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
of work requests; and (6) provides
within Create-IT system for management
of work requests; and (6) provides
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)
manages scientific and event
marketing to specific audiences; (9)
evaluating health communication and
programs in coordination with HHS for
delivering health information broadcast
products; (2) provides CDC with global
and multi-media health information
definition broadcast, webcast and
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
(CAUNDD). (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
drugs and establishes policies
and procedures with the CDC
Emergency Operations Center, Joint
Information Center; (4) manages CDC’s
ordering and distributing facility for
health publications; (5) liaisons with
contract suppliers, the Government

42 U.S.C. 1395b–6

Gene L. Dodaro,
Comptroller General of the United States.
[FR Doc. 2016–01264 Filed 1–27–16; 8:45 am]
Draft Guidances for Industry; Recommendations; Draft and Revised Product-Specific Bioequivalence

[Docket No. FDA–2007–D–0369]

Food and Drug Administration

[FR Doc. 2016–01676 Filed 1–27–16; 8:45 am]

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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 Guidelines 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 Guidelines 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:
Xiaouqi 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...