SMG 1263.13a

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 Specialty Medicine

Effective Date: September 25, 2019

1. Office of Specialty Medicine (DCDGJ).

A. Reviews notices of claimed exemptions for Investigational New Drugs (INDs) within classes of drugs regulated by this Office of Specialty Medicine and recommends appropriate action with respect to safety and effectiveness of clinical trials.

B. Evaluates for safety and effectiveness and approves New Drug Applications (NDAs) and Biologic Licensing Applications (BLAs) for products regulated by this Office of Specialty Medicine, and evaluates supplements that propose changes in the conditions upon which NDA/BLA approvals are based. Also evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs for products regulated by this Office of Specialty Medicine.

C. Develops policy and procedures governing the review and evaluation of drug investigations and NDAs/BLAs.

D. Performs medical and scientific evaluations of submissions on generic drugs, drugs under monograph, and Over-the-Counter drug products regulated by other offices in the Center, as applicable.

E. Works collaboratively with the Office of Surveillance and Epidemiology to conduct continuing surveillance and medical evaluation of labeling, clinical experience, and reports submitted by IND sponsors, by NDAs applicants, and from other sources

F. Monitors, evaluates, and develops policy for drug labeling. Initiates necessary actions to maintain industry compliance with drug labeling regulations.

G. Participates in Food and Drug Administration (FDA) sponsored consumer and professional educational programs on drug standards.

H. Develops, in coordination with other FDA components, guidance for staff, sponsors and the public that describes the FDA's interpretation of policy on regulatory and scientific issues that involve the office.

I. Oversees the development of policy and procedures governing the review and evaluation of imaging products.

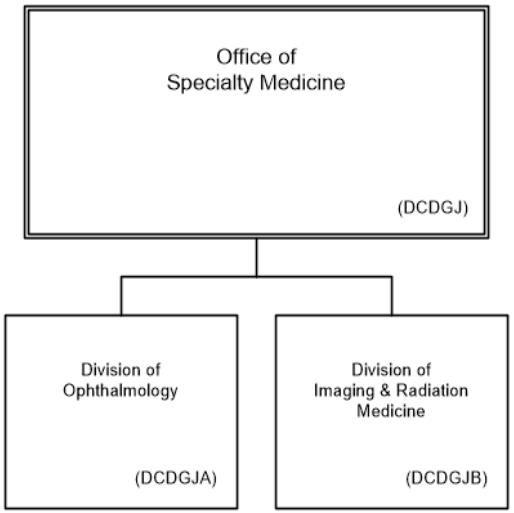
J. Oversees the development of policy and procedures governing the review and evaluation of reports submitted to the radioactive drugs research committee program.

K. Oversees the development of policy and procedures governing the review and evaluation of products used in the eye, used to diagnosis or treat ophthalmic conditions or which may cause ocular adverse reactions.

2. Authority and Effective Date.

The functional statements for this Office of Specialty Medicine were approved by the Secretary of Health and Human Services on September 25, 2019.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of New Drugs
Office of Specialty Medicine



Staff Manual Guide 1263.13a
Organizations and Functions
Effective Date: September 25, 2019

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 Specialty Medicine organization structure depicting all the organizational structures reporting to the Director.

Office of Specialty Medicine (DCDGJ).

These organizations report to the Office of Specialty Medicine:

Division of Ophthalmology (DCDGJA)

Division of Imaging & Radiation Medicine (DCDGJB)

Back to Organizations and Functions, Volume I (1000-1300)