SMG 1263.90

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of New Drugs

Office of Therapeutic Biologics and Biosimilars

Effective Date: December 14, 2018

1. Office of Therapeutic Biologics and Biosimilars (DCDGG).

A. Ensures scientific and regulatory decision-making for biosimilar and overlapping biological product issues is consistently and accurately addressed Food and Drug Administration (FDA) -wide.

B. Implements programmatic components pertaining to the current BsUFA program, including maintenance of supporting documentation for review staff.

D. Identifies and resolves scientific and regulatory questions associated with biosimilar and other biological products through product development interactions, application review, sponsor inquiries, and other forms of external stakeholder communication.

E. Works collaboratively with other Offices/Centers to address topics related to biosimilar and other biological product policy, applications, safety, and compliance.

F. Supports development and dissemination of educational materials to communicate accurate information about biosimilars to support safe and informed use of biosimilar products.

2. Policy Staff (DCDGG1).

A. Identifies, evaluates, and resolves regulatory issues related to biosimilar and other biological products based on existing commitments, guidances, and other relevant policy documents.

B. Resolves scientific policy issues associated with biosimilar and other biological products with Scientific Review Staff.

C. Identifies novel regulatory policy issues associated with biosimilar and other biological products and develops appropriate approach (e.g., guidance, MAPP, etc.) to resolve.

3. Scientific Review Staff (DCGG2).

A. Provides oversight and scientific review of biosimilars throughout the product lifecycle.

B. Identifies novel scientific policy issues associated with biosimilar and other biological products and coordinates resolution with Policy Staff.

4. Authority and Effective Date.

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

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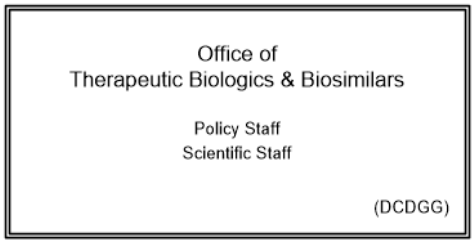

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs, Office of Therapeutic Biologics & Biosimilars organization structure depicting all the organizational structures reporting to the Director.

Office of Therapeutic Biologics & Biosimilars (DCDGG).

These organizations report to the Office of Therapeutic Biologics & Biosimilars:

Policy Staff

Scientific Staff

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