

Terminations of Agreements: .25–.5 hours.

Filing of Agreement meeting minutes: 2–5 hours.

Filing of Monitoring Reports:

VOCC Rate Discussion Agreements: 71–120 hours.

Alliance Agreements: 60–155 hours.

Other reporting agreements: 5–75 hours.

Total Annual Burden: The Commission estimates the total annual burden at 15,655 hours.

Rachel Dickon,

Secretary.

[FR Doc. 2020–00116 Filed 1–8–20; 8:45 am]

BILLING CODE 6731-AA-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, if any, 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)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than February 10, 2020.

A. Federal Reserve Bank of Atlanta (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to Applications.Comments@atl.frb.org:

1. *Pinnacle Financial Corporation, Elberton, Georgia*; to acquire SBT Bancorp, Inc., and thereby indirectly acquire Southern Bank & Trust, both of Clarkesville, Georgia.

Board of Governors of the Federal Reserve System, January 6, 2020.

Margaret M. Shanks,

Deputy Secretary of the Board.

[FR Doc. 2020–00185 Filed 1–8–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part J (Agency for Toxic Substances and Disease Registry) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (50 FR 25129–25130, dated June 17, 1985, as amended most recently at 82 FR 42555, dated September 8, 2017) is amended to reflect the reorganization of the Agency for Toxic Substances and Disease Registry. This reorganization will combine the programmatic, technical expertise and resources of two divisions into one.

I. Under Part C, Section C–B, Organization and Functions, the following organizational unit is deleted in its entirety:

- Division of Community Health Investigations (JAAM)
- Eastern Branch (JAAMB)
- Central Branch (JAAMC)
- Western Branch (JAAMD)
- Science Support Branch (JAAME)
- Division of Toxicology and Human Health Science (JAAN)
- Geospatial Research, Analysis and Services Program (JAAN12)
- Emergency Response Program (JAAN13)
- Environmental Epidemiology Branch (JAANB)
- Environmental Health Surveillance Branch (JAANC)
- Environmental Medicine Branch (JAAND)
- Environmental Toxicology Branch (JAANE)

II. Under Part C, Section C–B, Organization and Functions, make the following change:

- Update the functional statement for the Agency for Toxic Substances and Disease Registry (J)
- Update the functional statement for the Office of the Administrator (JA)
- Update the functional statement for the Office of the Director (JAA)
- Retitle the Office of Financial, Administrative, and Information

Services to the Office of the Office of Management and Analytics (JAA2)

- Retitle the Office of Policy, Planning and Evaluation to the Office of Policy, Partnerships, and Planning (JAA3)
- Update the functional statements for the Office of Communication (JAA7)
- Establish the Office of Science (JAA9)
- Establish the Office of the Associate Director (JAAQ)
- Establish the Office of Innovation and Analytics (JAAQB)
- Establish the Office of Community Health Hazard Assessment (JAAQC)
- Establish the Office of Capacity Development and Applied Prevention Science (JAAQD)

III. Under Part C, Section C–B, Organization and Functions, insert the following:

- *Agency for Toxic Substance and Disease Registry (J).* The mission of the Agency for Toxic Substances and Disease Registry (ATSDR) is to protect communities from harmful health effects of hazardous waste sites and hazardous material spills. The ATSDR responsibilities are specified in the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) as amended in the Superfund Amendments and Reauthorization Act of 1986 and in amendments (Hazardous and Solid Waste Amendments of 1984) to the Resource Conservation and Recovery Act (RCRA). ATSDR works closely with state, tribal, territory, local, other federal agencies, and other organizations to reduce or eliminate illness, disability, and death that result from exposure of the public to toxic substances at spill and waste disposal sites. Through additional laws, ATSDR provides environmental support to other national efforts, such as the disposal of medical wastes. To carry out its CERCLA mission, ATSDR:

