

of one felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 4-year period of debarment.

As a result of the foregoing finding, Jun Yang is debarred for a period of 4 years from importing articles of food or offering such articles for import into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Jun Yang is a prohibited act.

Any application by Mr. Yang for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2014-N-0964 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 26, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 80 FR 1417-1419, dated January 9, 2015) is amended to reflect the reorganization of the Office of Public Health Scientific Services, Centers for Disease Control and Prevention.

Section C-B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and functions statements for the *Health Information Technology and Surveillance Strategy Unit (CPA3), Office of the Director (CPA)*,

Delete in its entirety the title and the mission and function statements for the

*Center for Surveillance, Epidemiology and Laboratory Services (CPN)* and insert the following:

*Center for Surveillance, Epidemiology and Laboratory Services (CPN)* The mission of the Center for Surveillance, Epidemiology, and Laboratory Services (CSELS) is to provide scientific service, expertise, skills, and tools in support of CDC's efforts to promote health; prevent disease, injury and disability; and prepare for emerging health threats. CSELS focuses on improving information and data quality, laboratory systems, and the public health workforce, through modernization, innovation, and service. To carry out its mission, CSELS (1) leads and executes a national public health surveillance strategy for human health that builds upon current resources, establishes priorities for the nation's next-generation capability and provides timely, comprehensive, and accessible information to strengthen public health practice, and provide value to clinicians; (2) participates in the identification, development, evolution, and adoption of informatics standards; (3) facilitates and coordinates program and laboratory systems integration for the Agency; (4) provides leadership and support to strengthen the quality and safety of laboratory practices; (5) provides leadership for scientific workforce education and advances professional development; (6) provides leadership on public health genomics strategy, activities, and planning; (7) creates and promotes access to quality, timely and useful cross-cutting scientific guidance, products, and services to strengthen the science and practice of public health and to improve public health decision-making.

*Office of the Director (CPN1)*. (1) Provides strategic direction regarding surveillance, epidemiologic investigation, and data and information sciences; (2) supports OPHSS's CDC-wide coordination and strategic activities in areas of health informatics technology, including the meaningful use of electronic health records for public health surveillance and the coordination of partners and stakeholders for biosurveillance, genomics, and publication science; (3) leads the development of public health workforce training; (4) guides the development of laboratory systems standards for quality and safety, including the Clinical Laboratory Improvement Amendments (CLIA) and engagement with relevant federal advisory committees; (5) manages, directs, coordinates, and evaluates the activities of the Center; (6) defines goals and objectives for policy formation,

scientific oversight, and guidance in program planning and development; (7) establishes and implements a communications strategy in support of CSELS overarching goals and priorities; (8) provides oversight for the evaluation of programmatic performance of all CSELS activities to ensure health impact; (9) plans, coordinates, and manages all aspects of program business services including human and fiscal resources, extramural activities, space, and all administrative services; (10) devises information technology practices and procedures, and provides direction, innovation, planning and evaluation for information technology systems, services, security, and resources for CSELS; (11) provides leadership on issues management, budget formulation and performance integration; (12) manages inter-governmental and external affairs and cultivates strategic partnerships; (13) ensures scientific quality, integrity, and clearance across the Center; (14) provides guidance and strategic oversight to the processes within the Center that access, collect, manage, analyze, and visualize data, including assistance for involvement with federal advisory committees and other high level groups; (15) monitors projects for effective focus on the analytical, informatics, data management, and statistical infrastructure to deliver quality data, accurate analysis services and dependable software products and systems to customers and partners; (16) collaborates and consults with other Centers, working groups, state and local health departments, other federal agencies, and other partners, to accomplish the mission of the Center; (17) reviews, prepares, coordinates, and develops Congressional testimony and briefing materials; and (18) represents the CSELS and at times CDC at professional and scientific meetings, within and outside CDC.

*Division of Laboratory Systems (CPNB)*. The mission of the Division of Laboratory Systems (DLS) is to provide leadership, support, and cross-cutting services to continually strengthen the capability, sustainability, and quality of laboratory science, policy, and practice at CDC, in clinical and public health laboratories, both in the United States and with international partners. DLS strives to strengthen and align the capacity and ability of both clinical and public health laboratories to perform their critical roles in protecting the public's health. In this mission, DLS: (1) Fosters collaboration across the laboratory community; (2) strengthens integration of laboratory science,

practice, and informatics into public health and patient care; (3) develops and advances the use of standards, policies, and guidelines to ensure safe and accurate laboratory performance and strong laboratory systems; (4) conducts studies to evaluate and improve the quality of laboratory practices and services; (5) strengthens the laboratory workforce; and (6) enhances the efficiency, effectiveness, capacity and capability of the public health laboratory system through integration of CDC program support.

