

Time of designation. By NOTAM at least 12 hours in advance.

Controlling agency. FAA, Washington ARTCC.

Using agency. Chief, Wallops Station, National Aeronautics and Space Administration, Wallops Island, VA.

* * * * *

Issued in Washington, DC on November 1, 2016.

Leslie M. Swann,

Acting Manager, Airspace Policy Group.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

[Docket No. FDA–2012–N–0222]

Revision of Organization and Conforming Changes to Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to amend the regulations to reflect organization change in the Agency and to make other conforming changes. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

DATES: This rule is effective November 7, 2016.

FOR FURTHER INFORMATION CONTACT: Vanessa Starks, Management Analysis Services Staff, Food and Drug Administration, 11601 Landsdown St., 3WFN—5th Floor, Rm. 05D12, North Bethesda, MD 20857.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this final rule to amend its regulations by updating the organizational information in part 5 (21 CFR part 5).

The portion of this final rule updating the organizational information in part 5, subpart M, is a rule of Agency organization, procedure, or practice. FDA is issuing these provisions as a final rule without publishing a general notice of proposed rulemaking because such notice is not required for rules of Agency organization, procedure, or practice under 5 U.S.C. 553(b)(3)(A). For the conforming changes to the other regulations, the Agency finds good cause under 5 U.S.C. 553(b)(3)(B) to

dispense with prior notice and comment, and good cause under 5 U.S.C. 553(d)(3) to make these conforming changes effective less than 30 days after publication because such notice and comment and delayed effective date are unnecessary and contrary to the public interest. These changes do not result in any substantive change in the regulations.

II. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule simply updates the organizational information, it does not impose any additional costs on industry. Consequently, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

III. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IV. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority of the Commissioner of Food and Drugs, 21 CFR part 5 is revised to read as follows:

PART 5—ORGANIZATION

- 1. The authority citation for part 5 continues to read as follows:

Authority: 5 U.S.C. 552; 21 U.S.C. 301–397.

- 2. Revise § 5.1100 to read as follows:

§ 5.1100 Headquarters.

*Office of the Commissioner.*¹

Office of the Chief Counsel.

Office of the Executive Secretariat.

Freedom of Information Staff.

Dockets Management Staff.

*Office of the Chief Scientist.*¹

Office of Counter-Terrorism and

Emerging Threats.

Office of Scientific Integrity.

Office of Regulatory Science and

Innovation.

Division of Science Innovation and

Critical Path.

Division of Scientific Computing and

Medical Information.

Office of Scientific Professional

Development.

Office of Health Informatics.

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 Office of External Affairs.
 Office of Media Affairs.
 Office of Communications.
 Office of Health and Constituent Affairs.
 Office of Minority Health.
 National Center for Toxicological Research.²
 Office of the Center Director.
 Office of Management.
 Office of Research.
 Division of Biochemical Toxicology.
 Division of Genetic and Molecular Toxicology.
 Division of Microbiology.
 Division of Systems Biology.
 Division of Neurotoxicology.
 Division of Bioinformatics and Biostatistics.
 Office of Scientific Coordination.
 Office of Foods and Veterinary Medicine.³
 Communications and Public Engagement Staff.
 Executive Secretariat Staff.
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 Strategic Planning and Budget Formulation Staff.
 Risk Analytics Staff.
 Office of Coordinated Outbreak Response and Evaluation Network.⁴
 Prevention Staff.
 Response Staff.
 Center for Food Safety and Applied Nutrition.⁵
 Office of the Center Director.
 International Affairs Staff.
 Executive Operations Staff.
 Office of Management.
 Safety Staff.
 Division of Budget & Planning.
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 Office of Analytics and Outreach.
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 Division of Education, Outreach and Information.
 Education and Outreach Branch.
 Information Center Branch.
 Web Branch.
 Division of Public Health Informatics and Analytics.
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 Signals Management Branch.
 Consumers Studies Branch.
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Analysis.
 Risk Analysis Branch.
 Contaminant Assessment Branch.
 Exposure Assessment Branch.
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 Retail Food Production Staff.
 Multi-Commodity Foods Staff.
 Division of Seafood Science and Technology.
 Chemical Hazard Science Branch.
 Microbiological Hazards Science Branch.
 Division of Food Processing Science & Technology.
 Process Engineering Branch.
 Food Technology Branch.
 Division of Plant and Dairy Food Safety.
 Plant Products Branch.
 Dairy and Egg Branch.
 Division of Seafood Safety.
 Shellfish and Aquaculture Policy Branch.
 Seafood Processing and Technology Policy Branch.
 Division of Produce Safety.
 Fresh Produce Branch.
 Processed Produce Branch.
 Division of Dairy, Egg, and Meat Products.
 Milk and Milk Products Branch.
 Egg and Meat Products Branch.
 Division of Plant Products and Beverages.
 Plant Products Branch.
 Beverages Branch.
 Office of Cosmetics and Colors.
 Division of Color Certification and Technology.
 Division of Cosmetics.
 Office of Regulatory Science.
 Division of Analytical Chemistry.
 Methods Development Branch.
 Spectroscopy and Mass Spectrometry Branch.
 Division of Microbiology.
 Microbial Methods and Development Branch.
 Molecular Methods and Subtyping Branch.
 Division of Bioanalytical Chemistry.
 Chemical Contaminants Branch.
 Bioanalytical Methods Branch.
 Office of Food Additive Safety.
 Division of Food Contract Notifications.
 Division of Biotechnology and GRAS Notice Review.
 Division of Petition Review.
 Office of Compliance.
 Division of Enforcement.
 Division of Field Programs and Guidance.
 Office of Applied Research and Safety Assessment.
 Division of Molecular Biology.
 Division of Virulence Assessment.
 Virulence Mechanisms Branch.
 Immunobiology Branch.

