

University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073 or 513-745-3396.

Contact Persons:

For information regarding this notice: Steven Eastham, Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237, 513-679-2700, ext. 123, e-mail: steven.eastham@fda.hhs.gov.

For information regarding the conference and registration: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073, e-mail: phillipsm4@xavier.edu.

Registration: There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions,

breakfasts, lunches, dinners, and dinner speakers for the 3 days of the conference. Early registration ends May 14, 2010. Standard registration ends June 13, 2010. There will be onsite registration. The cost of registration is as follows:

TABLE 1.—REGISTRATION FEES¹

Attendees	Fees by May 14th	Fees by June 13th
Industry	\$995	\$1,200
Small Business (< 100 employees)	\$800	\$1,000
Academic/Government	\$600	\$700
Student	\$200	\$250
FDA Employee	Fee waived	Fee waived

¹ The fourth registration from the same company is free.

The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.

To register online for the public conference, please visit the "Registration" link on the conference Web site at <http://www.XavierGOC.com>. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, e-mail, and payment information for the fee to Xavier University, Attn: Sue Bensman, 3800 Victory Pkwy., Cincinnati, OH 45207. An e-mail will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarter hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West 5th Street, Cincinnati, OH 45202, 513-421-9100. To make reservations online, please visit the "Venue/Logistics" link at <http://www.XavierGOC.com>.

If you need special accommodations due to a disability, please contact Marla Phillips (see *Contact Persons*) at least 7 days in advance of the conference.

SUPPLEMENTARY INFORMATION: The public conference helps fulfill the Department of Health and Human Services and FDA's important mission to protect the public health. The conference will provide those engaged in FDA-regulated outsourcing with information on the following topics:

- FDA Center to present on initiatives from Congress and FDA, and resulting impact;
- Global regulator perspective on global compliance initiatives, challenges, and expectations;
- FDA Field perspective on the most common and significant deficiencies specific to outsourcing relationships;
- Global compliance of manufacturing in Asia;
- Pharmaceutical companies—how to manage varying global regulatory expectations while working with contractors in various states of compliance;
- Contract organizations—compliance strategy for managing global regulatory requirements while managing multiple client expectations;
- Contract Organization Selection Process;
- The Client Selection Process—the criteria a contract organization should use to consider saying no to a contract relationship;
- Regulatory challenges—Drug Master File Fitness;
- Due diligence audit—how to audit in 1 day;
- Quality Agreement Development throughout the product and process lifecycle;
- Supply Chain Transparency and Pedigree;
- How to Audit the Supply Chain;
- Rx-360 and International Pharmaceutical Excipients Council initiatives—impact to industry;
- Risk-based Performance Management best practices;
- International Conference on Harmonisation Triple Q's (Q8, Q9, and

Q10)—how quality can drive down the cost of business, and how innovation can increase business opportunities;

- Rebuilding the Trust case studies; and
- Small group discussion on sharing best practices.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121) by providing outreach activities by Government agencies to small businesses.

Dated: April 22, 2010.

Leslie Kux,

Acting Assistant 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 75 FR 14608, dated March 26, 2010) is amended to reflect the reorganization of the Office of Enterprise Communication, Office of the Director, Centers for Disease Control and Prevention.

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

Delete in its entirety the title and functional statements for the Office of *Enterprise Communication (CAU)*, and insert the following: *Office of the Associate Director for Communication (CAU)*. The mission of the Office of the Associate Director for Communication (OADC) is to support CDC's mission by leading customer-centered, science-based, and high-impact communication. In carrying out its mission, the OADC: (1) Serves as a key advisor on communication activities to CDC's Director and leadership; (2) conducts, oversees and promotes health communication science research and practices; (3) provides and manages communication services including broadcast, graphics, and photography; (4) facilitates open and transparent employee communication; (5) develops and implements internal and external public relations strategies to communicate upward and outward to customers, partners, and other stakeholders; and (6) guides news and electronic media activities to communicate disease prevention and health promotion messages.

Office of the Director (CAU1). (1) Manages, directs, coordinates, and evaluates the activities of the OADC; (2) ensures CDC communication activities follow policy directions established by the Department of Health and Human Services (HHS); (3) establishes, administers, and coordinates CDC's health communication and marketing policies to ensure communication efforts reflect the scientific integrity of all CDC research, programs, and activities, and information is factual, accurate, and targeted toward improving public health; (4) establishes and interprets policies and determines priorities for communicating the value and benefits of CDC programs; (5) provides guidance on leadership communication effectiveness; (6) provides leadership and guidance in using efficient and transparent processes to communicate the decision-making activities of CDC's leadership; (7) facilitates coordination throughout