*Office of the Director (CPNB1).* (1) Provides leadership and guidance for strategic planning and implementation, establishes goals and program priorities, and engages in policy development to advance the mission of the Division, the Center, and CDC; (2) directs and provides public health vision for laboratory practices and systems; (3) contributes to national cross-cutting efforts to standardize and accelerate electronic reporting of laboratory results to improve patient care and public health surveillance; (4) provides leadership, oversight, and guidance in the business management and operations, including budget formulation and planning, of the Division of Laboratory Systems (DLS) programs; (5) directs, applies, and translates research and evaluation initiatives for laboratory practices, standards, and services; (6) oversees laboratory specimen management policies and the CDC/ATSDR Specimen Packaging, Inventory, and Repository (CASPIR); (7) oversees, manages, and supports the CLIA program and relevant federal advisory committees; (8) collaborates with the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration in the CLIA program; (9) coordinates CDC efforts to support state and local public health laboratories in promoting sustainability of national testing services and capacity; (10) coordinates CDC's interaction with other government agencies; (11) performs scientific review and clearance for Division publications, presentations, and reports; (12) assists in the management the information collection and training to support the reporting and the implementation of CDC various regulatory requirements; (13) assist the agency in the development and management of laboratory domains for various trainings and fellowships; (14) provides communications, web support, responses to media requests, and Division communication outreach efforts; (15) advises the Center OD on matters relating to laboratory practice

and coordinates Division responses to requests for technical assistance or information about activities supported by the Division; (16) reviews, prepares, coordinates, and develops Congressional testimony and briefing materials; and (17) represents the Division and at times CSELS or CDC at professional and scientific meetings, within and outside CDC.

*Laboratory Training and Services Branch (CPNBC).* (1) Provides advanced laboratory training to maintain a competent, prepared, and sustainable national and global laboratory workforce for testing of public health importance; (2) engages agency and laboratory community experts to collaboratively develop effective training products which incorporate safety and quality laboratory practices; (3) assesses, designs, develops, and implements effective needs-based training pertaining to clinical and public health laboratory methodology, technology, safety and practice; (4) evaluates the efficiency and effectiveness of public health laboratory education and training for state and local public health, clinical, uniformed service, CDC, and other federal agency laboratory professionals; (5) evaluates the effectiveness and measures the outcomes of all training to ensure quality and safety; (6) provides oversight and management for CDC/ATSDR Specimen Packaging, Inventory, and Repository (CASPIR); (7) provides services for the safe storage, cataloging, assembly and shipping of isolates, panels, and other reference materials; (8) provides informatics support and project management for the specimen inventory management system and other databases related to public health laboratory services; and (9) evaluates the effectiveness of the branch's scientific support services and products to its customers.

*Laboratory Practice Standards Branch (CPNBD).* (1) Provides technical expertise and support for oversight and implementation of the CLIA program and relevant federal advisory committees; (2) develops laboratory practice standards and guidelines, and assists with their adoption and validation; (3) supplies technical assistance and review of laboratory accreditation, state licensure programs, and proficiency testing programs; (4) provides scientific consultation for inquiries about testing complexity, personnel qualifications, quality control and quality assessment, and proficiency testing; (5) evaluates the applicability of federal quality standards to new laboratory technologies and establishes new alternative quality assurance measures; (6) interprets and assists the

implementation of CLIA regulations; (7) collaborates to develop standards and guidance for laboratory information management in electronic health records and laboratory reporting for CDC's surveillance strategy; (8) supports the Clinical Laboratory Improvement Advisory Committee, its subcommittees, and workgroups; (9) provides scientific support for issues related to the development and implementation of cytology and related pathology standards; (10) assists in the development and review of laboratory performance standards and guidelines; and (11) disseminates information about laboratory standards and practices.

*Laboratory Research and Evaluation Branch (CPNBE).* (1) Encourages establishment and adoption of performance standards and guidelines for laboratory practice; (2) develops, evaluates, and implements systems for measuring and assessing laboratory quality; (3) facilitates and conducts research and demonstration projects to support the scientific development of performance standards and guidelines, evaluation systems, and regulatory standards; and assesses the efficacy of established standards; (4) develops, promotes, implements, and evaluates intervention strategies to improve general performance deficiencies in health laboratory systems and worker competencies; (5) provides a forum for exchange of information about laboratory practice and research and development activities to promote the coordination of federal, state, and clinical laboratory improvement efforts; (6) coordinates and conducts activities that provide technical and scientific support to CMS in its evaluation, development, and revision of standards and guidelines; (7) evaluates current and emerging practices and provides guidance to ensure and promote quality in the application of advanced molecular technologies; (8) evaluates emerging technology and the impact on clinical and public health laboratory practice; (9) collaborates with other CDC genomics programs, including the Office of Public Health Genomics, for broad genomics policy initiatives; and (10) collaborates in the development of standards and guidance for laboratory information management in electronic health records in support of CLIA objectives and electronic laboratory reporting to support CDC's surveillance strategy.

*Division of Public Health Information and Dissemination (CPNC).* The primary mission of the Division of Public Health Information and Dissemination (DPHID) is to serve as a hub for scientific publications, information and library

sciences, systematic reviews and recommendations, and public health genomics, thereby collaborating with CDC CIOs and the public health community in producing, disseminating, and implementing evidence-based and actionable information to strengthen public health science and improve public health decision-making.