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 Regulations and Special Government Employee Management Staff.
 Division of Social Sciences.
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 Food Labeling and Standards Staff.
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 Office of Dietary Supplement Program.
 Evaluation and Research Staff.
 Regulatory Implementation Staff.
 Center for Veterinary Medicine.⁶
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 Talent Development Staff.
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 Budget Planning and Evaluation Staff.
 Office of New Animal Drug Evaluation.
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 Division of Production Drugs.
 Division of Therapeutic Drugs for Non-Food Animals.
 Division of Human Food Safety.
 Division of Manufacturing Technologies.
 Division of Scientific Support.
 Division of Generic Animal Drugs.
 Division of Business Information Science and Management.
 Office of Surveillance and Compliance.
 Division of Surveillance.
 Division of Animal Feeds.
 Division of Compliance.
 Division of Veterinary Product Safety.
 Office of Research.
 Division of Residue Chemistry.
 Division of Applied Veterinary Research.
 Division of Animal and Food Microbiology.
 Office of Minor Use and Minor Species Animal Drug Development.
 OFFICE OF MEDICAL PRODUCTS AND TOBACCO
 Office of Medical Products and Tobacco—Immediate Office.⁷
 Office of Special Medical Programs—Immediate Office.⁸
 Advisory Committee Oversight and Management Staff.
 Good Clinical Practice Staff.
 Office of Pediatric Therapeutics.
 Office of Orphan Products Development.
 Office of Combination Products.
 Center for Biologics Evaluation and Research.⁹

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⁶ Mailing address: Food and Drug Administration, 7519 Standish Pl., Rockville MD 20855.

⁷ Mailing address: 10903 New Hampshire Ave., Bldg. 1, Silver Spring, MD 20993.

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Office of the Center Director.
Executive Operations Staff.
Regulatory Information Management Staff.
Regulations and Policy Staff.
Records Management Staff.
Bioinformatics Support Staff.
Business Operations Staff.
Office of Management.
Planning and Performance Management Staff.
Division of Program Services.
Program Operations Branch.
Program Services Branch.
Division of Budget and Resource Management.
Budget Analysis and Formulation Branch.
Resource Management Branch.
Division of Program Services.
Building Operations Staff.
Program Management Services Branch.
Program Operations Branch.
Division of Scientific Advisors and Consultants.
Division of Veterinary Services.
Office of Compliance and Biologics Quality.
Division of Case Management.
Blood and Tissue Compliance Branch.
Advertising and Promotional Labeling Branch.
Biological Drug and Device Compliance Branch.
Division of Manufacturing and Product Quality.
Product Release Branch.
Manufacturing Review Branch I.
Manufacturing Review Branch II.
Applications Review Branch.
Division of Inspections and Surveillance.
Program Surveillance Branch.
Bioresearch Monitoring Branch.
Division of Biological Standards and Quality Control.
Laboratory of Analytical Chemistry and Blood Related Products.
Quality Assurance Branch.
Laboratory of Microbiology, In-vivo Testing and Standards.
Office of Blood Research and Review.
Administrative Staff.
Policy and Publication Staff.
Regulatory Project Management Staff.
Division of Emerging and Transfusion Transmitted Diseases.
Laboratory of Molecular Virology.
Laboratory of Emerging Pathogens.
Laboratory of Bacterial and Transmissible Spongiform Encephalopathy Agents.
Product Review Branch.
Division of Hematology Clinical Review.
Hematology Product Review Branch.
Clinical Review Branch.
Division of Blood Components and

Devices.
Blood and Plasma Branch.
Devices and Review Branch.
Division of Hematology Research and Review.
Laboratory of Cellular Hematology.
Laboratory of Hemostasis.
Laboratory of Plasma Derivatives.
Laboratory of Biochemistry and Vascular Biology.
Office of Vaccine Research and Review.
Program Operations Staff.
Division of Bacterial, Parasitic, and Allergenic Products.
Laboratory of Immunobiochemistry.
Laboratory of Respiratory and Special Pathogens.
Laboratory of Bacterial Polysaccharides.
Laboratory of Mucosal Pathogens and Cellular Immunology.
Division of Viral Products.
Laboratory of Pediatric and Respiratory Viral Diseases.
Laboratory of Hepatitis Viruses.
Laboratory of Retroviruses.
Laboratory of DNA Viruses.
Laboratory of Vector-Borne Diseases.
Laboratory of Method Development.
Laboratory of Immunoregulation.
Division of Vaccines and Related Products Applications.
Clinical Review Branch 1.
Clinical Review Branch 2.
CMC Review Branch 1.
CMC Review Branch 2.
CMC Review Branch 3.
Review Management Support Branch.
Office of Communication, Outreach, and Development.
Division of Disclosure and Oversight Management.
Congressional and Oversight Branch.
Access Litigation and Freedom of Information Branch.
Division of Manufacturers Assistance and Training.
Career Development and Directed Training Branch.
Manufacturers Assistance and Technical Training Branch.
Division of Communication and Consumer Affairs.
Communication Technology Branch.
Consumer Affairs Branch.
Office of Biostatistics and Epidemiology.
Division of Biostatistics.
Vaccine Evaluation Branch.
Therapeutics Evaluation Branch.
Division of Epidemiology.
Pharmacovigilance Branch.
Analytic Epidemiology Branch.
Office of Cellular, Tissue and Gene Therapies.
Regulatory Management Staff.
Division of Cellular and Gene Therapies.
Cell Therapies Branch.
Gene Therapies Branch.

