U.S. FOOD & DRUG ADMINISTRATION

Regulatory Procedures Manual

Chapter 1 – Regulatory Organization
July 2018

This chapter includes the following sections:

1-1. INTRODUCTION

This Regulatory Procedures Manual (RPM) chapter is divided into sections based on major organizational units, and includes a section for all centers and the Office of Regulatory Affairs (ORA).

The purpose of this Regulatory Procedures Manual (RPM) chapter is to provides an overview of the organizational structure of the offices involved in compliance related functions within FDA. It is not the intent to provide a complete description of FDA's organizational structure. FDA's functional statement for each office and division may be found in various chapters of FDA's Staff Manual Guide (SMG). This guide is available on FDA's Intranet and Internet websites.

1-2. OFFICE OF REGULATORY AFFAIRS (ORA)

As a result of the ORA reorganization efforts, new offices and divisions in ORA headquarters were established with realigned, and combined functions to help support the rapid modernization and globalization of FDA's regulated products and new legislative authorities provided by Congress.

The Office of Regulatory Affairs (ORA) is under the direction of the Associate Commissioner of Regulatory Affairs (ACRA). The ACRA reports directly to the Commissioner of Food and Drugs.

1-2-1 OACRA Organization

The offices that report directly to the Office of the ACRA (OACRA) include:

A. Office of Communications and Project Management (OCPM),

B. Office of Enforcement and Import Operations (OEIO),

C. Office of Human and Animal Food Operations (OHAFO),

D. Office of Management (OM),

E. Office of Medical Products and Tobacco Operations (OMPTO),

F. Office of Partnerships and Operational Policy (OPOP),

G. Office of Regulatory Science (ORS),

H. Office of Training, Education and Development (OTED), and

I. Office of Criminal Investigations

1-2-2 OACRA Functions

The Immediate Office of the ACRA and the offices listed above are described on the page on FDA.gov at About FDA > FDA Organization > Organization Charts and on About the Office of Regulatory Affairs titled Office of Regulatory Affairs Organization Chart.

The functional statements for the Office of Regulatory Affairs and the offices within the OACRA are found in Staff Manual Guides starting at SMG 1120.1, Office of Regulatory Affairs.

1-3. CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

The Center for Biologics Evaluation and Research (CBER) described on the page on FDA.gov at About FDA > FDA Organization > Organization Charts > About the Center for Biologics Evaluation and Research.

The functional statements for CBER and the offices within the Center are found in FDA's Staff Manual Guides starting at SMG 1210.1 Center for Biologics Evaluation and Research. The CBER offices routinely involved in regulatory and compliance actions are:

A. Office of Compliance and Biologics Quality, with functional statements at SMG 1212.1 Office of Compliance and Biologics Quality.

B. Division of Case Management, with functional statements at SMG 1212.2 Division of Case Management.

C. Division of Inspections and Surveillance), with functional statements at SMG 1212.4 Division of Inspections and Surveillance.

D. Division of Manufacturing and Product Quality, with functional statements at SMG 1212.5 Division of Manufacturing and Product Quality.

E. Division of Biological Standards and Quality Control, with functional statements at SMG 1212.6 Division of Biological Standards and Quality Control.

1-4. CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

The Center for Drug Evaluation and Research (CDER) described on the page on FDA.gov at About FDA > FDA Organization > Organization Charts > About the Center for Drug Evaluation and Research.