In carrying out its mission, DPHID: (1) Provides leadership and overall direction for the execution of programs that produce scientific publications, strengthen public health science, and provide access to scientific research and innovative products for improving population health and public health decision making; (2) identifies what works in community preventive services and collaborates with CDC and the public health community to educate and encourage action to improve public health; (3) serves as a hub of research, information exchange, and learning for the CDC and the public health community; (4) provides access to scientific literature and systematic review support; (5) sets and ensures adherence to quality standards for manuscripts, reports, and other scientific products; (6) develops curriculum, training, and consultation services for CDC and other federal and non-federal partners to foster the development of skills in publication of public health information, systematic reviews, library sciences, and information literacy; (7) presents a selection of public health genomic approaches, studies, and lessons learned from efforts to build greater program collaboration and service integration; (8) advances the field of public health informatics for CSELS and the Agency through applied research and innovation; and (9) through strategic communications, fosters collaboration with CIOs across CDC and the public health community to encourage dialog about actions that can be taken to improve the quality of science and public health decision making.

*Office of the Director (CPNC1).* (1) Provides leadership and strategic direction on program priority setting to advance the mission of the Division, Center and CDC to achieve critical public health outcomes; (2) advises CSELS OD on matters relating to genomics, systematic reviews and recommendations, information and library sciences, scientific publications, dissemination and implementation, and informatics innovation; (3) defines goals and objectives for policy formation, scientific oversight, and guidance in program planning and development; (4) develops budgets, allocates resources,

monitors progress, and reports accomplishments, future directions, and resource requirements; (5) establishes and implements a communications strategy in support of the Division's overarching goals and priorities; (6) fosters engagement, collaboration, and strategic partnerships with CDC Programs, other federal agencies, and with the public health community in support of Division and Center priorities; (7) oversees and coordinates proactive and reactive issues management related to Division programs; (8) provides oversight for the evaluation of programmatic performance of all Division activities to ensure health impact; (9) ensures scientific quality and integrity across the Division; (10) performs scientific review and clearance and may provide direct managerial and editorial oversight for Division publications, presentations, and reports; (11) collaborates with CSELS OD and Division programs to ensure adherence to information technology standards, procedures and requirements; (12) provides Division-level oversight to management, administration, human resources, business, extramural, space, and support services, and coordinates with relevant offices and programs on administrative matters; (13) reviews, prepares, coordinates, and develops Congressional testimony and briefing materials; and (14) represents the Division and at times CSELS or CDC at professional and scientific meetings, within and outside CDC.

*Informatics Innovation Unit (CPNC12)* (1) Advances the field of public health informatics for CSELS and the Agency through applied research and innovation; (2) collaborates with CDC programs and the broader public health community to develop innovative technologies and techniques to positively impact public health practice; (3) transitions new informatics solutions, standards, and techniques to public health programs for deployment and implementation; (4) provides CDC and its external research and public health partners with consultation, evaluation, guidance, and support in the use of new informatics solutions for public health practice; (5) leverages its resources to rapidly create prototypes, conduct pilot projects, and examine and test hypotheses generated by CSELS, CDC, and its external partners to support innovative public health informatics solutions; (6) provides CDC, and its external partners an optimal (*i.e.*, flexible and scalable) environment for the rapid development of prototype and pilot public health informatics solutions

for collaboration, testing and evaluation purposes; (7) participates and represents CSELS within innovation committees, workgroups, organizations, and councils, within CDC and with other federal agencies as well; (8) facilitates public health informatics innovation within the Agency and the public health community, through partner outreach and collaboration, using crowdfunding, challenge grants, and other novel cost efficient mechanisms; (9) disseminates relevant knowledge to CDC and its partners via presentations, manuscripts, web-based content and other modalities; (10) provides education to fellows, colleagues, and partners on emerging informatics tools, techniques, and methodologies; and (11) provides regular updates to CSELS leadership as to the status of all projects in the technology laboratory.

*Office of Public Health Genomics (CPNC13).* The Office of Public Health Genomics is charged with identifying opportunities for genomics to improve health and transform health care, informing CDC and partners about evidence-based genomic applications to impact health, and integrating evidence-based genomic applications into practice and programs—including pathogen genomics (advanced molecular detection), genomic markers for birth defects, reproductive health, child health, chronic disease as well as environmental and occupational exposures. To accomplish these aims, the Office (1) integrates advances in pathogen and human (*e.g.*, birth defects) genomics responsibly and effectively into health care and disease prevention; (2) provides technical assistance and advice to CDC leadership and programs, other federal agencies, state health departments, and other external partners by identifying, evaluating, and implementing evidence-based genomics practices to prevent and control the country's leading chronic, infectious, environmental, and occupational diseases; (3) supports policy, education, and surveillance frameworks to promote effective implementation of evidence-based recommendations for genomic tests and family health history applications that can save lives now, as well as those applications that will emerge in the next decade and beyond; (4) fosters public health genomics programs at the state and national level by providing ongoing consultation and tools to state health departments, CDC programs, and other stakeholders to share successful approaches to promote the optimal use of genomic tests; (5) evaluates emerging genomic applications with the potential to