Gene Transfer and Immunogenicity Branch.
Tumor Vaccine and Biotechnology Branch.
Cellular and Tissue Therapy Branch.
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General Medicine Branch.
Pharmacology/Toxicology Branch.
Oncology Branch.
Division of Human Tissues.
Human Tissue and Reproduction Branch.
*Center for Tobacco Products.*¹⁰
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Regulatory Science and Management Staff.
Research Staff.
Division of Regulatory Project Management.
Regulatory Project Management Branch I.
Regulatory Project Management Branch II.
Regulatory Project Management Branch III.
Regulatory Project Management Branch IV.
Division of Regulatory Science Informatics.
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Division of Individual Health Science.
Division of Population Health Science.
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*Center for Drug Evaluation and Research.*¹¹
Office of the Center Director.
Controlled Substance Staff.
Professional Affairs and Stakeholder Engagement Staff.
Counter-Terrorism and Emergency

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Coordination Staff.
 Drug Shortages Staff.
Office of Regulatory Policy.
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 Division of Regulatory Policy III.
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 Budget Execution Branch.
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 Human Capital Programs Branch.
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 Property and Travel Services Branch.
 Leave and Performance Management Branch.
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 Brands Branch.
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 Division of Online Communications.
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 Division of Drug Quality I.
 Global Compliance Branch I.
 Global Compliance Branch II.
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 Global Compliance Branch III.
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 Division of Prescription Drugs.
 Prescription Drugs Branch.
 Compounding and Pharmacy Practices Branch.
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 Over-the-Counter Drugs Branch.
 Health Fraud Branch.
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 Compliance Enforcement Branch.
 Postmarketing Safety Branch.
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 Good Clinical Practice Compliance Oversight Branch.
 Good Clinical Practice Assessment Branch.

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 Recalls and Shortages Branch.
 Import Export Compliance Branch.
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 Supply Chain Strategy and Policy Branch.
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 Project Management and Coordination Staff II.
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 Division of Consumer Drug Promotion.
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 Division of Biometrics II.
 Division of Biometrics III.
 Division of Biometrics IV.
 Division of Biometrics V.
 Division of Biometrics VI.
 Division of Biometrics VII.
 Division of Biometrics VIII.
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 Division of Clinical Pharmacology I.
 Division of Clinical Pharmacology II.
 Division of Clinical Pharmacology III.
 Division of Clinical Pharmacology IV.
 Division of Clinical Pharmacology V.
 Division of Pharmacometrics.
 Division of Applied Regulatory Science.
Office of Computational Science.
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 Division of New Drug Bioequivalence Evaluation.
 Division of Generic Drug Bioequivalence Evaluation.
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 Training Design and Delivery Branch.
 Leadership and Organizational Development Branch.
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Office of Medication Error Prevention and Risk Management.
 Division of Medication Error Prevention and Analysis.
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Office of Pharmacovigilance and Epidemiology.
 Division of Epidemiology I.
 Division of Epidemiology II.
 Division of Pharmacovigilance I.
 Division of Pharmacovigilance II.
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 Program Management and Analysis Staff.
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 Division of Cardiovascular and Renal Products.
 Division of Neurology Products.
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Office of Drug Evaluation II.
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 Division of Pulmonary, Allergy, and Rheumatology Products.
 Division of Anesthesia, Analgesia, and Addiction Products.
Office of Drug Evaluation III.
 Division of Gastroenterology and Inborn Effects Products.
 Division of Bone, Reproductive and Urologic Products.
 Division of Dermatology and Dental Products.
Office of Antimicrobial Products.
 Division of Anti-Infective Products.
 Division of Anti-Viral Products.
 Division of Transplant and Ophthalmology Products.
Office of Drug Evaluation IV.
 Division of Nonprescription Drug Products.
 Division of Medical Imaging Products.
 Division of Pediatrics and Maternal Health.
Office of Hematology and Oncology Drug Products.
 Division of Oncology Products I.
 Division of Oncology Products II.
 Division of Hematology Products.
 Division of Hematology Oncology Toxicology.
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 Division of Business Management Services and Solutions.
 Division of Data Management Services and Solutions.
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 Division of Bioequivalence I.
 Division of Bioequivalence II.
 Division of Bioequivalence III.
 Division of Clinical Review.
Office of Generic Drug Policy.
 Division of Legal and Regulatory Support.
 Division of Policy Development.
Office of Regulatory Operations.
 Division of Labeling Review.
 Division of Filing Review.
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 Program Management and Analysis Staff.
Office of Biotechnology Products.
 Division of Biotechnology Review and Research I.
 Division of Biotechnology Review and Research II.
 Division of Biotechnology Review and Research III.
 Division of Biotechnology Review and Research IV.
Office of New Drug Products.
 Division of Life Cycle API.
 Life Cycle Branch I.
 Life Cycle Branch II.
 Life Cycle Branch III.
 Division of New Drug API.
 New Drug Branch I.
 New Drug Branch II.
 Division of New Drug Products I.
 New Drug Products Branch I.
 New Drug Products Branch II.
 New Drug Products Branch III.
 Division of New Drug Products II.
 New Drug Products Branch IV.
 New Drug Products Branch V.
 New Drug Products Branch VI.
 Division of Biopharmaceutics.
 Biopharmaceutics Branch I.
 Biopharmaceutics Branch II.
 Biopharmaceutics Branch III.
Office of Policy for Pharmaceutical Quality.
 Division of Regulations, Guidance and Standards.
 Policy Development and Evaluation Branch I.
 Policy Development and Evaluation Branch II.
 Compensial Operations and Standards Branch.
 Division of Internal Policies and Programs.
 Policy Development and Evaluation Branch I.
 Policy Development and Evaluation Branch II.
Office of Process and Facilities.
 Division of Process Assessment I.
 Process Assessment Branch I.
 Process Assessment Branch II.
 Process Assessment Branch III.
 Division of Process Assessment II.
 Process Assessment Branch IV.
 Process Assessment Branch V.
 Process Assessment Branch VI.
 Division of Process Assessment III.
 Process Assessment Branch VII.
 Process Assessment Branch VIII.
 Process Assessment Branch IX.
Division of Microbiology Assessment.
 Microbiology Assessment Branch I.
 Microbiology Assessment Branch II.
 Microbiology Assessment Branch III.
 Microbiology Assessment Branch IV.
Division of Inspectional Assessment.
 Inspectional Assessment Branch I.
 Inspectional Assessment Branch II.
 Inspectional Assessment Branch III.
Office of Surveillance.
 Division of Quality Intelligence, Risk Analysis, and Modeling.
 Data Integrity Branch.
 Quality Intelligence Branch.
 Analysis and Modeling Branch.
 Division of Quality Surveillance Assessment.
 Quality Deviation and Assessment Branch.
 Inspection Assessment Branch.
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 Division of Product Quality Research.
 Product Quality Branch I.
 Product Quality Branch II.
 Division of Pharmaceutical Analysis.
 Pharmaceutical Analysis Branch I.
 Pharmaceutical Analysis Branch II.
Office of Program and Regulatory Operations.
 Division of Regulatory and Business Process Management I.
 Regulatory and Business Process Management Branch I.
 Regulatory and Business Process Management Branch II.
 Division of Regulatory and Business Process Management II.
 Regulatory and Business Process Management Branch III.
 Regulatory and Business Process Management Branch IV.
 Division of Operational Excellence, Learning, and Professional Development.
 Learning and Professional Development Branch.
 Organizational Excellence Branch.
Office of Lifecycle Drug Products.
 Division of Immediate Release Products I.
 Immediate Release Branch I.
 Immediate Release Branch II.
 Immediate Release Branch III.
 Division of Immediate Release Products II.
 Immediate Release Branch IV.
 Immediate Release Branch V.
 Immediate Release Branch VI.
 Division of Modified Release Products.
 Modified Release Branch I.
 Modified Release Branch II.
 Modified Release Branch III.
 Division of Liquid-Based Products.
 Liquid-Based Branch I.
 Liquid-Based Branch II.
 Liquid-Based Branch III.
 Division of Post-Marketing Activities I.
 Post-Marketing Branch I.
 Post-Marketing Branch II.
 Division of Post-Marketing Activities II.
 Post-Marketing Branch III.
 Post-Marketing Branch IV.
 Post-Marketing Branch V.
*Center for Devices and Radiological Health.*¹²
Office of the Center Director.
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 Human Resources and Administrative Management Branch.
 Integrity, Conference and Committee Management Branch.
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 Planning Branch.
 Financial Management Branch.
Office of Compliance.
 Program Management Staff.
 Division of Bioresearch Monitoring.
 Bioresearch Compliance Branch I.
 Bioresearch Compliance Branch II.
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 Quality Management System and Executive Secretary Staff.
 Field Inspections Support Branch.
 Recall Branch.
 Registration and Risk Branch.
 Allegations of Regulatory Misconduct Branch.
 Division of Manufacturing and Quality.
 Physical Medicine, Orthopedic, Neurology, and Dental Devices Branch.
 Cardiovascular Devices Branch.