(1) Evaluates data and information on the release of hazardous substances into the environment to assess any current or future impact on public health, develops health advisories or other health recommendations, and identifies studies or actions needed to evaluate and mitigate or prevent adverse human health effects; (2) summarizes and interprets available data on the health effects of hazardous substances in consultation with the Environmental Protection Agency (EPA) and other programs and Public Health Service (PHS) agencies, and in cooperation with the National Toxicology Program, initiates toxicologic research to determine the health effects of designated hazardous substances, where needed; (3) provides health-related

support in public health emergencies, including public health advisories involving exposure to hazardous substances; (4) establishes and maintains a registry of persons exposed to chemical or disease specific hazardous substances and a registry of serious diseases and illnesses in persons exposed to specific toxic substances as a result of environmental exposure; (5) expands knowledge of the relationship between exposure to hazardous substances and adverse human health effects, through epidemiologic, toxicologic, laboratory, and human, animal, and other scientific studies on hazardous substances; (6) develops and disseminates to physicians and other health care providers informational materials on the health effects of toxic substances. To carry out its RCRA mission, ATSDR (1) provides immediate or short-term assistance to EPA regional and headquarters staff to provide health advice and health effect information about releases of hazardous substances at landfills and surface impoundments; and (2) conducts health assessments when environmental contamination has been found to pose a substantial potential risk to human health.

- *Office of the Administrator (JA)*. (1) Directs and evaluates the programs and activities of the Agency; (2) provides leadership for implementing statutory responsibilities; (3) approves the Agency's goals and objectives; (4) provides overall policy direction to the scientific/medical program; (5) plans, promotes, and coordinates an ongoing program to assure equal employment opportunities; (6) provides leadership for and assessment of administrative management activities; (7) assures coordination with appropriate PHS staff offices and other relevant agencies for administrative and program matters, such as coordinating emergency response activities that involve action at the PHS level.

- *Office of the Director (JAA)*. (1) Manages, directs, coordinates, and evaluates all health-related programs of the National Center for Environmental Health (NCEH) and ATSDR; (2) provides overall leadership in health-related activities for hazardous substances, hazardous waste sites and chemical releases; (3) provides overall coordination for the research programs and science policies of the agencies; (4) develops goals and objectives and provides leadership, policy formulation, scientific oversight, and guidance in program planning and development; (5) provides overall programmatic direction for planning and management oversight of allocated resources, human resource management and administrative

support; (6) provides information, publication and distribution services to NCEH/ATSDR; (7) maintains liaison with other federal, state, and local agencies, institutions, and organizations; (8) coordinates NCEH/ATSDR program activities with other Centers for Disease Control and Prevention (CDC) components, other federal, state and local government agencies, the private sector, and other nations; and (9) directs and coordinates activities in support of the Department's Equal Employment Opportunity program and employee development.

- *Office of Management and Analytics (JAA2)*. (1) Plans, manages, directs, and conducts the administrative and financial management operations of NCEH/ATSDR; (2) reviews the effectiveness and efficiency of administration and operation of all NCEH/ATSDR programs; (3) develops and directs systems for human resource management, financial services, procurement requisitioning, and travel authorization; (4) provides and coordinates services for the extramural award activities of NCEH/ATSDR; (5) formulates and provides overall programmatic direction for planning and management oversight of allocated resources, human resource management and administrative support; (6) develops and directs a system for cost recovery; and (7) enables and supports NCEH/ATSDR data management, systems development, and information security needs; (8) develops and directs employee engagement programs; and (9) analyzes NCEH/ATSDR workforce, systems, and resources.

- *Office of Policy, Partnerships and Planning (JAA3)*. (1) Coordinates, develops, recommends and implements strategic planning and tracking for NCEH/ATSDR; (2) develops and coordinates performance management to ensure achievement of goals in NCEH/ATSDR programs; (3) participates in reviewing, coordinating, and preparing legislation, briefing documents, Congressional testimony, and other legislative matters; (4) maintains liaison and coordinates with other federal agencies for program planning and performance; (5) assists in the development of NCEH/ATSDR budget and program initiatives; (6) provides liaison with staff offices and other officials of CDC; (7) monitors and prepares reports on health-related activities to comply with provisions of relevant legislation; (8) coordinates the development, review, and approval of Federal regulations, **Federal Register** announcements, Freedom of Information Act requests, Government Accountability Office and Department

of Health and Human Services (HHS) Inspector General reports, and related activities; (9) develops and strengthens strategic partnerships with key constituent groups; and (10) facilitates communication between NCEH/ATSDR and its partners.