impact population health; (6) supports the evaluation of genomic applications in the development of an evidence framework for introducing whole genome sequencing into practice, assessing the role of genomics and family history in recommendations for chronic disease; (7) identifies new emerging genomic applications with the potential to impact population health through horizon scanning and evidence summaries of validity and utility; (8) sponsors the development of stakeholder driven methods working group for accelerating research translation of genomics into practice and programs; (9) communicates evidence-based messages through well-established communications channels, including the Genomics and Health Impact Update & Blog, CDC Expert Commentary Series on Medscape, the CDC Web site, publications, and other means; (10) conducts programmatic efforts to implement public health genomics interventions and surveillance in partnership with state public health departments; and (11) conducts public health genomics epidemiologic studies and analyses based on health and biometric data.

*Community Guide Branch (CPNCC).* The Community Guide Branch collaborates with CDC and the public health community to identify effective community preventive services and to educate and encourage action to improve public health. To accomplish these aims, the Branch: (1) Convenes and provides ongoing administrative, research, and technical support for the operations of the independent Community Preventive Services Task Force (Task Force), as directed by statutory mandate; (2) conducts and oversees production of the systematic reviews that serve as the scientific basis for Task Force findings and recommendations; (3) coordinates and manages large and diverse teams of internal and external partners participating in the systematic review process; (4) participates with other CDC programs and other federal and non-governmental partners in developing and refining methods for conducting systematic reviews; (5) assists CDC and other federal and non-federal partners in understanding, using, and communicating methods for conducting systematic reviews; (6) assists CDC and other federal and non-federal partners in linking reviews of evidence to guidelines development and program implementation; (7) assists the Task Force in producing reports on evidence gaps and priority areas for further examination; (8) establishes, updates,

and evaluates the utility and use of the Community Guide Web site ([www.thecommunityguide.org](http://www.thecommunityguide.org)) by intended users; (9) convenes and participates with other CDC programs and other federal and non-governmental partners in (a) disseminating products and promotional materials throughout the U.S. health care and public health systems and to their multi-sectoral partners via a variety of media, such as journals, books, documents, the World Wide Web, and other media, (b) developing and testing policies and processes for referencing Task Force findings in research and programmatic funding announcements to increase use of Task Force findings and fill evidence gaps, and (c) developing, refining, and evaluating methods for assisting users in implementing Task Force recommendations; (10) convenes and participates with other CDC programs and other federal and non-governmental partners in establishing methods for evaluating implementation, use, and impact of Task Force-recommended strategies; (11) participates in the development of national and regional public and private partnerships to enhance prevention research and the translation of evidence into policy and action; (12) provides epidemiologic and scientific support for health departments, non-profit hospitals and other community-based organizations engaged in community health improvement; (13) maintains scientific expertise in cross-cutting measures of population health and population health determinants; (14) develops stakeholder-driven epidemiological resources including analytic tools and scientific resources for identifying community health priorities and health disparities, and monitoring and evaluating public health impact; (15) hosts and periodically updates the Community Health Status Indicators web application; and (16) participates with CDC and other federal and non-federal partners to encourage multi-sector collaborations that support shared ownership of community health improvement.

*Library Science and Services Branch (CPNCD).* The Stephen B. Thacker CDC Library supports CDC's scientific and public health information needs by serving as CDC's resource for library collections, electronic and hardcopy resources, customized library services and tools, and information exchange and learning. To accomplish these aims, the Branch: (1) Develops, curates, and sustains collections of public health information, including (a) providing a user-friendly portal to collections

through cataloging, classification, and metadata tagging that improves efficiency and access, (b) evaluating library resource usage data to assess collection usefulness and inform purchasing decisions; and (c) preserving collections that document CDC's role in public health missions, and unique, one-of-a-kind, historical, out-of-print and archival collections, (2) provides CDC scientists with ready and timely access to electronic and hardcopy scientific and public health programmatic resources, including (a) document delivery and interlibrary loan services, and (b) access to journals, databases, electronic and print books, (most via the CDC intranet to the employee's desktop); (3) provides library science technical assistance (including for systematic reviews), training, and tools including (a) tailored literature searches, (b) reference services at the main library and library branches, (c) subject matter depth to better assist CDC science staff including the science and practice of systematic reviews, (d) training CDC staff to utilize library resources more efficiently and effectively, and (e) delivery of Science Clips—a weekly summary of notable publications—to CDC scientists and external partners; (4) provides and manages facilities for scientific inquiry, learning and research including space for conferences, meetings, computer and other training, hoteling, accessing special collections, and checking email; (5) provides staff support to the Library Advisory Board, whose members ensure their CIO's needs are considered in library operations and planning; and (6) collaborates with other federal libraries, Atlanta medical libraries, other library and information scientists, and public health partners to increase access to resources and explore innovations in information and library science that will enhance efficiency and effectiveness in meeting the information needs of the public health workforce.