the agency to ensure the distribution of messages through the right channels and to the appropriate audience(s); (8) serves as the principal advisor on communication and marketing science, research, and practice; (9) establishes measures of success and effectiveness of CDC communication efforts and provides guidance to CDC programs on applying the measures; (10) ensures that the content of CDC communications is accessible (available, understandable, actionable) to audiences that may have specific health literacy needs; (11) identifies and implements strategies for health literacy and multilingual translation and delivery of CDC information tailored to specific audiences for maximum health impact; (12) chairs the CDC Excellence in Marketing Committee; (13) serves as liaison to Centers/Institute/Offices (CIO) Health Communication Science Offices; (14) provides agency-wide leadership, technical assistance, and consultation in reputational risk communication and reputational management; (15) conducts emergency risk communication training at the national, state, and local levels; (16) manages and coordinates the HHS and Office of Management and Budget clearances for CDC communications and marketing programs and research (17) provides leadership, oversight, and guidance in the management and operations of OADC's programs; (18) provides administrative management support, advice, and guidance to OADC, in the areas of fiscal management, personnel, travel, and other administrative services; (19) coordinates the development of the OADC's annual budget submission and spending plan; (20) plans, allocates, and monitors OADC's resources; (21) maintains liaison and collaborates with other CDC components, federal agencies, and external organizations in support of OADC management and operations, interagency agreements, memorandums of understanding, procurements, and material management; and (22) serves as the primary point of contact with PGO on procurement functions.

Division of News and Electronic Media (CAUB). (1) Supports OADC and CDC through the creation, design, development, and evaluation of effective communication technologies that enhance the presentation and distribution of CDC's products and services; (2) assists CDC information developers in planning, designing, usability testing, and maintaining Web sites, mobile applications/devices, and other communication technologies; (3) provides leadership and management for CDC's Web site ([http://](http://www.cdc.gov)

www.cdc.gov); (4) plans, organizes, administers, and, when appropriate, implements CDC's media activities consistent with policy direction established by the Assistant Secretary for Public Affairs, HHS; (5) provides leadership in the development of CDC's priorities, strategies, and practices for effective media relations; (6) provides for the content, policy review, and clearance of media materials including press releases, press kits, talking points, letters to editors, and fact sheets; (7) provides the public, through media channels, access to information systems, services, and materials that support or promote the health of individuals and communities; and (8) manages and responds to media requests for access to subject matter experts, reports, and publications.

Office of the Director (CAUB1). (1) Provides leadership and management of the agency's news and electronic media activities, including strategic direction, core functions, and organizational structure; (2) provides expertise, guidance and recommendations to CDC's director, leadership and CIOs on effective and appropriate use of news and electronic media; (3) helps plan, organize and direct the activities of the division; (4) establishes and regularly reviews the division's goals and objectives; (5) provides agency management with expertise and abilities to implement news and electronic media efforts and initiatives, including management of CDC's Web site and new/social media activities; (6) provides oversight and coordination for division activities related to media relations, media surveillance, electronic media, new media, social networks, and user experience with these channels; (7) provides advice, guidance, and direction on a wide range of media activities and administrative issues; (8) collaborates and coordinates with other organizational units on news and electronic media; (9) identifies need for updates or changes in the agency's news and electronic media activities, services and priorities and takes action to implement such updates or changes; and (10) serves as CDC's liaison to HHS Office of Assistant Secretary for Public Affairs on news and electronic media policies, procedures, and clearance.

Electronic Media Branch (CAUBB). (1) Provides leadership to CDC for the selection, use, design, development, and evaluation of e-Health and communication technologies that enhance the presentation and distribution of CDC's products, services, science, resources and recommendations; (2) leads and coordinates CDC.gov's governance

bodies (CDC.gov Council, CDC.gov Executive Board, CDC.gov Executive Committee, CDC en Espanol, and related workgroups) and c-Health-related Communities of Practice and work groups; (3) provides agency-wide leadership, coordination and support for CDC's Web site (<http://www.cdc.gov>) and CDC's new and social media use; (4) creates and distributes CDC.gov and social media guidance, standards, tools, and other resources for CDC centers and programs; (5) provides day-to-day management for CDC.gov/CDC en Espanol top tier sites and CDC's social media presences; (6) provides leadership, management, and oversight for CDC-wide Web and social media systems and architectures (i.e., Web Content Management System, mobile services, CDC.gov servers, Web translation services, search engine, content syndication); (7) conducts and supports research in user experience, health impact evaluation, and communication technology areas in collaboration with other CDC/HHS organizations; (8) leads, coordinates, and/or supports online collaborations with partners; (9) collects and analyzes user data/metrics from communication technologies to assess health impact, system performance, usability, accessibility, and usefulness; (10) coordinates CDC's risk and emergency social media communications; and (11) plans, organizes, administers, and, when appropriate, implements CDC's electronic media activities consistent with policy direction established by the Office of the Assistant Secretary for Public Affairs, HHS.

News Media Branch (CAUBC). (1) Provides leadership in the development of CDC's priorities, strategies, and practices for effective news media relations; (2) provides expertise, guidance, and recommendations to CDC's Director, leadership, and CIOs in effective and appropriate news media strategies, plans, responses, and initiatives; (3) provides for the content, policy review, and clearance of news media materials including press releases, press kits, talking points, letters to editors, and fact sheets; (4) manages and maintains CDC's online newsroom; (5) provides the public, through news media channels, access to information systems, services, and materials that support or promote the health of individuals and communities; (6) manages and responds to news media requests for access to subject matter experts, reports, and publications; (7) assists the CDC's CIOs in identifying and building needed expertise, technology, logistical support,

and other capacities required for effective news media relations; (8) creates and maintains liaison with the CDC's CIOs to share information about news media issues and opportunities; (9) coordinates the development, review, clearance, and dissemination of news media materials and information among CIOs and between CDC and HHS; (10) assists CIOs in identifying, evaluating and meeting news media-related needs and priorities; (11) provides news media/spokesperson training and technical assistance to CDC staff; (12) provides a central point of contact to CDC for news media representatives; and (13) periodically evaluates CDC's news media relations operations, activities, and services, including feedback from internal users and journalists.

Division of Communication Services (CAUD). (1) Provides agency-wide production and broadcast (audio and video) distribution support of communication materials directed to key target audiences; (2) provides and manages CDC-wide graphic design and production services; (3) collects and/or facilitates distribution of graphic, digital, and broadcast materials; (4) produces and collaborates on new broadcast communication mechanisms (e.g. HHS TV, CDC TV, radio/TV broadcasting, pod casting, web casting, and video-on-demand) for agency-level communications with the public and partners to include selection and promotion of content on selected channels and evaluation of its reach; (5) provides oversight for broadcast delivery mechanisms for inbound and outbound broadcast communications (e.g., press conferences, interviews); (6) provides consultation and links to resources to assist the CIOs in conducting formative, process and outcome research, and evaluation of specific applications of health communication and marketing in program areas; (7) assists the CIOs in identifying appropriate target audiences and messages; and (8) researches and works with other agency programs to develop new mechanisms to communicate with the public.

Office of the Director (CAUD1). (1) Develops, manages, directs, and coordinates the implementation of strategic priorities and programmatic activities of the division; (2) establishes division goals and objectives; (3) provides, manages, and consults around CDC-wide communication services including broadcast, audio, and video material production; graphic arts, photography, and related visual information services; (4) provides writer editor services for OADC; (4) manages

broadcast delivery mechanisms for outbound broadcast communications; and (5) researches and works with other agency programs to use existing or develop new mechanisms for agency-level communications with the public as well as partners such as public health professionals and business.

Broadcast Services Branch (CAUDB). (1) Develops, produces and manages use of audio, video, and multimedia health information products; (2) provides agency-wide and global communication capacity using state-of-the-art high-definition broadcast, webcast and emerging social and health media delivery channels on a real time and/or recorded basis; (3) manages media assets of all broadcast video and audio programming developed within CDC; (4) supports the communication needs of the CDC Emergency Operations Center to assure response capacity and capability for emergency broadcasts; (5) manages all CDC broadcast-grade audio and video production requirements; (6) develops and delivers programming, in coordination with HHS, to provide timely and accurate health information to the public, domestically and globally; (7) provides broadcast support for CDC public affairs programming; (8) provides audio-only production services; (9) provides and supports the creation and production of emerging social and health media products; (10) collaborates with other areas of CDC in reviewing potential audio and video technology; and (12) develops and manages distance education, health communication, and training products to reach public health partners and professionals.

Graphics Services Branch (CAUDC). (1) Coordinates agency-wide visual information activities; (2) designs, develops, and produces graphic illustrations, scientific posters, desktop published documents, visual presentations, conference materials, brochures and fact sheets, newsletters, and exhibits; (3) provides high-end medical illustration and motion graphics for CDC programs and services; (4) provides creative direction/ leadership for graphics products to ensure consistency with established agency guidelines and quality standards set within the division, and (5) assesses skills and training needs and provides training, directly or by referral, for graphics staff to assure that all are capable of providing quality graphic services for the agency.

