SMG 1263.131

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

Division of Ophthalmology

Effective Date: September 25, 2019

1. Division of Ophthalmology (DCDGJA).

A. Reviews Investigational New Drugs and requests for claimed investigational exemption regulated by this Division and decides on appropriate regulatory action. Develops policies and procedures pertinent to particular aspects of investigation of drugs and biologics for ophthalmologic products.

B. Evaluates New Drug Applications (NDAs) and Biologics License Applications (BLAs) for safety and effectiveness and formulates decisions or recommendations regarding approvability in accord with applicable regulations/statutes. Also evaluates supplements that propose changes in the conditions upon which NDA/BLA approvals are based. Develops regulatory and scientific policies and procedures applicable to the review and evaluation of drugs and biologics for ophthalmologic products.

C. Evaluates adequacy of information in proposed labeling for ophthalmologic products.

D. Evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs and BLAs for ophthalmologic products.

E. Provides advice and information to other components of the Center and to the Food and Drug Administration (FDA) on ophthalmologic products, products used in and around the eye and ophthalmologic adverse events with regard to medical and scientific issues, status of drug and biologics applications, appropriate policy, and proposed regulatory actions.

F. Utilizes the advisory committee process to obtain advice on product safety and effectiveness. Also participates in FDA sponsored consumer and professional educational programs on drug standards.

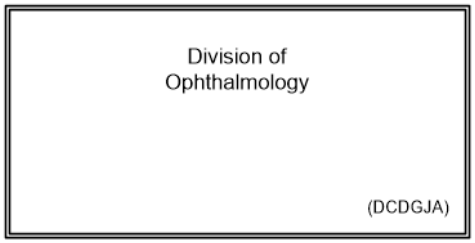
G. Develops, in coordination with other FDA components, guidance for staff, sponsors and the public that describes the FDA's interpretation of policy on regulatory issues that involve ophthalmologic products.

H. 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.

2. Authority and Effective Date.

The functional statements for the Division of Ophthalmology 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
Division of Ophthalmology



Staff Manual Guide 1263.131
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, Division of Ophthalmology organization structure depicting all the organizational structures reporting to the Director:

Division of Ophthalmology (DCDGJA).

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