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Gene L. Dodaro,

Comptroller General of the United States.

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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 76493–76499, dated December 9, 2015) is amended to reflect the reorganization of the Division of Communication Services, Office of the Associate Director for Communication, Centers for Disease Control and Prevention.

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

Delete in its entirety the title and the mission and function statements for the *Division of Communication Services (CAUD)* and insert the following:

Division of Communication Services (CAUD). The Division of Communication Services (DCS) provides agency-wide CDC graphics, broadcast, photography, translation, interpretation, public information, and communication consultation/analysis leadership and support. To carry out its mission, the division performs the following functions: (1) Ensures broadcast functionality/broadcast engineering support including connectivity among physical assets such as the Global Communications Center, Emergency Operations Center, and continuity of operations for CDC; (2) develops and disseminates video and audio production; (3) manages CDC graphic design and production services including CDC branding and identity standards; (4) supports new broadcast communication mechanisms (*e.g.* HHS TV, CDC TV, radio/TV broadcast, podcast, webcast, and videos-on-demand) for CDC programs; (5) provides support for broadcast delivery press conferences and media interviews; (6) provides scientific and events photography; (7) provides multilingual translation and interpretation, and cross cultural communication assistance to Centers, Institute and Offices (CIOs) across CDC; (8) provides consultation and analysis of consumer research data to CIOs used for developing and evaluating health communication and marketing to specific audiences; (9) manages day-to-day operations of meeting space within CDC's meeting center, the Global Communications Center; and (10) manages CDC–INFO (CDC's telephone, email, and publications fulfillment services center); (11) oversees the agency-wide print management program; (12) manages CDC-wide information services including electronic and postal distribution lists, and electronic announcements; and (13) provides writer-editor services on behalf of CDC Office of the Director.

Office of the Director (CAUD1). (1) Develops the strategic priorities and manages the program activities of the division; (2) provides leadership for ensuring all DCS products are of the highest quality; (3) helps CIOs use existing or develop new mechanisms for communicating with the public and CDC partners; (4) coordinates support for meetings held in the Global Communications Center with internal and external customers; (5) coordinates the use of the CDC exhibit for public health conferences; (6) manages overall IT-related functions for the division, including Create-IT (DCS' online internal tracking and triage system), Trados SDL (translation memory application), and CDC–INFO IT applications; (7) provides and manages multi-year, multi-vendor CDC-wide communication contracts mechanism for use by CIO clients; (8) updates and manages Create-IT system for tracking and triage of work requests including associated customer satisfaction and other performance metrics for internal and external (CIO) use; (9) oversees the agency-wide print management program; (10) manages CDC-wide information services including electronic distribution lists, and electronic announcements; (11) administers CDC wide multi-year, multi-vendor communication contracts mechanism; (12) advises on methods for gaining public input on health issues and priorities (*e.g.,* advisory mechanisms, focus groups, polling, legislative, and media tracking); (13) manages contract resources and provides analysis relative to audience segmentation and behavior, and (14) provides agency-wide multi-lingual service (MLS) support to include direct Spanish language translation, facilitating and coordinating support for other languages, and cross-cultural communication assistance as well as MLS leadership (*e.g.* implementation of agency Language Access Plan).

Broadcast Services Branch (CAUDB). (1) Develops and produces audio, video, and multi-media health information products; (2) provides CDC with global communication capacity for high-definition broadcast, webcast and emerging social and health media delivery channels; (3) supports the CDC Emergency Operations Center to provide response capacity and capability for emergency broadcasts; (4) develops and delivers health information broadcast programs in coordination with HHS for the public, including podcasts, CDC–TV and other channels; (5) creates and produces communication using new forms of social and electronic media; (6) collaborates with other areas of CDC to review and recommend potential audio and video technology; and (7) develops distance education, health communication, and training products to reach public health partners and professionals.

Graphics Services Branch (CAUDC). (1) Leads and coordinates CDC visual information activities; (2) develops and produces graphic illustrations, including scientific posters, infographics, desktop published documents, visual presentations, conference materials, brochures and fact sheets, newsletters, and exhibits; (3) manages scientific and event photography; (4) provides creative direction and brand management guidance for graphics products and sets guidelines and standards for quality and consistency across the agency; (5) manages tracking and triage function within Create-IT system for management of work requests; and (6) provides technical assistance on large or multidisciplinary projects to provide a consistent approach across communication products.

CDC–INFO and Print Services Branch (CAUDD). (1) Provides the public with accessible, accurate, and credible health information in English and Spanish, 24/7, to include phone, email and U.S. mail; (2) ensures the CDC–INFO call center standards are kept for quality assurance, customer satisfaction, performance, and health impact when dealing with the public; (3) provides surge (to include 24/7) support through the 1–800 call center for public health emergencies and establishes policies and procedures with the CDC Emergency Operations Center, Joint Information Center; (4) manages CDC's ordering and distribution facility for health publications; (5) liaisons with contract suppliers, the Government

Printing Office, HHS, and other agencies on matters pertaining to print and publication procurement; (6) analyzes and reports CDC–INFO data to inform communication planning and programs throughout the agency; and (7) provides writer-editor support for the Office of the Director.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 28, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for ''Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidances for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions:* To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Xiaoqiu Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/Guidance*