- *Office of Communication (JAA7)*. (1) Serves as the principal advisor to the Assistant Administrator, director and divisions on communication and marketing science, research, practice, and public affairs; (2) leads agency strategic planning for communication and marketing science and public affairs programs and projects; (3) analyzes context, situation, and environment to inform agency-wide communication and marketing programs and projects; (4) ensures use of scientifically sound research for marketing and communication programs and projects; (5) ensures accurate, accessible, timely, and effective translation of science for use by multiple audiences; (6) leads identification and implementation of information dissemination channels; (7) provides communication and marketing project management expertise; (8) collaborates with external organizations and the news, public service, and entertainment and other media to ensure that scientific findings and their implications for public health reach the intended audiences; (9) collaborates closely with divisions to produce materials tailored to meet the requirements of news and other media channels, including press releases, letters to the editor, public service announcements, television programming, video news releases, and other electronic and printed materials; (10) coordinates the development and maintenance of accessible public information through the internet, social media and other applicable channels; (11) provides training and technical assistance in the areas of health communication, risk communication, social marketing, and public affairs; (12) manages or coordinates communication services such as internet/intranet, application development, social media, video production, graphics, photography, CDC name/logo use and other brand management; (13) provides editorial services, including writing, editing, and technical editing; (14) facilitates internal communication to agency staff and allied audiences; (15) supervises and manages Office of Communication activities, programs, and staff; (16) serves as liaison to internal and external groups to advance the agency's mission; (17) collaborates with the CDC Office of the Associate Director for Communication on media

relations, electronic communication, health media production, and brand management activities; (18) collaborates with the Center for Preparedness and Response and other NCEH/ATSDR entities to fulfill communication responsibilities in emergency response situations; (19) collaborates with other CDC Centers/Institute/Offices in the development of marketing communications targeted to populations that would benefit from a cross-functional approach; (20) ensures NCEH/ATSDR materials meet CDC and HHS standards.

- *Office of Science (JAA9)*. (1) Ensures NCEH/ATSDR compliance with the various statutes, regulations, and policies governing the conduct of science by the federal government, including: Human subjects research determinations, the protection of human research subjects and the use of Institutional Review Boards (IRBs), the OMB Paperwork Reduction Act (relating to the collection of information from ten or more people in a 12-month period), the OMB Information Quality Bulletin, Confidentiality Protection, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA, and its "Privacy Rule"); and others; (2) develops and maintains the NCEH/ATSDR Clearance Policy and managing and conducting clearance for NCEH/ATSDR documents; (3) coordinates and manages document cross-clearance between NCEH/ATSDR and other parts of CDC; facilitating agency reviews of external documents, coordinating and managing information quality requests concerning NCEH/ATSDR documents; (4) coordinates and manages external peer review for NCEH/ATSDR documents and intramural programs; (5) coordinates and manages the activities of the NCEH/ATSDR Board of Scientific Counselors (a federal advisory committee and its subcommittees and workgroups); (6) coordinates interagency workgroups/committees such as the President's Task Force on Environmental Health Risks and Safety Risks to Children, and the National Toxicology Program Executive Committee; (7) coordinates and manages NCEH/ATSDR involvement in the Epidemic Intelligence Service (EIS) Program; (8) coordinates NCEH/ATSDR involvement in CDC public health ethics activities; (9) coordinates NCEH/ATSDR involvement in CDC science awards activities (e.g., the Shepard Award, and CDC/ATSDR Honor Awards); (10) organizes and sponsors select training opportunities (e.g., human subjects/IRB, OMB/PRA, and eClearance Training for Authors and

Reviewers); (11) represents NCEH/ATSDR on various CDC/ATSDR committees, work groups, and task forces, such as the CDC/ATSDR Office of the Chief Science Officer's Excellence in Science Committee, and the CDC Surveillance Science Advisory Group; (12) coordinates NCEH/ATSDR global health activities; (13) coordinates and manages the NCEH/ATSDR Healthy People 2020; (14) prepares an annual inventory of NCEH/ATSDR publications; and (15) pursuant to the National Environmental Policy Act, reviews draft Environmental Impact Statements on behalf of HHS where the proposed federal actions impact human health.