*Scientific Publications Branch (CPNCE).* Produces and disseminates timely, reliable, accurate, credible scientific information for public health action through publications and companion materials. Branch includes the *MMWR* Series and *Vital Signs*, and may accommodate other CDC publications. To accomplish these aims, the Branch: (1) Develops publications and companion materials that serve as primary vehicles for dissemination of CDC policy statements (*MMWR*) or calls to action (*Vital Signs*); (2) works directly, quickly and collaboratively with CDC programs and CDC OD, and actively solicits content; (3) provides

complete editorial services, from conception of content to final proofreading; (4) builds public health capacity to share information for public health action by publishing the work of state, local and foreign health departments and working with inexperienced authors, as well as, provides consultation and training on relevant publication matters; (5) assures that publications and companion materials meet current publications and scientific standards, facilitates compliance with OSTP memo to link published reports with underlying data, and advances publication platforms such as inclusion of interactive options; (6) actively seeks mechanisms to disseminate content further through collaboration with the CDC Office of the Associate Director for Communication (e.g., media releases, fact sheets, Web sites, and social media), non-CDC publications (e.g., *Journal of the American Medical Association*, *Journal of Public Health*, *Pediatrics*), and other federal, state and local government agencies and non-government partners; (7) leads innovation in publication standards across the publication field that affect CDC's mission, such as recommendations and guidelines, in collaboration with other scientific publications and the Council of Scientific Editors; (8) meets informational needs of primary and secondary audiences, including state and local health agencies, policy makers, public health practitioners, clinicians, nurses and school and health educators, and the general public; (9) monitors and evaluates dissemination strategies, publication impact, and public health impact to optimize publications and companion materials; (10) produces and disseminates evidence-based, actionable information on a selected topic each month to the public, media outlets, and public health and medical health providers; and (11) coordinates and manages all aspects of Vital Signs releases by the Office of the Director, CDC.

*Division of Scientific Education and Professional Development (CPND).* The primary mission of the Division of Scientific Education and Professional Development (DSEPD) is to improve health outcomes through a competent, sustainable, and empowered public health workforce. In carrying out its mission, DSEPD: (1) Plans, directs and manages programs that develop the current and future public health workforce (including the field of public health laboratory science and practice); (2) provides leadership in scientific workforce education and development,

including quality assurance, technical consultation and evaluation; and (3) provides leadership to facilitate or coordinate CDC and partner strategic workforce initiatives to increase capability of the current workforce, expand pipeline programs to recruit new talent, strengthen systems to support the workforce, and leverage partnerships to maximally achieve goals.

*Office of the Director (CPND1).* (1) Provides leadership and overall direction for DSEPD; (2) develops goals and objectives, and provides leadership, policy formation, scientific oversight, and guidance in scientific education and professional development program planning and development; (3) plans, coordinates, and develops workforce-related research plans for DSEPD; (4) ensures adherence and provides training to DSEPD on CDC and HHS science-related policies; (5) oversees and manages DSEPD clearance process for scientific, technical, and programmatic documents; (6) manages DSEPD communication activities, including communication product development, promotion and dissemination strategies, media relations coordination, and DSEPD Web sites; (7) responds to freedom of information requests and controlled correspondence; (8) coordinates all DSEPD program reviews; (9) reviews, prepares, coordinates, and develops Congressional testimony and briefing materials; (10) leads Division programmatic evaluation activities, assists DSEPD programs in establishing performance metrics, and coordinates quarterly reviews with programs to ascertain status on meeting of the metrics; (11) coordinates DSEPD budget formulation and negotiation related to program initiatives and goals management; (12) provides leadership, oversight, and guidance in the management and operations of DSEPD programs, including agency-wide assistance with OMB requirements and policy; (13) ensures and promotes the use of best practices in scientific education and professional development processes, services, and products; (14) provides leadership and guidance on new developments and national trends for public health workforce education and training; (15) establishes policies and standards for public health education and training activities and initiatives, including but not limited to, competency development, quality assurance, and evaluation, and works collaboratively within DSEPD and other components of CDC to ensure their implementation and adoption; (16) develops and implements

a crosscutting framework for planning, implementing, and evaluating fellowship training programs that provide service to the organizations where fellows are assigned (e.g., CIOs, SLHDs) and the communities they serve, and are responsive to the needs of CDC's internal workforce and to the needs of DSEPD's external partners, including the academic sector; (17) manages pilot fellowship programs in early stages of development, as needed; (18) develops and manages unified DSEPD-wide administrative systems and supports the commitment of resources for application development; (19) coordinates management information systems and analyses of data for improved use of DSEPD resources; and (20) directs systems analysis and design, programming, and systems training as it relates to implementation of new and existing administrative, management, and executive information systems; (21) provides leadership to coordinate CDC and partner strategic workforce initiatives to increase capability of existing workforce, expand pipeline programs to recruit new talent, and strengthen systems to support the workforce; and (22) represents the Division and at times CSELS or CDC at professional and scientific meetings, within and outside CDC.

