DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0013]

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has conducted a reorganization to modify its structure, to align similar functions under common executive leadership, and to reduce and change the reporting relationships to the Agency head. The reorganization creates four ''directorates'' within which most of FDA's activities will reside—Administrative operations, food and veterinary medicine, medical products and tobacco, and foreign and domestic regulatory operations. However, this restructuring will not change the basic form of FDA's programs, which will continue to reside in the Agency's seven operating Centers and the Office of Regulatory Affairs. It is intended to provide a more efficient span of control for executive leadership and to organize like activities together, not to change the essential programmatic activities under which FDA implements the Federal Food, Drug, and Cosmetic Act.

FOR FURTHER INFORMATION CONTACT: Kimberly A. Holden, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4239, Silver Spring, MD 20993–0002, 301–796–4750.

I. Summary

Part D, Chapter D–B (Food and Drug Administration), Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 60 FR 56605, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009) is amended to reflect the restructuring of the Office of the Commissioner and other components, FDA that was approved by the Secretary of Health and Human Services on July 8, 2011 as follows. This reorganization is explained in Staff Manual Guide 1111.1, 1118.1, 1140.1, 1114.1, 1117.1, 1160.1, 1180.1, and 1115.1.

Under Part D, FDA, the Office of the Commissioner has been restructured as follows:

DA. ORGANIZATION—FDA is headed by the Commissioner of Food and Drugs (the Commissioner) and includes the following organizational units that report to the Commissioner:

Office of the Commissioner
Office of the Counselor to the Commissioner
Office of Legislation
Office of Policy and Planning
Office of External Affairs
Office of the Chief Scientist
Office of Operations
Office of Foods
Office of Medical Products and Tobacco
Office of Global Regulatory Operations and Policy
Office of Women's Health
Office of Minority Health

The following organizations remain substantively unchanged: Center for Veterinary Medicine, Center for Food Safety and Applied Nutrition, Center for Devices and Radiological Health, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Tobacco Products, National Center for Toxicological Research, Office of Regulatory Affairs, Office of International Programs, and Office of Special Medical Programs.

However, some organizations will have different reporting relationships under the new organizational structure, as follows:

Office of the Commissioner

Headed by the Commissioner, the Office of the Commissioner will be comprised of the Office of the Counselor to the Commissioner, the Office of Legislation, the Office of Policy and Planning, the Office of External Affairs, the Office of the Chief Scientist, the Office of Women's Health, and the Office of Minority Health. Those offices will remain unchanged, with the exception of the realignment of functions of the Office of Budget from the Office of Policy, Planning and Budget (OPPB) to the Office of Operations, and the renaming of OPPB to the Office of Policy and Planning. The administrative functions that were formerly within the Office of the Commissioner will be relocated to the new Office of Operations. Although the National Center for Toxicological Research will remain unchanged as an operating Center, the Chief Scientist will assume direct line authority over the Center.

Office of Operations

Directed by a Chief Operating Officer (COO), the Office of Operations will assume the functions previously overseen by the Deputy Commissioner for Administration. The COO will, on behalf of the Commissioner, have Agency-wide authority for strengthening the management of business programs and operations of the Agency. The COO oversees day-to-day management issues, effective implementation of Congressional and Commissioner priorities and initiatives, and the delivery of quality services by the Agency and its Centers. Under this new structure, the COO will have direct line authority over the Office of Information Management, the Office of Management, the Office of Equal Employment Opportunity, and a new Office of Finance, Budget and Acquisition (which will receive the Office of Budget from the former Office of Policy, Planning and Budget). The Offices overseen by the COO were previously located within the Office of the Commissioner.

Office of Foods

This office, headed by a Deputy Commissioner for Foods is unchanged. The Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition remain within this Office and are unchanged. This Deputy Commissioner will continue the goal established in the 2009 creation of this Office to integrate all of FDA's food-related functions into one seamless enterprise, as well as provide executive direction to the two Centers under the Deputy Commissioner's direction.