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Abdominal and Surgical Devices Branch.
 Respiratory, Ear/Nose/Throat, General Hospital, and Ophthalmic Devices Branch.
 Division of Premarket and Labeling Compliance.
 Surveillance and Enforcement Branch I.
 Surveillance and Enforcement Branch II.
 Division of International Compliance Operations.
 Foreign Enforcement Branch.
 Imports Branch.
 Exports Branch.
Office of Device Evaluation.
 Program Management Staff.
 Program Operations Staff.
 Pre-Market Approval Staff.
 Investigational Device Exemption Staff.
 Pre-Market Notification Section.
 Division of Cardiovascular Devices.
 Circulatory Support Devices Branch.
 Cardiac Diagnostics Devices Branch.
 Implantable Electrophysiology Devices Branch.
 Vascular Surgery Devices Branch.
 Structural Heart Devices Branch.
 Interventional Cardiology Devices Branch.
 Cardiac Electrophysiology Devices Branch.
 Peripheral Interventional Devices Branch.
 Division of Reproductive, Gastro-Renal, and Urological Devices.
 Obstetrics/Gynecology Devices Branch.
 Urology and Lithotripsy Devices Branch.
 Renal Devices Branch.
 Gastroenterology Devices Branch.
 Division of Orthopedic Devices.
 Restorative and Repair Devices Branch.
 Joint and Fixation Branch I.
 Joint and Fixation Branch II.
 Anterior Spine Devices Branch.
 Posterior Spine Devices Branch.
 Division of Ophthalmic and Ear, Nose, and Throat Devices.
 Intraocular and Corneal Implant Devices Branch.
 Diagnostic and Surgical Devices Branch.
 Contact Lenses and Retinal Devices Branch.
 Ear, Nose and Throat Devices Branch.
 Division of Anesthesiology, General Hospital, Respiratory Infection Control, and Dental Devices.
 General Hospital Devices Branch.
 Infection Control Devices Branch.
 Dental Devices Branch.
 Anesthesiology Devices Branch.
 Respiratory Devices Branch.
 Division of Neurological and Physical

Medicine Devices.
 Neurostimulation Devices Branch.
 Neurodiagnostic and Neurosurgical Devices Branch.
 Physical Medicine Devices Branch.
 Division of Surgical Devices.
 General Surgery Devices Branch I.
 General Surgery Devices Branch II.
 Plastic and Reconstructive Surgery Devices Branch I.
 Plastic and Reconstructive Surgery Devices Branch II.
Office of Science and Engineering Laboratories.
 Division of Biology, Chemistry, and Materials Science.
 Division of Biomedical Physics.
 Division of Imaging, Diagnostics, and Software Reliability.
 Division of Applied Mechanics.
 Division of Administrative and Laboratory Support.
Office of Communication and Education.
 Program Management Operations Staff.
 Digital Communication Media Staff.
 Division of Health Communication.
 Web Communication Branch.
 Strategic Communication Branch.
 Division of Industry and Consumer Education.
 Postmarket and Consumer Branch.
 Premarket Programs Branch.
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 Freedom of Information Branch A.
 Freedom of Information Branch B.
 Division of Employee Training and Development.
 Employee Development Branch.
 Technology and Learning Management Branch.
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 Program Management Staff.
 Informatics Staff.
 Signal Management Staff.
 Division of Biostatistics.
 Therapeutic Statistics Branch I.
 Therapeutic Statistics Branch II.
 Therapeutic Statistics Branch III.
 Diagnostic Statistics Branch I.
 Diagnostic Statistics Branch II.
 Division of Postmarket Surveillance.
 Product Evaluation Branch I.
 Product Evaluation Branch II.
 Product Evaluation Branch III.
 Information Analysis Branch.
 MDR Policy Branch.
 Division of Patient Safety Partnership.
 Clinical Outreach Branch I.
 Clinical Outreach Branch II.
 Division of Epidemiology.
 Epidemiologic Evaluation and Research Branch I.
 Epidemiologic Evaluation and Research Branch II.
 Epidemiologic Evaluation and Research Branch III.
Office of In Vitro Diagnostics and Radiological Health.

Division of Chemistry and Toxicology Devices.
 Chemistry Branch.
 Diabetes Branch.
 Toxicology Branch.
 Cardio-Renal Diagnostics Branch.
 Division of Immunology and Hematology Devices.
 Hematology Branch.
 Immunology and Flow Cytometry Branch.
 Division of Microbiology Devices.
 Viral Respiratory and HPV Branch.
 General Viral and Hepatitis Branch.
 General Bacterial and Antimicrobial Susceptibility Branch.
 Bacterial Respiratory and Medical Countermeasures Branch.
 Division of Radiological Health.
 Magnetic Resonance and Electronic Products Branch.
 Diagnostic X-Ray Systems Branch.
 Nuclear Medicine and Radiation Therapy Branch.
 Mammography, Ultrasound and Imaging Software Branch.
 Division of Mammography Quality Standards.
 Program Management Branch.
 Information Management Branch.
 Division of Program Operations and Management.
 Division of Molecular Genetics and Pathology.
 Molecular Pathology and Cytology Branch.
 Molecular Genetics Branch.
*Office of Global Regulatory Operations and Policy.*¹³
*Office of International Programs.*¹⁴
*Office of Regulatory Affairs.*¹⁵
Office of the Associate Commissioner for Regulatory Affairs.
 Executive Secretariat Staff.
 Information Technology Staff.
*Office of Resource Management.*¹⁶
 Division of Planning Evaluation and Management.
 Program Planning and Workforce Management Branch.
 Program Evaluation Branch.
 Division of Budget Formulation and Execution.
 Division of Human Resources Development.
 Division of Management Operations.
*Office of Criminal Investigations.*¹⁷
 Mid-Atlantic Area Office.
 Philadelphia Resident Unit.

¹³ Mailing address: 10903 New Hampshire Ave., Bldg. 1, Silver Spring, MD 20993.

¹⁴ Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

¹⁵ Mailing address: 10903 New Hampshire Ave., Bldg. 31, Silver Spring, MD 20993.

¹⁶ Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

¹⁷ Mailing address: 7500 Standish Pl., MPN2 Building, Rockville, MD 20855.

Midwest Area Office.
 Northeast Area Office.
 Boston, MA Resident Unit.
 Pacific Area Office.
 San Francisco, CA Resident Unit.
 Southeast Area Office.
 San Juan, PR Resident Unit.
 Atlanta, GA Resident Unit.
 New Orleans, LA Resident Unit.
 Southwest Area Office.
 Dallas, TX Resident Unit.
Office of Communications and Quality Program Management.
 Quality Management Systems Staff.
 Project Coordination Staff.
 Division of Communications.
 Public Affairs and Editorial Services Branch.
 Web and Digital Media Strategies Branch.
*Office of Partnerships.*¹⁸
 Standards Implementation Staff.
 Contracts and Grants Staff.
*Office of Policy and Risk Management.*¹⁹
 Food and Feed Policy Staff.
 Medical Products and Tobacco Policy Staff.
 Risk Management Staff.
 Division of Planning Evaluation and Management.
 Program Evaluation Branch.
 Work Planning Branch.
*Office of Operations.*²⁰
 Audit Staff.
*Office of Enforcement and Import Operations.*²¹
 Division of Enforcement.
 Division of Compliance Systems.
 Enforcement Systems Branch.
 Import Compliance Systems Branch.
 Division of Import Operations.
 Import Operations and Maintenance Branch.
 Import Program Development and Implementation Branch.
*Office of Regulatory Science.*²²
 Food and Feed Scientific Staff.
 Medical Products and Tobacco Scientific Staff.
 Laboratory Operations and Support Staff.
*Office of Food and Feed Operations.*²³
 Division of Food Defense Targeting.
 Division of Food and Feed Program Operations and Inspections.
 Food and Feed Program Operations