- *Office of the Associate Director (JAAQ)*. (1) Provides leadership in directing, coordinating, evaluating, and managing all programmatic and administrative operations of ATSDR; (2) develops programmatic goals and objectives and provides leadership, policy formation, and guidance in program planning, development, and evaluation; (3) coordinates activities with other components of ATSDR and other federal, tribal, state, and local agencies; (4) works with the Washington, DC regional office to ensure coordination with EPA at the national level; (5) ensures the quality and consistency in the science and format used in the development of products and materials; (6) develops outreach messages following the procedures and policies of the Agency's Office of Communications; (7) provides timely responses to policy activities (i.e., FOIA, congressional inquiries, budget formulation, and briefings); (8) develops measures of divisional productivity and reports to the Agency and CDC director; (9) coordinates NCEH and ATSDR emergency management resources to support efforts to protect the public's health from environmental threats; (10) provides incident management and coordination for complex emergency management including the development, approval, and updating of standardized processes to enable appropriate and adequate management of resources; (11) develops, implements, and manages programs to enhance the emergency response readiness of CDC and other national, regional, state, local, and international public health programs; and (12) develops capacity within the states to integrate new and existing epidemiological and scientific principles into operational and programmatic expertise in emergency preparedness, response, and recovery and; (13) manages and conducts a

records management program, including the National Archives and Records Administration standards, for ATSDR in accordance with Congressional mandate.

- *Office of Innovation and Analytics (JAAQB)*. (1) Uses best practices to collect, analyze, and interpret data and disseminate scientific information to enable internal and external partners to make actionable decisions regarding exposure to hazardous substances; (2) provides analytical and modeling expertise, develops new analytical tools, and integrates the use of geospatial science in public health activities; (3) conducts environmental and biological computer simulation and other statistical modeling expertise to support internal and external stakeholders; (4) integrates geospatial science, data analytics and visualization, and manages processes, and analyzes data; (5) supports the CDC Emergency Operations Center as requested; (6) identifies, develops, and promotes new tools through authoring manuscripts, reports, and community-facing products as well as through leveraging new technologies in order to maintain and improve ATSDR's state of the art science practice; (7) develops toxicological profiles and repositories of data, conducts synthesis of research, evaluates methodological and programmatic best practices internal and externally, and conducts surveillance and registry programs; (8) coordinates the development of contaminant-specific information, and provides chemical-specific toxicologic consultations; (9) determines health guidelines which estimates the highest level of exposure to a toxic substance that is thought to not have adverse health effects, and exposure-dose reconstruction; (10) creates and maintains surveillance systems and registries to understand the relationship between toxic exposure and health; and (11) develops repository of programmatic methodological best practices through meta-analyses of ATSDR documents, databases, and analyses.

- *Office of Community Health Hazard Assessment (JAAQC)*. (1) Conducts public health assessments, health consultations, and other related public health activities to determine the health implications of releases or threatened releases of toxic substances into the environment; in particular, such activities are conducted for Superfund and RCRA sites, petition requests, and other sites or instances where communities have been or may have been exposed to toxic substances in the environment; (2) plans, manages,