Office of Medical Products and Tobacco

This new Office will be comprised of four Centers that previously reported directly to the Commissioner—the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Center for Tobacco Products. Directed by the Deputy Commissioner for Medical Products and Tobacco, it will also oversee the Office of Special Medical Programs, which contains four Offices that were previously in the Office of the Commissioner (the Office of Orphan Product Development, the Office of Pediatric Therapeutics, the Office of Combination Products, and the Office of Good Clinical Practice). The newly created position of Deputy Commissioner for Medical Products and Tobacco will have direct line authority over the four medical product Centers and the special medical programs and, as such, will provide advice and counsel to the Commissioner on all FDA medical product and tobacco-related programs and issues. The Centers and special medical programs remain unchanged in this reorganization.

Office of Global Regulatory Operations and Policy

This new office, directed by a Deputy Commissioner for Global Regulatory Operations and Policy, will be

comprised of two existing organizations that will otherwise remain unchanged—the Office of Regulatory Affairs and the Office of International Programs. In addition to exercising direct line authority over those two existing Offices, this new Deputy Commissioner will provide executive oversight, strategic leadership, and policy direction to FDA's domestic and international product quality and safety efforts, including global collaboration, global data-sharing, development and harmonization of standards, field operations, compliance, and enforcement activities.

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

Persons interested in seeing the complete Staff Manual Guide can find it on FDA's Web site at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm*

Dated: July 25, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Review and Qualification of Clinical Outcome Assessments; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop to discuss measurement principles for clinical outcome assessments (COAs) for use in clinical trials for new drugs. COAs include patient-reported outcome (PRO) measures, clinician-reported outcome (ClinRO) measures, and observer-reported outcome (ObsRO) measures. This public workshop is intended to provide information for and gain perspectives from patient advocates, health care providers, researchers, regulators, individuals from academia, industry, and other interested persons on various aspects of the development and implementation of COAs in the evaluation of treatment benefit. Regulatory review issues regarding context of use and documentation of the measurement properties of a COA will be covered during panel discussions. The input from this public workshop will be published in the form of a white paper or a series of manuscripts.

DATES: *Date and Time:* The public workshop will be held on October 19, 2011, from 8:30 a.m. to 5 p.m. Participants are encouraged to arrive early to ensure time for parking and routine security check before the workshop.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* Attendees are responsible for their own accommodations.

The public workshop will also be available to be viewed online via Web cast at *https://collaboration.fda.gov/coaworkshop/.* Persons interested in participating by Web cast must register online by October 17, 2011.

Contact Person: Shauna Shupe, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6417, Silver Spring, MD 20993–0002, 301–796–0900, *e-mail: Shauna.Shupe@fda.hhs.gov.*

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early because space is limited to 150 attendees. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. Registration will close after the workshop is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 7:30 a.m.

To register electronically, e-mail registration information (including name, title, firm name, address, telephone, and FAX number) to *COAworkshop@fda.hhs.gov.* For those without Internet access, please call Shauna Shupe (see *Contact Person)* to register.

If you need special accommodations due to a disability, please contact Shauna Shupe at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The Center for Drug Evaluation and Research (CDER) reviews COAs including PRO measures, (ClinRO) measures, and ObsRO measures when submitted with an investigational new drug application, a new drug application, or a biologics licensing application. The FDA guidance for industry entitled ''Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims,'' available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf,* explains how FDA reviews PRO measures.

CDER also reviews a COA when submitted for qualification as a drug development tool (DDT). Qualification of a COA is a regulatory determination that the COA is well-suited for a specific context of use in drug development. Following a public announcement of the qualification decision by FDA, the COA will be publicly available for use in any appropriate drug development program. Because the qualification process is separate from the drug marketing application process, qualification is conducive to public-private partnerships engaging in this COA development effort. Such collaborative approaches may increase the efficiency of COA development when more than one entity is interested in the use of a COA for a specific context of use. The FDA draft guidance for industry entitled ''Qualification Process for Drug Development Tools,'' available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM230597.pdf,* provides the draft process for CDER participation in the consultation, advice, and qualification review for COAs and other DDTs.

This workshop will focus on FDA review principles specific to all type of COAs, *i.e.,* PRO, ClinRO, and ObsRO measures. More specifically, the workshop will provide researchers involved in the drug development process with information on the following topics concerning FDA review of COAs for treatment benefit evaluation:

- COA measurement principles;
- COA nomenclature;