Branch.
 Food and Feed Inspection Branch.
 Food and Feed Trip Planning Branch.
*Office of Medical Products and Tobacco Operations.*²⁴
 Division of Products and Tobacco Program Operations.
 Medical Device and Tobacco Program Operations Branch.
 Team Biological Branch.
 Division of Medical Products and Tobacco Inspections.
 Medical Products and Tobacco Inspection Branch.
 Drug Inspection Branch.
 Medical Products and Tobacco Trip Planning Branch.
*Regional Field Office, Northeast Region, Jamaica, NY.*²⁵
 Operations Staff.
 Intergovernmental Affairs Staff.
 District Office New York.²⁶
 Domestic Compliance Branch.
 Domestic Investigations Branch.
 Resident Post Long Island, NY.
 Resident Post White Plains, NY.
 Resident Post Albany, NY.
 Resident Post Binghamton, NY.
 Resident Post Rochester, NY.
 Resident Post Newburgh, NY.
 Resident Post Syracuse, NY.
 Import Operations Branch (Downstate).
 Resident Post Port Elizabeth, NJ.
 Import Operations Branch (Upstate).
 Resident Post Champlain, NY.
 Resident Post Alexandria Bay, NY.
 Resident Post Massena, NY.
 Resident Post Ogdensburg, NY.
 Northeast Regional Laboratory.²⁷
 Microbiological Science Branch.
 Chemistry Branch 1.
 Chemistry Branch 2.
 New England District Office.²⁸
 Compliance Branch.
 Investigations Branch.
 Resident Post Augusta, ME.
 Resident Post Bridgeport, CT.
 Resident Post Concord, NH.
 Resident Post Hartford, CT.
 Resident Post Providence, RI.
 Resident Post Worcester, MA.
 Resident Post Calais, ME.
 Resident Post Houlton, ME.
 Resident Post Highgate, VT.
 Winchester Engineering and Analytical Center.²⁹
 Analytical Branch.

Engineering Branch.
*Regional Field Office, Southwest Region, Dallas, TX.*³⁰
 State Cooperative Programs Staff.
 Resident Post Pharr.
 Dallas District Office.³¹
 Compliance Branch.
 Investigations Branch.
 Resident Post Austin, TX.
 Resident Post Fort Worth, TX.
 Resident Post Houston, TX.
 Resident Post San Antonio, TX.
 Resident Post Oklahoma City, OK.
 Resident Post Little Rock, AR.
 Kansas City District Office.³²
 Investigations Branch.
 Resident Post Wichita, KS.
 Resident Post Omaha, NE.
 Resident Post Des Moines, IA.
 Resident Post Springfield, MO.
 Resident Post St Louis, MO.
 Resident Post Davenport, IA.
 Compliance Branch.
 Denver District Office.³³
 Compliance Branch.
 Investigations Branch.
 Resident Post Salt Lake City, UT.
 Resident Post Albuquerque, NM.
 Arkansas Regional Laboratory.³⁴
 General Chemistry Branch.
 Pesticide Chemistry Branch.
 Microbiology Branch.
 Southwest Import District Office Dallas, TX.³⁵
 Compliance Branch.
 Investigations Branch.
 Resident Post Calexico.
 Resident Post Eagle Pass.
 Resident Post El Paso Bota.
 Resident Post El Paso Bota Westmoreland.
 Resident Post El Paso Ysleta Bridge.
 Resident Post Houston (SWID).
 Resident Post Laredo #2 Bridge.
 Resident Post Laredo Columbia Bridge.
 Resident Post Laredo World Trade Bridge.
 Resident Post Los Tomates.
 Resident Post Nogales #1.
 Resident Post Nogales #2.
 Resident Post Otay Mesa #1.
 Resident Post Otay Mesa #2.
 Resident Post Pharr.
 Resident Post Rio Grande City.
 Resident Post San Luis.
 Kansas City Laboratory.³⁶

³⁰ Mailing address: 4040 North Central Expressway, Dallas, TX 75204-3128.

³¹ Mailing address: 4040 North Central Expressway, Suite 300, Dallas, TX 75204-3128.

³² Mailing address: 8050 Marshal Dr., Suite 250, Lenexa, KS 66214.

³³ Mailing address: Sixth Avenue and Kipling Street, Building 20, P.O. Box 25087, Denver, CO 80255-0087—Denver Federal Center.

³⁴ Mailing address: 3900 NCTR Rd., Bldg. 26, Jefferson, AR 72079.

³⁵ Mailing address: 4040 North Central Expressway, Suite 300, Dallas, TX 75204-3128.

³⁶ Mailing address: 11510 West 80th St., Lenexa, KS 66214.

¹⁸ Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

¹⁹ Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

²⁰ Mailing address: 10903 New Hampshire Ave., Bldg. 31, Silver Spring, MD 20993.

²¹ Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

²² Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

²³ Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

²⁴ Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

²⁵ Mailing address: 158-15 Liberty Ave., Jamaica, NY 11433.

²⁶ Mailing address: 158-15 Liberty Ave., Jamaica, NY 11433.

²⁷ Mailing address: 158-15 Liberty Ave., Jamaica, NY 11433.

²⁸ Mailing address: 1 Montvale Ave., 4th Floor, Stoneham, MA 02180-3500.

²⁹ Mailing address: 109 Holton St., Winchester, MA 01890.

Denver Laboratory.³⁷
Central Regional Field Office Chicago
 IL.³⁸

State Cooperative Programs Staff I.
 State Cooperative Programs Staff II.
 Regional Operations Staff.
 Baltimore District Office Baltimore,
 MD.³⁹

Compliance Branch.
 Investigations Branch.
 Resident Post Charleston, WV.
 Resident Post Falls Church, VA.
 Resident Post Seva.
 Resident Post Richmond, VA.
 Resident Post Roanoke, VA.
 Resident Post Dundalk Marine
 Terminal, MD.

Resident Post Morgantown, WV.
 District Office Cincinnati, OH.⁴⁰

Compliance Branch.
 Investigations Branch.
 Resident Post Brunswick, OH.
 Resident Post Columbus, OH.
 Resident Post Toledo, OH.
 Resident Post Louisville, KY.
 Forensic Chemistry Center.⁴¹
 Inorganic Chemistry Branch.
 Organic Chemistry Branch.
 District Office Parsippany, NJ.⁴²
 Compliance Branch.
 Investigations Branch.
 Resident Post Voorhees, NJ.
 Resident Post North Brunswick, NJ.
 District Office Philadelphia, PA.⁴³

Compliance Branch.
 Investigations Branch.
 Resident Post Harrisburg, PA.
 Resident Post Pittsburgh, PA.
 Resident Post Wilkes-Barre, PA.
 Resident Post Wilmington, PA.
 District Office Chicago, IL.⁴⁴
 Compliance Branch.
 Investigations Branch.
 Resident Post Peoria, IL.
 Resident Post Hinsdale, IL.
 Resident Post Gurnee, IL.
 Resident Post Springfield, IL.
 Resident Post O'Hare Airport.
 District Office Minneapolis, MN.⁴⁵
 Compliance Branch.
 Investigations Branch.

