§ 3.9 Mailing address: 10903 New Hampshire Ave., Silver Spring, MD 20906.

The Office of the Chief Counsel (also known as the Food and Drug Division, Office of the General Counsel, Department of Health and Human Services), while administratively within the Office of the Commissioner, is part of the Office of the General Counsel of the Department of Health and Human Services.

§ 3.9 Effect of letter of designation.

(a) The letter of designation constitutes an agency determination that is subject to change only as provided in paragraph (b) of this section.

(b) The product jurisdiction officer may change the designated agency component with the written consent of the sponsor, or without its consent to protect the public health or for other compelling reasons. A sponsor shall be given 30 days written notice of any proposed nonconsensual change in designated agency component. The sponsor may request an additional 30 days to submit written objections, not to exceed 15 pages, to the proposed change, and shall be granted, upon request, a timely meeting with the product jurisdiction officer and appropriate center officials. Within 30 days of receipt of the sponsor’s written objections, the product jurisdiction officer shall issue to the sponsor, with copies to appropriate center officials, a written determination setting forth a statement of reasons for the proposed change in designated agency component. A nonconsensual change in the designated agency component requires the concurrence of the Principal Associate Commissioner.


§ 3.10 Stay of review time.

Any filing with or review by the product jurisdiction officer stays the review clock or other established time periods for agency action for an application for marketing approval or required investigational notice during the pendency of the review by the product jurisdiction officer.

Subpart B [Reserved]
Office of Crisis Management.
Office of Emergency Operations.
Office of the Chief Of Staff.1
Executive Secretariat.
Office of Special Medical Programs.
Office of Good Clinical Practice.
Office of Combination Products.4
Office of Orphan Products Development.
Office of Pediatric Therapeutics.3
Office of International Programs.3
Office of External Affairs.
Office of External Relations.3
Communications Staff.
Office of Public Affairs.1
Web Communications Staff.
Office of Special Health Issues.3
Medwatch Staff.
Office of Foods.1
Office of the Chief Scientist.1
Office of Counter-Terrorism and Emerging Threats.3
Office of Critical Path Programs.
Office of Scientific Integrity.
Office of Science and Innovation.
Office of International Programs.3
Office of Administration.1
Office of Equal Employment Opportunity & Diversity Management.3
Conflict Prevention and Resolution Staff.
Compliance Staff.
Diversity Staff.
Office of Acquisitions and Grants Services.5
Division of Acquisition Operations.
Division of Acquisition Support and Grants.
Division of Acquisition Programs.
Division of Information Technology.
Office of Executive Operations.1
Office of Financial Operations.6
Office of Financial Management.6
Controls, Compliance, and Oversight Staff.

4 Mailing address: 15800 Crabbs Branch Way, Rockville, MD 20855.
5 Mailing address: 5630 Fishers Lane, Rockville, MD 20857.
6 Mailing address: 1350 Piccard Dr., Rockville, MD 20850.
7 Mailing address: 2094 Gaither Rd., Rockville, MD 20850.
8 Mailing address: 2098 Gaither Rd., Rockville, MD 20850.

Business Transformation, Administration and Management Staff.
User Fees Staff.
Financial Systems Support Staff.
Division of Accounting.
Division of Budget Execution and Control.
Office of Financial Services.
Division of Payment Services.
Division of Travel Services.
Office of Information Management.6
Division of Business Partnership and Support.6
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Division of Technology.8
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Office of Business Operations and Human Capital Programs.
Office of Management Programs.
Office of Security Operations.
Office of White Oak Services.1
Division of Logistics Services and Facilities Operations.
Division of White Oak Consolidation.
Office of Shared Services.5
Office of Real Property Services.
Jefferson Laboratories Complex Staff.
Division of Engineering Services.
Environment, Safety And Strategic Initiatives Staff.
Division of Facilities Operations.
Portfolio Development Staff.
Employee Resource & Information Center.
Office of Public Information and Library Services.
Division of Dockets Management.
Division of Freedom of Information.
FDA Biosciences Library.
Public Services Branch.
Technical Services Branch.
FDA History Office.
§ 5.1100