The functional statements for CDER and the offices within the Center are found in FDA's Staff Manual Guides starting at SMG 1260.1 Center for Drug Evaluation and Research. The CDER offices routinely involved in regulatory and compliance actions are:

A. Office of Compliance, with functional statements at SMG 1262.1 Office of Compliance

F. Office of Unapproved Drugs and Labeling Compliance, with functional statements at SMG 1262.3 Office of Unapproved Drugs and Labeling Compliance

G. Office of Manufacturing Quality, with functional statements at SMG 1262.4 Office of Manufacturing Quality

H. Office of Drug Security, Integrity and Recalls, with functional statements at SMG 1262.6 Office of Drug Security, Integrity, and Response

I. Office of Scientific Investigations , with functional statements at SMG 1262.5 Office of Scientific Investigations

J. Office of Pharmaceutical Quality, with functional statements at SMG 1280.1a Office of Pharmaceutical Quality

1-5. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

The Center for Devices and Radiological Health (CDRH) described on the page on FDA.gov at About FDA > FDA Organization > Organization Charts > Center for Devices and Radiological Health.

The functional statements for CDRH and the offices within the Center are found in FDA's Staff Manual Guides starting at SMG 1250.1 Center for Devices and Radiological Health. The CDRH offices routinely involved in regulatory and compliance actions are:

A. Office of Compliance, with functional statements at SMG 1252.1 Office of Compliance

B. Division of Bioresearch Monitoring, with functional statements at SMG 1252.3 Division of Bioresearch Monitoring

C. Division of Enforcement A, with functional statements at SMG 1252.5 Division of Enforcement A Division of Enforcement B, with functional statements at SMG 1252.6, Division of Enforcement B

D. Division of Manufacturing Quality, with functional statements at SMG 1252.7, Division of Manufacturing and Quality

E. Division of Premarket and Labeling Compliance, with functional statements at SMG 1252.8, Division of Premarket and Labeling Compliance

F. Division of International Compliance Operation , with functional statements at SMG 1252.9, Division of International Compliance Operations

G. Office of Communication and Education, with functional statements at SMG 1255.1, Office of Communication and Education

H. Division of Mammography Quality and Radiation Programs, with functional statements at SMG 1255.6, Division of Mammography Quality and Radiation Programs

I. Office of In Vitro Diagnostic Device Evaluation and Safety with functional statements at SMG 1257.1, Office of In Vitro Diagnostics and Radiological Health.

1-6. CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)

The Center for Food Safety And Applied Nutrition (CFSAN) is described on the page on FDA.gov at About FDA > FDA Organization > Organization Charts > Center for Food Safety and Applied Nutrition.

The functional statements for CFSAN and the offices within the Center are found in FDA's Staff Manual Guides starting at SMG 1230A.1 Center for Food Safety and Applied Nutrition. The CFSAN offices routinely involved in regulatory and compliance actions are:

A. Office of Compliance, with functional statements at SMG 1231.17, Office of Compliance

B. Division of Enforcement, with functional statements at SMG 1231.171, Division of Enforcement

C. Division of Field Programs and Guidance, with functional statements at SMG 1231.172, Division of Field Programs and Guidance.

D. Office of Cosmetics and Colors, with functional statements at SMG 1231.14, Office of Cosmetics and Colors

E. Division of Color Certification and Technology, with functional statements at SMG 1231.141, Division of Color Certification and Technology

F. Division of Cosmetics, with functional statements at SMG 1231.142, Division of Cosmetics

G. Office of Food Additive Safety, with functional statements at SMG 1231.16 Office of Food Additive Safety

H. Division of Biotechnology and GRAS Notice Review, with functional statements at SMG 1231.162, Division of Biotechnology and GRAS Notice Review

I. Division of Petition Review, with functional statements at SMG 1231.163, Division of Petition Review

J. Division of Food Contact Notifications, with functional statements at SMG 1231.161, Division of Food Contract Notifications

K. Office of Food Safety, with functional statements at SMG 1231.13, Office of Food Safety

L. Produce Safety Staff, with functional statements at SMG 1231.135, Division of Produce Safety

M. Division of Plant and Dairy Food Safety, with functional statements at SMG 1231.133, Division of Plant and Dairy Food Safety

N. Division of Seafood Safety, with functional statements at SMG 1231.134, Division of Seafood Safety

O. Division of Seafood Science & Technology, with functional statements at SMG 1231.132, Division of Seafood Science and Technology