³⁷ Mailing address: Sixth Avenue and Kipling Street, Building 20, Denver, CO 80255-0087—Denver Federal Center.

³⁸ Mailing address: 20 N. Michigan Ave., Suite 510, Chicago, IL 60602.

³⁹ Mailing address: 6000 Metro Dr., Suite 101, Baltimore, MD 21215.

⁴⁰ Mailing address: 6751 Steger Dr., Cincinnati, OH 45237.

⁴¹ Mailing address: 6751 Steger Dr., Cincinnati, OH 45237.

⁴² Mailing address: 10 Waterview Blvd., 3rd Floor, Parsippany, NJ 07054—Waterview Corporate Center.

⁴³ Mailing address: 200 Chestnut St., Room 900, Philadelphia, PA 19106—U.S. Customs House.

⁴⁴ Mailing address: 550 West Jackson Blvd., Suite 1500, Chicago, IL 60661.

⁴⁵ Mailing address: 250 Marquette Ave., Suite 600, Minneapolis, MN 55401.

Resident Post La Crosse, WI.
 Resident Post Green Bay, WI.
 Resident Post Milwaukee, WI.
 Resident Post Madison, WI.
 Resident Post Fargo, ND.
 Resident Post Stevens Point, WI.
 Resident Post Sioux, SD.

District Office Detroit, MI.⁴⁶
 Compliance Branch.

Investigations Branch.
 Resident Post Kalamazoo, MI.
 Resident Post South Bend, IN.
 Resident Post Indianapolis, IN.
 Resident Post Evansville, IN.
 Resident Post
 Philadelphia Laboratory.⁴⁷
 Detroit Laboratory.⁴⁸

Southeast Regional Field Office Atlanta,
 GA.⁴⁹

State Cooperative Programs Staff
 Atlanta District Office.⁵⁰
 Compliance Branch.
 Investigations Branch.
 Resident Post Savannah, GA.
 Resident Post Tifton, GA.
 Resident Post Charlotte, NC.
 Resident Post Greensboro, NC.
 Resident Post Greenville, NC.
 Resident Post Raleigh, NC.
 Resident Post Charleston, SC.
 Resident Post Columbia, SC.
 Resident Post Greenville, SC.
 Resident Post Asheville, NC.
 Florida District Office.⁵¹

Compliance Branch.
 Investigations Branch.
 Resident Post Jacksonville, FL.
 Resident Post Miami, FL.
 Resident Post Tallahassee, FL.
 Resident Post Tampa, FL.
 Resident Post Boca Raton, FL.
 Resident Post Ft. Meyers, FL.
 Resident Post Port Everglades, FL.
 New Orleans, LA, District Office.⁵²
 Compliance Branch.
 Investigations Branch.
 Resident Post Baton Rouge, LA.
 Resident Post Lafayette, LA.
 Resident Post Covington, LA.
 Resident Post Jackson, MS.
 Resident Post Mobile, AL.
 Nashville Branch.
 Resident Post Knoxville, TN.
 Resident Post Memphis, TN.
 Resident Post Birmingham, AL.
 Resident Post Montgomery, AL.

⁴⁶ Mailing address: 300 River Pl., Suite 5900, Detroit, MI 48207.

⁴⁷ Mailing address: 200 Chestnut St., Room 900, Philadelphia, PA 19106—U.S. Customs House.

⁴⁸ Mailing address: 300 River Pl., Suite 5900, Detroit, MI 48207.

⁴⁹ Mailing address: 60 Eighth St. NE., Atlanta, GA 30309.

⁵⁰ Mailing address: 60 Eighth St. NE., Atlanta, GA 30309.

⁵¹ Mailing address: 555 Winderley Pl., Suite 200, Maitland, FL 32751.

⁵² Mailing address: 404 BNA Dr., Building 200, Suite 500, Nashville, TN 37217.

San Juan District Office.⁵³
 Compliance Branch.
 Investigations Branch.
 Resident Post Aquada, PR.
 Resident Post Ponce, PR.
 Southeast Regional Laboratory
 Atlanta, GA.⁵⁴
 Chemistry Branch I.
 Microbiology Branch.
 Atlanta Center for Nutrient Analysis.
 Chemistry Branch II.
 San Juan Laboratory.⁵⁵

Regional Field Office, Pacific Region,
 Oakland, CA.⁵⁶

State Cooperative Programs Staff.
 District Office San Francisco, CA.⁵⁷
 Compliance Branch.
 Investigations Branch.
 Resident Post Las Vegas, NV.
 Resident Post Fresno, CA.
 Resident Post Sacramento, CA.
 Resident Post Honolulu, HI.
 Resident Post San Jose, CA.
 Resident Post Stockton, CA.
 Resident Post South San Francisco.
 District Office Los Angeles, CA.⁵⁸
 Compliance Branch.
 Import Operations Branch.
 Resident Post Los Angeles Airport.
 Resident Post Ontario, CA—Import.
 Domestic Investigations Branch.
 Resident Post Woodland Hills, CA.
 Resident Post San Diego, CA.
 Resident Post Tempe, AZ.
 Resident Post Ontario, CA—Domestic.
 District Office Seattle, WA.⁵⁹
 Compliance Branch.
 Investigations Branch.
 Resident Post Anchorage, AK.
 Resident Post Boise, ID.
 Resident Post Portland, ID.
 Resident Post Spokane, WA.
 Resident Post Oroville, WA.
 Resident Post Portland, OR—Airport.
 Resident Post Blaine, WA.
 Resident Post Helena, MT.
 Resident Post Sweetgrass, MT.
 Resident Post Tacoma, WA.
 Resident Post Puget Sound, WA.
 Pacific Regional Laboratory
 Southwest.⁶⁰
 Food Chemistry Branch.
 Drug Chemistry Branch.
 Microbiology Branch.