directs, and conducts the regional operations of the agency; (3) provides liaison, technical advice, and consultation to the EPA, other federal, tribal, state, and local agencies, private organizations, community groups, and individuals on eliminating or mitigating public health problems resulting from the release of hazardous substances into the environment; (4) conducts and evaluates exposure pathways analyses and other exposure screening analyses to identify impacted communities, to include exposure investigations (biologic sampling, personal monitoring, etc.), and related environmental assessments, as appropriate; (5) issues public health advisories when a release or threatened release of a toxic substance poses an imminent health hazard; (6) provides technical support and field presence for routine emergency and disaster response as appropriate; (7) engages with regional partners to accomplish special programs that promote environmental health; (8) provides scientific expertise in environmental epidemiology; (9) designs and conducts human health, including epidemiologic, studies to evaluate the association between exposure to hazardous substances and adverse health effects; (10) provides expert medical and environmental epidemiologic consultation; and (11) implements extramural research programs that involve human health investigations.

- *Office of Capacity Development and Applied Prevention Science (JAAQD).* (1) Builds capabilities by translating science into tools and actions that individuals, communities, and organizations apply to identify, reduce, or prevent health effects from exposures to hazardous substances; (2) coordinates and conducts training, community engagement, and system development that addresses internal and external needs as well as builds capacity of end-users; (3) develops best practices, tools, and strategies for engaging with communities, and providing community engagement consultation to internal ATSDR partners (e.g., health educators); (4) conducts grant management, project officers' activities, and builds capacity development through strategy development, monitoring, and training; (5) serves as an incubator for new preventions, interventions, and implementation science; supports testing, development, and material design for community and health professional audiences; (6) designs and standardizes intervention initiatives for community audiences, evaluating intervention design methods, and

designing education campaigns; (7) designs and standardize intervention initiatives for health professionals, evaluating intervention design methods, and promoting environmental health content within clinical education programs; (8) designs, reviews and evaluates the scientific accuracy and clarity of health education materials; (9) informs and promotes integration of environmental health content within clinical education programs (e.g., coursework, clinical rotations, and primary care residency programs) and environmental medicine practice; (10) identifies and cultivates partnerships with academic and professional organizations to encourage uptake of environmental public health awareness curricula and career tracks; (11) develops community/population and clinical intervention initiatives to reduce risk factors associated with environmental exposures; (12) develops integrated clinical support guidance for patient care; (13) provides, promotes, and/or implements ATSDR-approved tools and training to partners (both internal [e.g., health educators] and external [e.g., state partners]) so that they can effectively engage communities using a standardized approach; (14) provides evaluation guidance and facilitates evaluation feedback loops related to ATSDR intervention initiatives, guidance materials, and support tools for continuous quality improvement and effectiveness of grant-supported work; (15) implements ATSDR's Site-Specific Cooperative Agreement Program; (16) plans, prepares, and executes appropriate community involvement and health educational strategies/activities/programs for communities affected or potentially affected by toxic substances released into the environment; (17) develops and tests metrics that could be used for public health surveillance or evaluation of intervention effectiveness; and (18) partners with relevant internal and external stakeholders to incorporate prevention strategies into existing programs, policies, and practices.

IV. *Delegations of Authority:* All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

(Authority: 44 U.S.C. 3101)

Alex M. Azar II,
Secretary.

[FR Doc. 2020-00181 Filed 1-8-20; 8:45 am]

BILLING CODE 4163-70-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-5254]

Fresenius USA, Inc., et al.; Proposal To Withdraw Approval of 249 Abbreviated New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of 249 abbreviated new drug applications (ANDAs) from multiple holders of those ANDAs and is announcing an opportunity for the ANDA holders to request a hearing on this proposal. The basis for the proposal is that these ANDA holders have repeatedly failed to file required annual reports for those ANDAs.

DATES: The ANDA holders may submit a request for a hearing by February 10, 2020. Submit all data, information, and analyses upon which the request for a hearing relies by March 9, 2020. Submit electronic or written comments by March 9, 2020.

ADDRESSES: The request for a hearing may be submitted by the ANDA holders by either of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments to submit your request for a hearing. Comments submitted electronically to <https://www.regulations.gov>, including any attachments to the request for a hearing, will be posted to the docket unchanged.

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
 - Because your request for a hearing will be made public, you are solely responsible for ensuring that your request does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such