Strategic and Proactive Communications Branch (CAUDD). (1) Accepts, tracks, and triages client requests for OADC and Division services; (2) manages and maintains an online request, workflow triage and

tracking, performance measurement, and program service indicator system; (3) manages large or multidisciplinary projects through a team of client service staff who serve as the division's creative project coordinators in collaboration with other CDC organizations and programs; (4) gathers and monitors customer satisfaction information and addresses concerns as necessary; (5) monitors and manages performance, and evaluates and communicates findings to the division's leadership and other appropriate staff for follow-up and potential action; (6) provides/manages scientific and event photography; (7) identifies or develops/updates, disseminates, and ensures CDC communication program staff are familiar with and follow policy directions established by both CDC HHS; (8) ensures analytic function for interpretation of data from centralized marketing databases, sources of environmental scanning, and communication literature for use in development and implementation of strategies for communication activities; (9) provides for systematic mechanisms for gaining public input on health issues and priorities (e.g., advisory mechanisms, focus groups, polling, legislative, and media tracking) and for the systematic application of knowledge gained from such input into agency decision-making; (10) establishes measures of success and effectiveness of CDC communication efforts and provides guidance to CDC programs on applying these measures; and (11) provides consultation to the agency on strategic communication planning and implementation, and evaluation of health communication and social marketing theories and techniques that support programmatic health objectives.

Division of Community Engagement (CAUE). (1) Provides leadership and guidance on developing and implementing external public relations strategies to communicate upward and outward to customers, partners, and other stakeholders; (2) provides leadership and guidance on developing and implementing internal public relations strategies to communicate to the agency's workforce; (3) collaborates with stakeholders and partners, responsible for the planning, coordination and management of CDC's Global Communications Center (GCC); (4) provides conference management support to internal and external customers for meetings held in the GCC; (5) provides leadership for CDC-INFO, CDC's telephone, e-mail, and fulfillment services center; and (6) facilitates CDC's

participation in external community events and activities.

Office of the Director (CAUE1). (1) Develops, manages, directs, and coordinates the implementation of strategic priorities and programmatic activities of the division; (2) establishes division goals and objectives; (3) creates a recognized and valued system of employee communication that helps improve communication between CDC leadership and employees, and across employee groups; (4) manages the Global Health Odyssey, CDC's scientific museum and learning center; (5) develops and implements external public relations strategies to communicate upward and outward to customers, partners, and other stakeholders; (6) manages the infrastructure support for the CDC Director's All Hands Sessions; (7) manages and coordinates the use of the CDC exhibit at public health conferences; (8) maintains an active relationship with the CDC Foundation to promote the CDC in the greater community; (9) provides leadership and guidance in documenting the history of CDC's science and programs; (10) provides leadership and guidance for established and new community initiatives; and (11) manages the GCC.

Employee Communications (CAUE12). (1) Designs, plans, organizes, develops, and implements employee communication activities; (2) provides infrastructure, support and oversight of OADC's Intranet Web site, CDC's Intranet leadership Web site, and CDC's www.cdc.gov About CDC Web site; (3) provides the central point of contact to CDC for the CDC Intranet and CDC announcements; (4) provides leadership in the development and branding of CDC's Intranet sites and pages; (5) creates and maintains liaison with the CDC's CIOs to share information about employee communication and assists in meeting employee communication goals; (6) develops communication for information dissemination through CDC Connects and other employee communication mechanisms; (7) conducts employee research to enhance and improve CDC Connects and other channels of employee communication; (8) provides employees access to information systems, services, and materials held on the intranet that support or promote their health, morale, and work efficiency; and (9) serves as liaison to former employees and retirees.

CDC-INFO (CAUE13). (1) Provides the public with accessible, accurate, and credible health information in English and Spanish, 24/7, through phone, e-mail, and postal mail channels; (2)

assesses and maintains contact center standards for quality assurance, customer satisfaction, contact center performance, and health impact; (3) provides contact center surge support to the Agency per established policies and procedures in collaboration with the CDC Emergency Operations Center, Joint Information Center; (4) manages CDC's health publications distribution facility, publications ordering pages, and internal publications ordering systems; (5) collects and manages CDC-INFO data to inform CDC programmatic and communication planning; and (6) assesses and maintains exemplary service to internal program customers.

Dated: April 19, 2010.

William P. Nichols,

Chief Operating Officer, Centers for Disease Control and Prevention.

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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 75 FR 14608, dated March 26, 2010) is amended to reflect the reorganization of the Office of the Chief of Staff, Office of the Director, Centers for Disease Control and Prevention.

Section C-B, Organization and Functions, is hereby amended as follows: Delete in their entirety the title and functional statements for the Office of the Chief of Staff (CAT) and insert the following:

Office of the Chief of Staff (CAT). The Office of the Chief of Staff (OCS) is accountable for providing strategic advice to the Director and ensuring proactive coordination of agency-wide priorities and policies in direct support of CDC's mission. In carrying out its mission, the OCS: (1) Serves as the principal advisor to the Director, CDC, on internal and external affairs of CDC; (2) convenes key leadership for assessment, management, mitigation options, and resolution of issues and initiatives affecting CDC's priorities and goals; (3) provides information to senior