⁵³ Mailing address: 466 Fernandez Juncos Ave., San Juan, PR 00901.

⁵⁴ Mailing address: 60 Eighth St., Atlanta, GA 30309.

⁵⁵ Mailing address: 466 Fernandez Juncos Ave., San Juan, PR 00901.

⁵⁶ Mailing address: 1301 Clay St., Room 1180N, Oakland, CA 94612.

⁵⁷ Mailing address: 1431 Harbor Bay Pkwy., Alameda, CA 94502.

⁵⁸ Mailing address: 19701 Fairchild Rd., Irvine, CA 92612.

⁵⁹ Mailing address: 22215 26th Ave. SE., Suite 210, Bothell, WA 98021.

⁶⁰ Mailing address: 19701 Fairchild Rd., Irvine, CA 92612.

Pacific Regional Laboratory
Northwest.⁶¹
Chemistry Branch.
Microbiology Branch.
Seafood Products Research Center.
Office of Operations.
Office of Business Services.
Business Operations Staff.
Employee Resource and Information
Center.
Division of Ethics and Integrity.
Office of Equal Employment
Opportunity.
Compliance Staff.
Office of Finance, Budget, and
Acquisitions.
Office of Budget.
Division of Budget Formulation.
Division of Budget Execution and
Control.
Office of Acquisition and Grant
Services.
Division of Acquisition Operations.
Division of Acquisition Programs.
Division of Acquisition Support and
Grants.
Division of Information Technology.
Office of Financial Operations.
Office of Financial Management.
Office of Financial Services.
Office of Human Resources.
Commission Corps Affairs Staff.
Management Analysis Services Staff.
Business Operations Staff.
Division of Workforce Relations.
Division of Policy, Programs, and
Executive Resources.
Division of Human Resource Services
for Office of the Commissioner/
Office of Operations.
Division of Human Resource Services
for Office of Foods and Veterinary
Medicine/Office of Global
Operations and Policy.
Division of Human Resource Services
for Office of Medical Products and
Tobacco.
FDA University.
Office of Facilities, Engineering and
Mission Support Services.
Jefferson Laboratories Complex Staff.
Division of Operations Management
and Community Relations.
Division of Planning, Engineering and
Safety Management.
Office of Information Management and
Technology.
Office of Information Management.
Office of Technology and Delivery.
Division of Infrastructure Operations.
Division of Application Services.
Division of Delivery Management and
Support.
Office of Business and Customer
Assurance.
Division of Business Partnership and

Support.
Division of Management Services.
Office of Enterprise and Portfolio
Management.
Office of Safety, Security, and Crisis
Management.
Office of Security Operations.
Office of Crisis Management.
Office of Emergency Operations.
Office of Policy, Planning, Legislation,
*and Analysis.*⁶²
Management and Operations Staff.
Intergovernment Affairs Staff.
Office of Policy.
Regulations Policy and Management
Staff.
Policy Development and Coordination
Staff.
Office of Planning.
Planning Staff.
Program Evaluation and Process
Improvement Staff.
Economics Staff.
Risk Communication Staff.
Office of Legislation.
Office of Public Health Strategy and
Analysis.

Dated: November 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26799 Filed 11–4–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2016–0922]

Special Local Regulation; San Diego Fall Classic; Mission Bay, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement
regulation.

SUMMARY: The Coast Guard will enforce the special local regulation on the waters of Mission Bay, California during the San Diego Fall Classic boat racing event from 6:00 a.m. to 12:00 p.m. on November 13, 2016. These special local regulations are necessary to provide for the safety of the participants, crew, spectators, sponsor vessels, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area unless authorized by the Captain of the Port, or his designated representative.

DATES: The regulations in 33 CFR 100.1101 will be enforced from 6 a.m. through 12 p.m. on November 13, 2016 for Item 1 in Table 1 of § 100.1101.

FOR FURTHER INFORMATION CONTACT: If you have questions about this publication of enforcement, call or email Lieutenant Robert Cole, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone (619) 278–7656, email D11MarineEventsSD@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation in 33 CFR 100.1101 for the San Diego Fall Classic in Mission Bay, CA in 33 CFR 100.1101, Table 1, Item 1 of that section from 6 a.m. until 12 p.m. on November 13, 2016. This enforcement action is being taken to provide for the safety of life on navigable waterways during the races. The Coast Guard's regulation for recurring marine events in the San Diego Captain of the Port Zone identifies the regulated entities for this event. Under the provisions of 33 CFR 100.1101, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area of Mission Bay, to include South Pacific Passage, Fiesta Bay and the waters surrounding Vacation Isle, unless authorized by the Captain of the Port, or his designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

This document is issued under authority of 5 U.S.C. 552(a) and 33 CFR 100.1101. In addition to this document in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners, Broadcast Notice to Mariners, and local advertising by the event sponsor.

If the Captain of the Port Sector San Diego or his designated representative determines that the regulated area need not be enforced for the full duration stated on this document, he or she may use a Broadcast Notice to Mariners or other communications coordinated with the event sponsor to grant general permission to enter the regulated area.

Dated: October 21, 2016.

J.R. Buzzella,

Captain, U.S. Coast Guard, Captain of the Port San Diego.

[FR Doc. 2016–26869 Filed 11–4–16; 8:45 am]

BILLING CODE 9110–04–P

⁶¹ Mailing address: 22201 23rd Dr. SE., Bothell, WA 98021–4421.

⁶² Mailing address: 10903 New Hampshire Ave., Silver Spring, MD 20993.