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH.\(^9\)
Office of the Center Director.
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Quality Assurance Staff.
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Regulatory Information Management Staff.
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Division of Veterinary Services.
Division of Program Services.
Division of Scientific Advisors & Consultants.
Building Operations Staff.
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Division of Case Management.
Division of Inspections and Surveillance.
Division of Manufacturing and Product Quality.
Office of Biostatistics and Epidemiology.
Division of Biostatistics.
Division of Epidemiology.
Office of Information Management.
Division of Information Operations.
Division of Information Development.
Office of Blood Research and Review.
Policy and Publications Staff.
Division of Emerging and Transfusion Transmitted Diseases.
Division of Hematology.
Division of Blood Applications.
Office of Vaccines Research and Review.
Program Operation Staff.
Division of Product Quality.
Division of Bacterial, Parasitic, and Allergenic Products.
Division of Viral Products.
Division of Vaccines and Related Product Applications.
Office of Cellular, Tissue, and Gene Therapies.
Regulatory Management Staff.
Division of Cellular and Gene Therapies.

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\(^9\)Mailing address: 1401 Rockville Pike, Rockville, MD 20852.
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Division of Nonprescription Clinical Evaluation.
Division of Nonprescription Regulation Development.
Division of Medical Imaging Products.
Office of Oncology Drug Products.

10 Mailing address: 10903 New Hampshire Ave., White Oak Bldg. 51, Silver Spring, MD 20993.
11 Mailing address: 10903 New Hampshire Ave., White Oak Bldg. 22, Silver Spring, MD 20993.
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10Mailing address: 7519 Standish Pl., Bldg. MPN4, Rockville, MD 20855.
11Mailing address: 10903 New Hampshire Ave., White Oak Bldg. 21, Silver Spring, MD 20993.
12Mailing address: 5100 Paint Branch Pkwy., College Park, MD 20740-3835.
Food and Drug Administration, HHS

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Office of Criminal Investigations.17

15 Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.
16 Mailing address: 3900 NCTR Rd., Jefferson, AR 72079.
17 Mailing address: 7500 Standish Pl., Rockville, MD 20855.
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Mid-Atlantic Area Office.3
Midwest Area Office.18
Northeast Area Office.19
Pacific Area Office.20
Southeast Area Office.21
Southwest Area Office.22
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Division of Animal Research.
Division of Animal and Food Microbi-
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Animal Drug Development.28

§ 5.1105 Chief Counsel, Food and Drug
Administration.

The Office of the Chief Counsel’s
mailing address is 5600 Fishers Lane,
rm. 6–05, Rockville, MD 20857.1

§ 5.1110 FDA public information of-

(a) Division of Dockets Management.
The Division of Dockets Management
public room is located in rm. 1061, 5630
Fishers Lane, Rockville, MD 20852,
(b) Division of Freedom of Information.
The Freedom of Information public
room is located in rm. 6–30, Parklawn
Bldg., 5600 Fishers Lane, Rockville, MD
(c) Press Relations Staff. Press offices
are located in White Oak Bldg. 1, 10903
New Hampshire Ave., Silver Spring,
MD 20993, Telephone: 301–827–6242; and
at 5100 Paint Branch Pkwy., College
Park, MD 20740, Telephone: 301–436–
2335.

PART 7—ENFORCEMENT POLICY

Subpart A—General Provisions

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7.3 Definitions.
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Subpart B [Reserved]

Subpart C—Recalls (Including Product
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7.40 Recall policy.
7.41 Health hazard evaluation and recall
classification.

28 Mailing address: 7500 Standish Pl., Bldg.
MPN2, rm. N378, Rockville, MD 20855.
1 The Office of the Chief Counsel (also
known as the Food and Drug Division, Office
of the General Counsel, Department of
Health and Human Services), while adminis-
tratively within the Office of the Commis-
sioner, is part of the Office of the General
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Human Services.