SMG 1113B.2

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Commissioner

Office of Clinical Policy and Programs

Office of Clinical Policy

Effective Date: December 14, 2018

1. Office of Clinical Policy (DCJA).

A. Serves as the Food and Drug Administration (FDA) focal point for special programs and initiatives that are cross-cutting and clinical, scientific, and/or regulatory in nature to support innovation in medical product development and review.

B. Provides leadership for councils and committees to support FDA priorities where advancing clinical policies will support meeting the FDA's mission

2. Good Clinical Practice Staff (DCJAA1)

A. Provides executive leadership to the Office to:

a. Advises and assists the Commissioner and Principal Deputy Commissioner, and other key officials on Good Clinical Practice (including human subject protection) issues arising in clinical trials regulated by the FDA that have an impact on policy, direction and long-range goals.

b. Supports and administers FDA's Human Subject Protection (HSP)/Bioresearch Monitoring (BIMO) Council that manages and sets agency policy on Good Laboratory Practices, Bioresearch Monitoring, and Good Clinical Practices.

c. Represents the FDA to other government agencies, State and local governments, industry, academia, consumer organizations, Congress, national and international organizations, and the scientific community on Good Clinical Practice policy issues.

d. Provides leadership and direction on human subject protection and Good Clinical Practice matters and stimulates the application of these principles in the FDA

e. Evaluates the adequacy of Good Clinical Practice resources available to the FDA and initiates action as appropriate.

f. Coordinates FDA policies related to the protection of human subjects in research, including institutional review and ethical considerations.

g. Plans training programs for external use and for FDA staff on the FDA's Good Clinical Practice policies.

h. Coordinates and provides oversight of Good Clinical Practice policy working groups developed on the recommendation of the FDA HSP/BIMO Council.

i. Fosters the science of bioresearch monitoring within the Centers and the Regulatory Affairs program and coordinates for the Office of the Commissioner.

j. Serves as the FDA coordinating point for Good Clinical Practice regulation, harmonization, and outreach activities.

k. Serves as liaison between the FDA's HSP/BIMO Council and the FDA’s Management Council.

l. Coordinates and assists in implementation of regulations, policies, operational initiatives, and program priorities related to clinical bioresearch monitoring as developed by the HSP/BIMO Council.

m. Monitors FDA activities and leads the development of a quality assurance and quality improvement program to ensure uniform application of clinical bioresearch monitoring policies across the FDA.

n. Serves as a liaison with other federal agencies and outside organizations, the regulated industry, and public interest groups on clinical bioresearch monitoring policy and regulatory matters.

3. Authority and Effective Date.

The functional statements for the Office of Clinical Policy were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

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Good Clinical Practice Staff

(DCJA)

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Clinical Policy and Programs, Office of Clinical Policy organization structure depicting all the organizational structures reporting to the Director.

The organization below reports to the Office of Clinical Policy (DCJA):

- Good Clinical Practice Staff

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