P. Division of Food Processing Science and Technology, with functional statements at SMG 1231.132, Division of Food Processing Science and Technology

Q. Office of Regulatory Science, with functional statements at SMG 1231.15, Office of Regulatory Science

R. Division of Analytical Chemistry, with functional statements at SMG 1231.151, Division of Analytical Chemistry

A. Division of Microbiology, with functional statements at SMG 1231.152 Division of Microbiology

B. Division of Bioanalytical Chemistry, with functional statements at SMG 1231.153, Division of Bioanalytical Chemistry

C. Office of Dietary Supplement Programs, with functional statements at SMG 1231.21, Office of Dietary Supplement Programs

D. Office of Nutrition and Food Labeling, with functional statements at SMG 1231.20, Office of Nutrition and Food Labeling

1-7. CENTER FOR VETERINARY MEDICINE (CVM)

The Center for Veterinary Medicine (CVM) is described on the page on FDA.gov at About FDA > FDA Organization > Organization Charts > Center for Veterinary Medicine.

The functional statements for CVM and the offices within the Center are found in FDA's Staff Manual Guides starting at SMG 1240.1 Center for Veterinary Medicine. The CVM offices routinely involved in regulatory and compliance actions are:

A. Office of Surveillance and Compliance, with functional statements at Office of Surveillance and Compliance

B. Division of Surveillance, with functional statements at SMG 1244.10, Division of Surveillance

C. Division of Animal Feeds, with functional statements at SMG 1244.11, Division of Animal Feeds

D. Division of Compliance, with functional statements at SMG 1244.12, Division of Compliance

E. Division of Veterinary Product Safety, with functional statements at, SMG 1244.13, Division of Veterinary Product Safety

1-8. CENTER FOR TOBACCO PRODUCTS (CTP)

The Center for Tobacco Products (CTP) is described on the page on FDA.gov at About FDA > FDA Organization > Organization Charts > Center for Tobacco Products.

The functional statements for CTP and the offices within the Center are found in FDA's Staff Manual Guides starting at SMG 1350.1 Center for Tobacco Products. The CTP offices routinely involved in regulatory and compliance actions are:

A. Office of Compliance and Enforcement, with functional statements at SMG 1357.1 Office of Compliance and Enforcement

B. Enforcement and Manufacturing, with functional statements at SMG 1357.2, Division of Enforcement and Manufacturing

C. Promotion, Advertising and Labeling, with functional statements at SMG 1357.3, Division of Promotion, Advertising and Labeling

D. State Programs, with functional statements at SMG 1357.4, Division of State Programs

1-9. ENFORCEMENT POLICY TELEPHONE DIRECTORY

The most current version of this directory is available on FDA's Intranet website.

1-9-1 Office of Regulatory Affairs – Headquarters and field

See "Contact ORA" on Home > About FDA> FDA Organization > Office of Global Regulatory Operations and Policy > About the Office of Regulatory Affairs > Contact ORA

1-9-2 FDA Centers

A. Center for Biologics Evaluation and Research (CBER)

About the Center for Biologics Evaluation and Research

CBER Offices & Divisions

CBER Key Staff Directory

B. Center for Drug Evaluation and Research (CDER)

1. About the Center for Drug Evaluation and Research
2. CDER Key Officials List (PDF)
3. CDER Offices and Divisions

C. Center for Devices and Radiological Health (CDRH)

1. About the Center for Devices and Radiological Health
2. *CDRH Management Directory by Organization* is available on the FDA Intranet.

D. Center For Food Safety And Applied Nutrition (CFSAN)

1. Contact CFSAN
2. *CFSAN Management Directory* is available on the FDA Intranet.

E. Center for Veterinary Medicine (CVM)

1. Contact CVM
2. *CVM Staff Phone List* is available on the FDA Intranet.

F. Center for Tobacco Products (CTP)

1. Contact CTP
2. *CTP Directory by Office* is available on the FDA Intranet.