*Education and Training Services Branch (CPNDB).* (1) Plans, directs, and manages training design, development, consultation, and delivery, and accredits educational activities for entry level public health professionals and the existing public health workforce; (2) identifies and implements best practices and methods for developing the public health workforce; (3) develops evidence-based policies and standards for public health education and training activities and initiatives, including but not limited to, competency development, quality assurance, and evaluation, and provides technical assistance within DSEPD and other components of CDC to ensure their implementation and adoption; (4) develops and maintains appropriate liaisons with all fellowship programs in DSEPD, and provides technical assistance to other programs across the agency to ensure the development of rigorous educational programs based on the science of adult learning and instructional technology; (5) facilitates a cross-cutting approach and sharing of educational/evaluation lessons learned and tools across DSEPD programs, as well as other programs across the agency; (6) provides guidance in planning and implementation of the educational components of complex

systems and processes to support learners, such as fellows and other learners seeking continuing education to ensure data requirements are consistent with the evaluation framework and capture educational outcomes of learners; (7) provides consultation, guidance, and technical assistance to course developers, incorporating principles of learning theory to ensure consistent design and delivery of accredited educational activities; (8) maintains knowledge of continuing education standards and applies quality assurance practices required to uphold national accreditations; (9) assesses need and demand for additional accreditations to support professional license and certification needs of technical and professional staff within the health workforce; (10) develops and maintains internal and external partnerships to foster best practices in the design and delivery of educational activities and training; (11) maintains knowledge of information technology and learning standards as they apply to education and training to demonstrate and promote compliance and best practices by CDC programs; (12) applies the principles of instructional systems design and learning theory to design, develop, deliver, and evaluate informational and instructional products; (13) implements and maintains technology-based systems to support learners, such as CDC Training and Continuing Education Online, a web-based accreditation and registration system; (14) coordinates educational opportunities and resources for learners across public health and health care through the CDC Learning Connection Web site, which includes CDC TRAIN, an online portal that provides learners no-cost access to a comprehensive catalog of learning products; (15) adapts information systems and processes to reflect current best practices and adherence to accreditation requirements; and (16) provides technical assistance and guidance to learners to ensure accreditation and learner support.

*Epidemiology Workforce Branch (CPNDC).* (1) Plans, directs, and manages CDC-wide training and service programs for teaching and training future public health professionals, and supports the existing workforce in applied epidemiology, including but not limited to the Epidemic Intelligence Service Program, Epidemiology Elective for Senior Medical and Veterinary Students, and the CDC-Hubert Global Health Fellowship; (2) plans, directs, and evaluates elementary and high school student program pipeline

activities intended to increase the number of individuals aware of and choosing a career in public health; (3) sponsors complementary activities to train teachers to develop lesson plans of public health significance for middle and high school students; (4) establishes and implements overall Branch policies, plans, and procedures; (5) develops and implements a formal plan to evaluate the effectiveness of all fellowship program activities, including the completion of program activities by EIS officers (EISOs), quality of field and HQ assignments, performance of officers, and effectiveness of educational activities; (6) conducts site visits and maintains liaison with supervisors of EISOs within CDC and in field assignments; (7) coordinates the assignment and deployment of EISOs in response to natural disasters, terrorist events, and other large scale public health emergencies; (8) provides technical assistance, consultation, resources, and training for DSEPD, other components of CDC, and the broader health workforce (*e.g.*, state and local workers), including, but not limited to the development and dissemination of standard curricula, training, and related materials, in epidemiology; (9) maintains liaison with alumni within and outside CDC to assist with training, recruitment, and promotional activities; (10) responds to domestic and international requests for assistance and consultation (*e.g.*, Epi-Aids); (11) maintains liaison with other governmental agencies, academic institutions and organizations, state and local health agencies, private health organizations, professional organizations, and other outside groups; (12) assumes an active national and international leadership role in applied epidemiology training; and (13) collaborates, as appropriate, with the CDC/OD, other CIOs, and domestic and international agencies to carry out the functions of the branch.

*Population Health Workforce Branch (CPNDD).* (1) Plans, directs, and manages CDC-wide training and service programs for teaching and training future public health professionals, and supports the existing workforce in applied public health sciences, including but not limited to the Preventive Medicine Residency/Fellowship, Public Health Informatics Fellowship, Prevention Effectiveness Fellowship, and the Presidential Management Fellows Program; (2) operates and maintains an accredited preventive medicine residency program for physicians in CDC through the Accreditation Council for Graduate

Medical Education and a complementary fellowship program for public health veterinarians; (3) establishes and implements overall Branch policies, plans, and procedures; (4) develops and implements a formal plan to evaluate the effectiveness of all fellowship program activities, including the completion of program activities by fellows and residents, the quality of field and HQ assignments, performance of fellows/residents, and effectiveness of educational activities; (5) conducts site visits and maintains liaison with supervisors of fellows/residents within CDC and in field assignments; (6) coordinates the assignment and deployment of fellows/residents in response to natural disasters, terrorist events, and other large scale public health emergencies; (7) provides technical assistance, consultation, resources, and training for DSEPD, other components of CDC, and the broader health workforce (*e.g.*, state and local workers), including, but not limited to the development and dissemination of standard curricula, training, and related materials, in preventive medicine, informatics, prevention effectiveness and leadership/management and policy; (8) maintains liaison with alumni within and outside CDC to assist with training, recruitment, and promotional activities; (9) responds to domestic and international requests for assistance and consultation (*e.g.*, Info-Aids, Econ-Aids); (10) maintains liaison with other governmental agencies, academic institutions and organizations, state and local health agencies, private health organizations, professional organizations, and other outside groups; (11) assumes an active national and international leadership role in applied public health sciences training in preventive medicine, public health informatics, prevention effectiveness, and leadership and management, and policy; (12) collaborates, as relevant, with the CDC/OD, other CIOs, and domestic and international agencies to carry out the functions of the branch; (13) fosters closer linkages between academia and public health practice; (14) supports and provides oversight for cooperative agreements with academic partner organizations to enhance development of public health and health professionals skilled in improving the health of populations; (15) provides technical consultation to academic associations regarding improvements in curriculum and experiential learning opportunities; and (16) works with partners in academia, state and local health agencies, public health and health professional

organizations to address public health educational needs, including developing population health competencies for academia to improve health professional education (e.g., schools of medicine, nursing, and public health).

*Division of Health Informatics and Surveillance Systems (CPNE).* The mission of the Division of Health Informatics and Surveillance Systems (DHIS) is to provide leadership and cross-cutting support in developing public health information systems, managing public health surveillance programs, and provisioning health-related data required to monitor control, and prevent the occurrence and spread of diseases and other adverse health conditions. DHIS strives to improve surveillance and the quality of data for decision making through a focus on transparency and trust in collaborations with public health partners while applying new and efficient information technologies, standardized data collection processes, improved data analysis methods, and versatile and user friendly information systems. DHIS promotes a multidisciplinary approach (which includes epidemiology, statistics, analytics, data management, informatics, and evaluation sciences) to assure that the surveillance programs, information systems, and data serve public health program objectives.

*Office of the Director (CPNE1).* (1) Provides leadership and overall direction for execution of programs that support public health surveillance, access to data for public health decision making, development of public health information systems, and the application of epidemiology and informatics to improve public health, playing a significant role in advising CDC senior leadership; (2) conducts strategic planning and establishes Division goals, objectives and priorities and assures alignment with the Center's and CDC goals, objectives and priorities; (3) provides coordination and guidance for a portfolio of projects and activities that address notifiable disease reporting, syndromic surveillance, surveillance best practices, data standards and harmonization, cutting edge IT solutions, analytic data management, software development for epidemiologic investigations, and partnership engagement on Division programs; (4) promotes a multidisciplinary approach (epidemiology, statistics, analytics, data management, informatics, evaluation sciences, and contract management) to assure that CDC surveillance and information systems serve public health program objectives; (5) works with internal and external partners to

monitor and inform strategies related to informatics, data standards, health information technology, and health care-public health integration; (6) monitors progress in implementation of Division projects and activities, and evaluates the impact of Division initiatives that support CDC and the Center's goals, objectives, and priorities; (7) provides oversight and approval of scientific products including manuscripts, Web sites, databases, reports, and other documents; (8) assures compliance with all federal rules and regulations regarding research with human subjects, the paperwork reduction act, and data sharing; (9) facilitates scientific, policy, communication, technology, and program collaboration among Divisions and centers, and between CDC and other federal and non-federal partners; (10) provides communication and policy expertise in support of Division activities and responds to requests for information from CSELS OD and Divisions, OPHSS OD, and other internal and external organizations; (11) provides Division-level management, administration, support services, and coordinates with appropriate offices on program and administrative matters; (12) develops Division budget, monitors progress and allocation of resources, and plans for future resource requirements; (13) coordinates Division requirements relating to procurement, grants, cooperative agreements, material management, and interagency agreements; (14) provides fiscal management and stewardship of grants, contracts, and cooperative agreements, serving as a resource for robust contract management for CSELS; (15) develops and implements administrative policies, procedures, and operations for the Division; (16) represents the Division and at times CSELS and CDC at official professional and scientific meetings, both within and outside of CDC; (17) advises CSELS OD on workforce engagement CSELS-wide; (18) reviews, prepares, coordinates, and develops Congressional testimony and briefing materials; and (19) performs scientific review and clearance for Division publications, presentations, and reports.

