SMG 1113B.4

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 Orphan Products Development

Effective Date: December 14, 2018

1. Office of Orphan Products Development (DCJC).

A. Manages the implementation of the provisions of the Orphan Drug Act and its amendments as well as implementation of provisions of statute related to humanitarian devices and pediatric devices and manages a program to encourage the development of drugs and devices of limited commercial value for use in rare or common diseases and conditions.

B. Develops and communicates Food and Drug Administration (FDA) policy and makes decisions on approval of sponsor requests and incentives under the Federal Food, Drug, and Cosmetic Act, including orphan drug protocol assistance per section 525, orphan drug designation per section 526, orphan drug exclusivity per section 527, orphan drug grants and contracts to support clinical research, humanitarian devices, pediatric device consortia grants and other areas of FDA policy related to the development of products for rare disorders.

C. Represents the Commissioner or serves as the FDA's principal authority and spokesperson to governmental committees, industry, foreign regulatory bodies, professional, patient advocates and consumer associations requesting FDA participation in orphan product development activities.

D. Reviews investigational new drug and biologics applications and investigational device exemptions to locate the existence of products under investigational study that show promise for effectiveness for rare or common diseases but lack commercial sponsorship. Assists sponsors, researchers, and investigators in communicating with FDA regulatory officials and expediting solutions to problems in obtaining investigational or market approval status.

E. Manages extramural programs of clinical research and consortia to evaluate safety and effectiveness of orphan products by funding grants and contracts, requesting applications for funding, organizing peer review of applications, monitoring and guiding investigators, and evaluating study results.

2. Authority and Effective Date.

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

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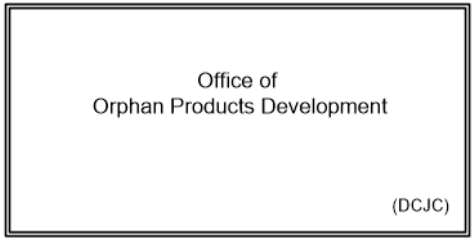

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Clinical Policy and Programs, Office of Orphan Products Development organization structure depicting all the organizational structures reporting to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

Office of Orphan Products Development (DCJC)

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