practicable for authorizations of unapproved products and discretionary for authorizations of unapproved uses of approved products. Moreover, some conditions may apply to manufacturers of an EUA product, while other conditions may apply to any person who carries out any activity for which the authorization is issued. Section 564 of the FD&C Act also gives the Commissioner authority to establish other conditions on an authorization that he or she finds to be necessary or appropriate to protect the public health. Additionally, sections 564A and 564B established streamlined mechanisms to facilitate preparedness and response activities involving certain FDA-approved products without requiring FDA to issue an EUA, including expiration date extension authority.

For purposes of estimating the annual burden of reporting (table 1), FDA has established four categories of respondents: (1) Those who file a request for FDA to issue an EUA or a substantive amendment to an EUA that has previously been issued, assuming that a requisite declaration under section 564 of the FD&C Act has been made and criteria for issuance have been met; (2) those who submit a request for FDA to review information/data (*i.e.,* a pre-EUA package) for a candidate EUA product or a substantive amendment to an existing pre-EUA package for preparedness purposes; (3) manufacturers who carry out an activity related to an unapproved EUA product (*e.g.,* administering product, disseminating information) who must