*Surveillance and Data Branch (CPNEC).* (1) Provides leadership, operational support, and data management for two national surveillance programs, the National Notifiable Disease Surveillance System (NNDSS) and the National Syndromic Surveillance Program (NSSP); (2) collaborates with stakeholders to identify and analyze surveillance needs and align them with informatics

solutions and data management practices and policies; (3) provides subject matter expertise (SME) and technical assistance for harmonizing data collection across surveillance programs and employing current data standards; (4) uses analytic data management techniques to provision surveillance data to CDC programs and partners, and provides analysis and interpretation for MMWR tables and reports based on NNDSS data; (5) works with CDC programs and State, Tribal, Local and Territorial (STLT) programs on business requirements for the IT solutions used for surveillance including the CDC Platform and Message Validation Processing System (CDCP-MVPS) and the BioSense application; (6) manages data use agreements and memorandums of understanding for data sharing and acquisition of external data sources (e.g., CMS, MarketScan, VA data) for use by CDC programs; (7) provides technical assistance and consultation on analytic methods, analytic data management, and analysis of complex data to other units within CDC; (8) supports the acquisition of analytic tools, and the development of analytic and visualization methods for data analysis; (9) develops and maintains the WONDER Web site for the dissemination of multiple data sources; (10) collaborates with CDC and STLT programs on studies of data quality, representativeness, and investigations of disease or condition occurrences; and (11) provides technical monitoring for cooperative agreements with public health partners on informatics and surveillance related projects.

*Information Systems Branch CPNEB.* (1) Provides innovative informatics solutions and services that support public health information systems for CDC programs and external partners; (2) develops and supports a portfolio of preparedness information systems including the Countermeasure Tracking Systems and the Laboratory Reporting Network; (3) provides subject matter expertise (SME) and technical support to client programs in information technology systems design, project management, data interchange strategies, data management, security, architecture, systems integration, technical standards, best practices, federal regulations, and protocols for deploying and operating systems at CDC; (4) finds opportunities for and develops shared information technology components that can be used by multiple programs and partners in order to increase efficiency, decrease cost, and promote interoperability and

information sharing; (5) provides information technology services to CDC programs and external partners including modernization of legacy applications; (6) provides IT project management for two surveillance programs—the National Notifiable Disease Surveillance System and the National Syndromic Surveillance Program—including the development of the CDC Platform and Message Validation Processing System (CDCP–MVPS) the BioSense application, and the NEDSS Base System (NBS); (7) develops, maintains, and improves epidemiologic tools for data collection, data management, and data analysis, including Epi Info; (8) provides training, technical assistance, and support to public health partners and entities using Epi Info for outbreak investigations, studies, and surveillance; (9) provides SMEs, specifications, and services for standards-based data interchanges, electronic messaging, vocabulary management, message validation, security and credential management, routing and directory management; (10) provides consultation and technical assistance to CDC programs and to external partners on technical and informatics aspects of systems and tools required or endorsed by CDC; (11) provides Public Health Information Network (PHIN) certification; and (12) provides support, technical assistance, and strategic counsel to CDC programs for the transition from ICD–9 to ICD–10 (and future iterations).

*Partnerships and Evaluation Branch (CPNED).* (1) Supports CDC and STLT Programs in the conduct of national surveillance; (2) supports and manages STLT and partner organizations cooperative agreements with regard to fiscal support and monitoring of expenditures; (3) coordinates the development of Funding Opportunity Announcements, Interim Progress Report Guidance, and Continuation Applications; (4) monitors activities of partner organizations and STLT cooperative agreements to assure program goals, objectives and key performance indicators are achieved; (5) assesses technical assistance needs of grantees and develops strategies to address those needs; (6) collaborates with other DHIS branches and programs in the development of evaluation criteria and performance measures for program planning and improvement; (7) leads and coordinates or develops and implements guidelines, uniform reporting procedures, performance measures, and evaluation criteria for STLT and other external partner cooperative agreements and grants; (8)

works with other DHIS branches to synthesize, translate, and disseminate evaluation findings, success stories, and lessons learned; (9) coordinates and supports Division training activities related to analytic data bases and data collection and information systems; (10) develops and manages collaborative relationships with grantees and partners to increase awareness, understanding, and support for DHIS initiatives and priorities; (11) supports and facilitates partnership outreach and communications to existing and new partners; (12) provides guidance and support on the establishment and governance of Communities of Practice associated with DHIS programs; and (13) provides leadership for coordinating technical assistance and support to other CDC programs, STLT grantees, and other external partners or organizations.

**James Seligman,**

*Acting Chief Operating Officer, Centers for Disease Control and Prevention.*

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**BILLING CODE 4160–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Prospective Grant of Start-Up Exclusive Evaluation Option License Agreement: Pre-Clinical Evaluation and Commercial Development of Anti-Tyrosine Kinase-Like Orphan Receptor 1 Antibody-Drug Conjugates for the Treatment of Human Cancers**

##### *Correction*

In notice document 2015–06486 appearing on pages 15226–15227 in the issue of Monday, March 23, 2015 make the following correction:

On page 15226, in the third column, under the **DATES** heading, in the last line, “April 6, 2015” should read “April 7, 2015”.

[FR Doc. C1–2015–06486 Filed 3–31–15; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID FEMA–2015–0001; Internal Agency Docket No. FEMA–B–1474]**

#### **Changes in Flood Hazard Determinations**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Title 44, Part 65 of the Code of Federal Regulations (44 CFR part 65). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

**DATES:** These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

**ADDRESSES:** The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at [www.msc.fema.gov](http://www.msc.fema.gov) for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

**FOR FURTHER INFORMATION CONTACT:** Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA,