SMG 1263.42

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF NEW DRUGS

OFFICE OF DRUG EVALUATION III

DIVISION OF GASTROENTEROLOGY AND INBORN EFFECTS PRODUCTS

Effective Date: 07/08/2011

1. DIVISION OF GASTROENTEROLOGY AND INBORN EFFECTS PRODUCTS (DKKNRCB)

A. Reviews investigational new drugs (INDs) and decides on appropriate action, including approval or disapproval of research plans and protocols, modifications, and restrictions. Develops policies and procedures pertinent to particular aspects of drug investigation

B. Evaluates new drug applications (NDAs) for safety and effectiveness and formulates decisions or recommendations regarding approvability in accord with applicable delegations of authority. Develops policies and procedures applicable to the review and evaluation of drugs regulated by the division

C. Evaluates adequacy of directions for use, warning, and other information in proposed labeling for products regulated by the division

D. Evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs for drugs regulated by the division

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

F. Provides advice and information to other components of the Center and to the Agency on gastroenterological and inborn effects drug products with

regard to medical and scientific issues, status of processing of drug applications, appropriate policy, and proposed regulatory actions

G. Utilizes the advisory committee process to obtain advice on product safety and effectiveness

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

2. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Division were approved by the Secretary of the Department of Health and Human Services on July 8, 2011.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	05/01/2005	N/a	OC/OO/ OM/OMP	Acting Director, Center for Drug Evaluation and Research
Revision	03/16/2011	N/a	CDER/OM	Director, Center for Drug Evaluation and Research
Revision	07/08/2011	N/a	CDER/OM	Secretary of the Department of Health and Human Services

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Staff Manual Guide 1263.42
Organizations and Functions
Effective Date: July 8, 2011

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of New Drugs, Office of Drug Evaluation III, Division of Gastroenterology and Inborn Effects Products organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR