Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of July 3, 2024. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved new drug application violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on July 3, 2024 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become volatile, whichever occurs first.

Dated: May 29, 2024.

Lauren K. Roth, Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of the Commissioner, Headquarters organizations, and Centers have modified their organizational structure.

DATES: This organization was approved by the Secretary of Health and Human Services on March 5, 2024, and became effective on May 13, 2024.


The Food and Drug Administration (FDA) is focused on transforming its organization structure to be more efficient, nimble, and ready for the future with the ever-changing and complex industries we regulate, including the emergence of new food and medical product technologies, the impacts of globalization, climate change and other factors that require FDA to quickly adapt to a consistently evolving world. FDA carefully reviewed the findings and recommendations of the Reagan-Udall Foundation evaluation, an internal review of FDA’s infant formula response and feedback from external and internal stakeholders during events such as listening sessions with FDA employees. The approved changes in the Human Foods Program (HFP) would allow us to fully realize the preventive vision laid out in the FDA Food Safety Modernization Act, elevate the importance of nutrition, strengthen local, state, and international partnerships, position the FDA to regulate innovative food and agricultural products more effectively, and uphold safety of the nation’s food supply. The organizational changes impact other products that FDA regulates, such as medical products and cosmetics, by promoting more streamlined, efficient decision-making and strengthening the enterprise-wide structure to enhance collaboration across FDA.

The intent is to have a modernized FDA that optimizes resources to help the agency meet its public health mission; provide employees with clearer priorities and more career opportunities; and comply with recent legislation such as the Food and Drug Omnibus Reform Act of 2022 (FDORA) mandating the establishment of the Office of Critical Foods, and the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) to ensure the safety of cosmetics products.

The reorganization establishes the HFP by realigning the functions of the Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Policy and Response, as well as key functions from the Office of Regulatory Affairs (ORA) including human foods compliance, Human and Animal Food Laboratories, and State Partnerships to this new organization. The reorganization will also:

- Realign ORA’s compliance functions to Center for Biologics Evaluation and Research’s Office of Compliance and its substructure organizations, and the Center for Veterinary Medicine’s Office of Surveillance and Compliance.
- Realign ORA’s laboratory safety functions and resources as well as the Medical Product and Specialty Laboratories safety functions and resources to the Office of the Chief Scientist.
- Realign emergency response functions and resources from the Office of Operations’ Office of Security and Emergency Management to OII.

Realignment of functions to strengthen the Office of the Commissioner (OC) and headquarter organizations, including:
- Establish, within OC immediate organization, the Office of Enterprise Transformation to focus on key information technology transformation projects across FDA.
- Realign the Office of Planning, Evaluation and Risk Management, within OC immediate organization, to focus on strategic initiatives for FDA.
- Realign the Office of Clinical Policy and Programs and realign functions to form the Office of the Chief Medical Officer.
- Realign the Office of External Affairs’ Stakeholder Engagement Staff to Public Engagement Staff.

Retitle the Informatics and Business Operations Staff from the ORA Office of Regulatory Science to the OCS immediate organization.

- Merge the Office of Counter-Terrorism and Emerging Threats, and the Office of Regulatory Science and Innovation, to form the Office of Regulatory and Emerging Science. Establish the Communications and Outreach Staff, the Preparedness Research Staff and the Regulatory Science Staff to this new organization.

- Merge the Office of Laboratory Safety and OO’s ESOH within OFEMS to the organization titled as the Office of Occupational Safety and Health (OOSH). Within the OOSH, merge the functions of the former OO ESOH with those of the OCS Office of Laboratory Safety, and establish the Occupational Safety Staff and the Occupational Health Services Staff to this new organizational component.

- Realign the Office of Cosmetics and Colors organization, including its divisions and branches, functions and resources, from CFSAN to OCS.

- Establish the Office of Analytical and Regulatory Laboratories and realign resources from the ORA Office of Medical Products Laboratory Operations and substructure organizations, and realign functions from within the CFSAN Office of Regulatory Science to this new organization which will be a direct report to OCS.

- Establish the Office of Specialty Laboratories and Enforcement Support and realign functions from the ORA’s Office of Medical Products Laboratory Operations within the Office of Regulatory Science to this new organization which will be a direct report to OCS.
Establish the Office of Science and Laboratory Advancement and realign functions from ORA’s Office of Safety within the Office of Regulatory Science to this new organization which will be a direct report to OCS.

DCA. ORGANIZATION. To reflect these changes, Part D, Section D–B, is replaced with the following:
The Office of the Commissioner is headed by the Commissioner of Food and Drugs, and includes the following organizational units:
Office of the Commissioner (DCA)
Office of the Chief Counsel (DCAA)
Office of the Executive Secretariat (DCAB)
Office of the Counselor to the Commissioner (DCAC)
Office of Digital Transformation (DCAD)
Strategy and Operations Staff (DCDA1)
Office of Information Management and Technology (DCADA)
Office of Technology and Delivery (DCADAA)
Delivery Management Support Staff (DCADAAA)
Division of Infrastructure Operations (DCADAAA)
Infrastructure Management Services Staff (DCADAAA1)
Implementation Branch (DCADAAA2)
Infrastructure Engineering Branch (DCADAAA3)
Systems Monitoring and Response Branch (DCADAAA4)
Systems Operations Branch (DCADAAA5)
Network and Communications Operations Branch (DCADAAA6)
Division of Application Services (DCADAB)
Application Management Services Staff (DCADAB1)
Data Management and Operations Branch (DCADAB2)
Medical Products Branch (DCADAB3)
OC, CVM, CTP Branch (DCADAB4)
ORA, CFSAN Branch (DCADAB5)
Enterprise Application Branch (DCADAB6)
Office of Business and Customer Assurance (DCADAB)
Division of Business Partnership and Support (DCADABA)
Internet and Intranet Branch (DCADABA1)
Call Center Branch (DCADABA2)
Regional Support Branch (DCADABA3)
Property Receiving and Distribution Branch (DCADABA4)
Employee Resource and Information Center (DCADABA5)
Division of Management Services (DCADABB)
Office of Enterprise Portfolio Management (DCADAC)
Office of Information Security (DCADB)
Office of Data Analytics and Research (DCADC)
Data Staff (DCADC1)
Health Informatics Staff (DCADC2)
Knowledge Management Staff (DCADC3)
Office of Enterprise Transformation (DCADE)
Office of Planning, Evaluation, and Risk Management (DCAG)
Administrative Staff (DCAG1)
Strategic Planning and Change Management Staff (DCAG2)
Evaluation and Analytics Staff (DCAG3)
Enterprise Risk Management Staff (DCAG4)
Performance Management Staff (DCAG5)

DCBC. ORGANIZATION. The Office of Compliance and Biologics Quality within the Center for Biologics Evaluation and Research is headed by the Director for Compliance and Biologics Quality and includes the following organizational units:
Office of Compliance and Biologics Quality (DCBC)
Division of Case Management (DCBCA)
Blood and Tissue Compliance Branch (DCBCA1)
Advertising and Promotional Labeling Branch (DCBCA2)
Biological Drug and Device Compliance Branch 1 (DCBCA3)
Biological Drug and Device Compliance Branch 2 (DCBCA4)
Division of Inspections and Surveillance (DCBCB)
Program Surveillance Branch (DCBCB1)
Bioresearch Monitoring Branch (DCBCB2)
Field Surveillance Branch (DCBCB3)
Division of Manufacturing and Product Quality (DCBCC)
Product Release Branch (DCBCC1)
Manufacturing Review Branch 1 (DCBCC2)
Manufacturing Review Branch 2 (DCBCC3)
Manufacturing Review Branch 3 (DCBCC4)
Applications Review Branch (DCBCC5)
Division of Biological Standards and Quality Control (DCBCD)
Quality Assurance Branch (DCBCD2)
Laboratory of Microbiology, In-Vivo Testing and Standards Branch (DCBCD3)
Laboratory of Analytical Chemistry (DCBCD4)
Laboratory of Biochemistry, Virology, and Immunohematology Branch (DCBCD5)
Laboratory of Blood Related Products Branch (DCBCD6)

DCDF. ORGANIZATION. The Office of Compliance and includes the following organization units:
Office of Compliance (DCDF)
Program Management and Analysis Staff (DCDF1)
Office of Manufacturing Quality (DCDFA)
Manufacturing Guidance and Policy Staff (DCDFA1)
Regulatory Compliance and Analysis Staff (DCDFA2)
Division of Drug Quality I (DCDFAA)
Division of Drug Quality II (DCDFAB)
Division of Drug Quality III (DCDFD)
Office of Unapproved Drugs and Labeling Compliance (DCDFB)
Division of Unapproved New Drugs and Labeling (DCDFB1)
Fraud Drugs Branch (DCDFBB2)
Prescription Drugs Branch (DCDFBB3)
Division of Labeling, Regulation, Regulation and Unapproved Drugs (DCDFBC)
Over-The-Counter Drug Branch (DCDFBC1)
Drug Registration and Listing Branch (DCDFBC2)
Office of Scientific Investigations (DCDFC)
Policy Staff (DCDFC1)
Division of Good Clinical Practice Compliance (DCDFCA)
Good Clinical Practice Enforcement Branch (DCDFCA1)
Good Clinical Practice Assessment Branch (DCDFCA2)
Division of Safety Compliance (DCDFCB)
Division of Enforcement and Post-market Safety (DCDFCC)
Compliance Enforcement Branch (DCDFCC1)
Post-marketing Safety Branch (DCDFCC2)
Division of Clinical Compliance Evaluation (DCDFCD)
Good Clinical Practice Compliance Oversight Branch (DCDFCD1)
Good Clinical Practice Assessment Branch (DCDFCD2)
Office of Drug Security Integrity and Response (DCDFD)
Division of Global Drug Distribution and Policy (DCDFDA)
Imports Compliance Branch (DCDFDA3)
Exports Compliance Branch (DCDFDA4)
Division of Supply Chain Integrity (DCDFDB)
Incidents, Recalls, and Shortage Branch (DCDFDB1)
Supply Chain Security Branch (DCDFDB4)
Office of Program and Regulatory Operations (DCDFE)
Program and Regulatory Operations Staff 1 (DCDFE1)
Program and Regulatory Operations Staff 2 (DCDFE2)
Project Management and Coordination
Staff 3 (DCDFE4)
Office of Compounding Quality and
Compliance (DCDF)
Division of Compounding I (DCDDFA)
Compounding Branch 1 (DCDDFA1)
Compounding Branch 2 (DCDDFA2)
Compounding Branch 3 (DCDDFA3)
Division of Compounding II (DCDDFFB)
Compounding Branch 4 (DCDDFFB2)
Compounding Branch 5 (DCDDFFB3)
Compounding Branch 6 (DCDDFFB4)
Division of Compounding Policy and
Ourtreach (DCDDFFC)
Compounding Branch 7 (DCDDFFC3)
Compounding Branch 8 (DCDDFFC4)

DCGD. ORGANIZATION. The Office of
Surveillance and Compliance within the
Center for Veterinary Medicine is
headed by the Director of Surveillance
and Compliance and includes the
following organization units:
Office of Surveillance and Compliance
(DCGD)
Regulatory Counsel Staff (DCGD1)
Business Management and Operations
Staff (DCGD2)
Division of Pharmacovigilance and
Surveillance (DCGDA)
Marketed Product Information Branch
(DCGDA1)
Food Animal, BioPharm, Small Animal
Antiparasitics and Endectocides
Branch (DCGDA2)
Small Animal Antibiotics/Antiinfectives/
NSAIDS/Oncology/Others Branch
(DCGDA3)
Division of Animal Food Ingredients
(DCGDB)
Program-Business Branch (DCGDB1)
Biotechnology Branch (DCGDB2)
Chemistry Manufacturing and Controls
(CMC) Tech Additives Branch
(DCGDB3)
Nutrients Claims Branch (DCGDB4)
Division of Drug Compliance (DCGDC)
Drug and Devices—Veterinary Medical
Support Branch (DCGDC1)
Drug and Devices—Compliance Support
Branch (DCGDC2)
Biorheesearch Monitoring (BIMO) and
Current Good Manufacturing Practice
(CGMP) Branch (DCGDC3)
Division of Food Compliance (DCGDE)
Complaints, Emergencies, and Recall
Team (CERT) Branch (DCGDE1)
Field Operations and Investigations
Branch (DCGDE2)
Regulatory Policy and Program Branch
(DCGDE3)
Science Policy Branch (DCGDE4)
Compliance Action Branch (DCGDE5)

DCJ. ORGANIZATION. The Office of
the Chief Medical Officer is headed by
the Chief Medical Officer, and includes
the following organization units:
Office of the Chief Medical Officer (DCJ)
Office of Clinical Policy (DCJA)
Office of Combination Products (DCJB)
Office of Orphan Products Development
(DCJ)
Office of Pediatric Therapeutics (DCJD)
Office of Public Health Preparedness
and Response (DCJE)

DCK. ORGANIZATION. The Office of
External Affairs is headed by the
Associate Commissioner for External
Affairs, and includes the following
organization units:
Office of External Affairs (DCK)
Operations Staff (DCK1)
Public Engagement Staff (DCK3)
Web and Digital Services Staff (DCK4)
Office of Editorial and Creative Services
(DCKA)
Office of Media Affairs (DCKB)

DCN. ORGANIZATION. The Office of
Operations is headed by the Deputy
Commissioner for Operations and Chief
Operations Officer and includes the
following organization units:
Office of Operations (DCN)
Office of Management and Enterprise
Services (DCNA)
Office of Disclosure, Information,
Governance, and Accessibility
(DCNAF)
Division of Information Governance
(DCNAFA)
eDiscovery Branch (DCNAFA1)
Records Management Branch
(DCNAFA2)
Paperwork Reduction Act Branch
(DCNAFA3)
Privacy Branch (DCNAFA4)
Dockets Management Branch
(DCNAFA5)
Division of Information Disclosure
(DCNAFB)
Freedom of Information Branch
(DCNAFB1)
Disclosure Branch (DCNAFB2)
Division of Headquarters Freedom of
Information (DCNAFC)
Division of Conflict Prevention, and
Accessibility (DCNAFD)
Conflict Prevention and Resolution
Branch (DCNAFD1)
Reasonable Accommodations Branch
(DCNAFD2)
Office of Management (DCNAG)
Division of Resources Management
(DCNA)
Office of the Commissioner Resource
Management Branch (DCNAGA1)
Global Policy and Strategy Resource
Management Branch (DCNAGA2)
Division of Human Capital (DCNAGB)
Human Capital Management Branch
(DCNAGB1)
Human Capital Programs Branch
(DCNAGB2)
Division of Acquisitions Management
(DCNACG)
Acquisitions Management Branch
(DCNACG1)
Acquisitions Support Branch
(DCNACG2)
Division of Management Services
(DCNAGD)
Communications Branch (DCNAGD1)
Governance Branch (DCNAGD2)
Office of Ethics and Integrity (DCNB)
Office of Equal Employment
Opportunity (DCNC)
Compliance Staff (DCNC1)
Office of Finance, Budget, and
Acquisitions (DCNE)
Business Management Services Staff
(DCN1A)
Office of Budget (DCNEA)
Division of Budget Formulation
(DCNAA)
Division of Budget Execution and
Control (DCNEAB)
Division of Reorganizations and
Delegations of Authority (DCNEAC)
Office of Acquisitions and Grants
Services (DCNEB)
Training and Development Staff
(DCNB1)
Division of Acquisition Operations
(DCNB1A)
Service Contracts Branch (DCNEBA1)
Contracts Operations Branch
(DCNB2A)
Scientific Support Branch (DCNEB3)
Division of Acquisition Programs
(DCNB3)
Field Operations Branch (DCNEBB2)
Facilities Support Branch (DCNEBB3)
ORA Inspection Branch (DCNEBB4)
CTP Inspection Branch (DCNEBB5)
Division of Grants, Agreements and
Acquisitions Support (DCNEBC)
Grants and Assistance Agreements
Branch (DCNEBC1)
Contracts Administration Branch
(DCNB2C4)
Division of Information Technology
Acquisitions (DCNBED)
Information Technology Acquisitions
Branch (DCNBED1)
Systems Technology Acquisitions
Branch (DCNBED2)
IT Strategic Support Branch (DCNBED3)
Division of Policy, Systems and Program
Support (DCNEBE)
Acquisitions Policy and Oversight
Branch (DCNEBE1)
Innovation Systems and Data Quality
Branch (DCNEBE3)
Office of Financial Management
(DCNCE)
Financial Systems Support Staff
(DCNCE1)
User Fee Support Staff (DCNEC2)
Operations Support Staff (DCNEC3)
Controls, Compliance and Oversight
Staff (DCNEC4)
Division of Accounting (DCNECA)
Division of Payment Services (DCNECC)
Division of Travel Services (DCNECD)
Office of Facilities, Engineering and
Mission Support Services (DCNG)
Environmental Microbiology Branch (DCRMB1A)
Virology and Parasitology Branch (DCRMB1A2)
Microbial Methods Development Branch (DCRMB1A3)
Division of Food Safety Genomics (DCRMBB)
Genomics Development and Application Branch (DCRMBB1)
Metagenomic Diversity and Ecology Branch (DCRMBB2)
Molecular Genetic Methods Branch (DCRMBB3)
Division of Food Processing Science and Technology (DCRMBC)
Chemistry and Process Engineering Branch (DCRMBC1)
Microbiology and Food Technology Branch (DCRMBC1)
Division of Seafood Science and Technology (DCRMBCB)
Chemical Hazards Science Branch (DCRMBCB1)
Microbiological Hazards Science Branch (DCRMBCB2)
Office of Chemistry and Toxicology (DCRMCC)
Division of Analytical Chemistry (DCRMCC1)
Method Development Branch (DCRMCC1)
Spectroscopy and Mass Spectrometry Branch (DCRMCC1)
Division of Bioanalytical Chemistry (DCRMCCB)
Bioanalytical Methods Branch (DCRMCCB1)
Chemical Contaminants Branch (DCRMCCB2)
Division of Toxicology (DCRMCCB2)
Predictive Toxicology Branch (DCRMCCB2)
Systems Toxicology Branch (DCRMCCB2)
Office of Scientific Coordination and Computational Sciences (DCRMCD)
Senior Science Advisor Staff (DCRMCD1)
Research Coordination Staff (DCRMCD2)
GenomeTrakr and Computational Science Staff (DCRMCD3)
Office of Quality Assessment and Management (DCRN)
Quality Assessment Staff (DCRN1)
Quality Management Staff (DCRN2)
Office of Microbiological Food Safety (DCR0)
Operations Staff (DCR01)
Office of Dairy and Seafood Safety (DCROA)
Division of Dairy Safety (DCROA)
Dairy Safety Policy Branch (DCROA1)
Egg, Meat, and Laboratory Policy Branch (DCROA2)
Dairy Operations East Branch (DCROA3)
Dairy Operations West Branch (DCROA4)
Division of Seafood Safety (DCROAB)
Shellfish and Aquaculture Policy Branch (DCROAB1)
Seafood Processing and Technology Policy Branch (DCROAB2)
Shellfish Operations Branch 1 (DCROAB3)
Shellfish Operations Branch 2 (DCROAB4)
Office of Produce Safety (DCROB)
Division of Fresh Produce Safety (DCROB3)
Fresh Produce Policy Branch (DCROB3)
Produce Safety Engagement Branch (DCROB3)
Division of Processed Food and Beverages Safety (DCROBB)
Processed Food and Beverages Policy Branch (DCROBB1)
Processed Produce Policy Branch (DCROBB2)
DCS. ORGANIZATION. The Office of Inspections and Investigations is headed by the Associate Commissioner for Inspections and Investigations, and includes the following organizational units:
Office of Inspections and Investigations (DC)
Office of the Associate Commissioner for Inspections and Investigations (DCSA)
Division of Organizational Communication and Engagement (DCSAA)
Strategic Communication Staff (DCSAA1)
Executive Secretariat Staff (DCSAA2)
Office of Management (DCSB)
Office of Budget, Facilities and Travel Support (DCSBA)
Division of Financial Operations (DCSBA)
Human and Animal Food Budget Execution Branch (DCSBA1)
Budget Formulation Branch (DCSBA2)
Medical Products and Tobacco Budget Execution Branch (DCSBA3)
Division of Facilities and Property Management (DCSBA)
Real Property Branch 1 (DCSBA1)
Real Property Branch 2 (DCSBA2)
Real Property Branch 3 (DCSBA3)
Fleet and Personal Property Management Branch (DCSBA4)
Real Property Branch 4 (DCSBA5)
Real Property Branch 5 (DCSBA6)
Real Property Branch 6 (DCSBA7)
Division of Contracts and Grants (DCSBAC)
Operational Contracts and Agreements Branch 1 (DCSBAC1)
Operational Contracts and Agreements Branch 2 (DCSBAC2)
Division of Travel Operations (DCSBD)
Domestic Travel Branch (DCSBD1)
Foreign Travel Branch 1 (DCSBD2)
Foreign Travel Branch 2 (DCSBD3)
Foreign Travel Branch 3 (DCSBD4)
Foreign Travel Branch 4 (DCSBD5)
Office of Workforce Management (DCSBB)
Executive and Scientific Resource Staff (DCSBB1)
Division of Human Capital Staffing Services (DCSBB1A)
Talent Acquisition Branch 1 (DCSBB1A1)
Talent Acquisition Branch 2 (DCSBB1A2)
Talent Acquisition Branch 3 (DCSBB1A3)
Division of Human Capital Programs (DCSBB1B)
Performance Management and Engagement Branch (DCSBB1B1)
Management Analysis Branch (DCSBB1B2)
Office of Animal Food Inspectorate (DCSC)
Division of Animal Food Inspectorate I (DCSCA)
Animal Food Investigations Branch 1 (DCSCA1)
Animal Food Investigations Branch 2 (DCSCA2)
Animal Food Investigations Branch 3 (DCSCA3)
Division of Animal Food Inspectorate II (DCSCB)
Animal Food Investigations Branch 1 (DCSCB1)
Animal Food Investigations Branch 2 (DCSCB2)
Animal Food Investigations Branch 3 (DCSCB3)
Office of Biologics Inspectorate (DCSD)
Biologics Global Operations Staff (DCSD1)
Division of Biologics Inspectorate I (DCSDB)
Biologics Investigations Branch 1 (DCSDB1)
Biologics Investigations Branch 2 (DCSDB2)
Biologics Investigations Branch 3 (DCSDB3)
Biologics Investigations Branch 4 (DCSDB4)
Division of Biologics Inspectorate II (DCSDC)
Biologics Investigations Branch 1 (DCSDC1)
Biologics Investigations Branch 2 (DCSDC2)
Biologics Investigations Branch 3 (DCSDC3)
Division of Biologics Inspectorate III (DCSDD)
Biologics Investigations Branch 1 (DCSDD1)
Biologics Investigations Branch 2 (DCSDD2)
Biologics Investigations Branch 3 (DCSDD3)
Division of Biotechnology Inspectorate (DCSDE)
Biotechnology Investigations Branch 1 (DCSDE1)
Biotechnology Investigations Branch 2 (DCSDE2)
Office of Bioresearch Monitoring Inspectorate (DCSE)
Division of Bioresearch Monitoring Global Operations (DCSEA)
Bioresearch Monitoring Foreign Investigations Branch 1 (DCSEA1)
Bioresearch Monitoring Foreign Investigations Branch 2 (DCSEA2)
Bioresearch Monitoring Inspectorate Expert Support Branch (DCSEA3)
Division of Bioresearch Monitoring Inspectorate I (DCSEB)
Bioresearch Monitoring Investigations Branch 1 (DCSEB1)
Bioresearch Monitoring Investigations Branch 2 (DCSEB2)
Bioresearch Monitoring Investigations Branch 3 (DCSEB3)
Bioresearch Monitoring Investigations Branch 4 (DCSEB4)
Division of Bioresearch Monitoring Inspectorate II (DCSEC)
Bioresearch Monitoring Investigations Branch 1 (DCSEC1)
Bioresearch Monitoring Investigations Branch 2 (DCSEC2)
Bioresearch Monitoring Investigations Branch 3 (DCSEC3)
Division of Bioresearch Monitoring Inspectorate III (DCSED)
Bioresearch Monitoring Investigations Branch 1 (DCSED1)
Bioresearch Monitoring Investigations Branch 2 (DCSED2)
Bioresearch Monitoring Investigations Branch 3 (DCSED3)
Division of Bioresearch Monitoring Inspectorate IV (DCSEF)
Bioresearch Monitoring Investigations Branch 1 (DCSEF1)
Bioresearch Monitoring Investigations Branch 2 (DCSEF2)
Bioresearch Monitoring Investigations Branch 3 (DCSEF3)
Office of Business Informatics and Solutions Management (DCSF)
Division of Import Business Informatics and Solutions (DCSFB)
Import Business Informatics Branch (DCSFB1)
Import Business Solutions Branch (DCSFB2)
Division of Regulatory Business Informatics and Solutions (DCSFC)
Regulatory Business Informatics Branch (DCSFC1)
Regulatory Business Solutions Branch (DCSFC2)
Division of Solutions Planning, Management and Governance (DCSF)
Integrated Management and Investments Branch (DCSF1)
Program Solutions and Services Branch (DCSF2)
Division of Work Planning and Analytics (DCSF3)
Work Planning and Analytics Branch (DCSF4)

Informatics and Process Quality Branch (DCSF5)
Office of Criminal Investigations (DCSG)
Metro Washington Field Office (DCSGA)
Philadelphia Resident Unit (DCSGA1)
Chicago Field Office (DCSGB)
New York Field Office (DCSGC)
Boston, MA Resident Unit (DCSGC1)
Los Angeles Field Office (DCSGD)
San Francisco, CA Resident Unit (DCSGD1)
Miami Field Office (DCSGE)
San Juan, PR Resident Unit (DCSGE1)
Atlanta, GA Resident Unit (DCSGE2)
New Orleans, LA Resident Unit (DCSGE3)
Kansas City Field Office (DCSGF)
Dallas, TX Resident Unit (DCSGF1)
Office of Field Operations and Response (DCSH)
Organizational Quality Staff (DCSH1)
Office of Field Regulatory Operations (DCSHA)
Division of Field Enforcement (DCSHA1)
Health Fraud Inspectorate Branch (DCSHA1)
Field Recall Effectiveness Branch (DCSHA2)
Division of Inspectorate Policy (DCSHAB)
Food Inspectorate Policy Branch (DCSHAB1)
Medical Products and Tobacco Inspectorate Policy Branch (DCSHAB2)
Division of Tobacco Inspectorate (DCSHAC)
Tobacco Investigations Branch 1 (DCSHAC1)
Tobacco Investigations Branch 2 (DCSHAC2)
Office of Emergency Response (DCSHB)
Division of Emergency Response (DCSHBA)
Field Emergency Response Coordinators Branch 1 (DCSHBA1)
Field Emergency Response Coordinators Branch 2 (DCSHBA2)
Incident Coordination Branch (DCSHBA3)
Division of Emergency Preparedness and Support (DCSHBB)
Emergency Planning, Exercises and Evaluation Branch (DCSHBB2)
Program Operations and Coordination Branch (DCSHBB3)
Office of Training, Education, and Development (DCSI)
Division of Programmatic Training (DCSIA)
Programmatic Training Branch 1 (DCSIA1)
Programmatic Training Branch 2 (DCSIA2)
Division of Multi-Program, Leadership, and Management Training (DCSIB)
Multi-Program, Leadership, and Management Branch (DCSIB1)

Leadership, Management, and Mentoring Training Branch (DCSIB2)
Division of Instructional Systems and Technology (DCSIC)
Instructional Systems Branch (DCSIC1)
Learning Management Technology and Multimedia Branch (DCSIC2)
Certification Branch (DCSIC3)
Office of Human and Animal Drug Inspectorate (DCSJ)
Division of Human and Animal Drug Foreign Inspectorate (DCSJF)
Human and Animal Drug Foreign Investigations Branch 1 (DCSJF1)
Human and Animal Drug Foreign Investigations Branch 2 (DCSJF2)
Human and Animal Drug Foreign Operations Branch (DCSJF3)
Division of Human and Animal Drug Global Operations (DCSJF)
Human and Animal Drug Program Operations Branch (DCSJF)
Human and Animal Drug Mutual Recognition Branch (DCSJF)
Division of Human and Animal Drug Inspectorate I (DCSJ)
Human and Animal Drug Investigations Branch 1 (DCSJ)
Human and Animal Drug Investigations Branch 2 (DCSJ)
Human and Animal Drug Investigations Branch 3 (DCSJ)
Human and Animal Drug Investigations Branch 4 (DCSJ)
Human and Animal Drug Investigations Branch 5 (DCSJ)
Division of Human and Animal Drug Inspectorate II (DCSJ)
Human and Animal Drug Investigations Branch 1 (DCSJ)
Human and Animal Drug Investigations Branch 2 (DCSJ)
Human and Animal Drug Investigations Branch 3 (DCSJ)
Human and Animal Drug Investigations Branch 4 (DCSJ)
Human and Animal Drug Investigations Branch 5 (DCSJ)
Division of Human and Animal Drug Inspectorate III (DCSJ)
Human and Animal Drug Investigations Branch 1 (DCSJ)
Human and Animal Drug Investigations Branch 2 (DCSJ)
Human and Animal Drug Investigations Branch 3 (DCSJ)
Human and Animal Drug Investigations Branch 4 (DCSJ)
Human and Animal Drug Investigations Branch 5 (DCSJ)
Division of Human and Animal Drug Inspectorate IV (DCSJ)
Human and Animal Drug Investigations Branch 1 (DCSJ)
Human and Animal Drug Investigations Branch 2 (DCSJ)
Human and Animal Drug Investigations Branch 3 (DCSJ)
Human and Animal Drug Investigations Branch 4 (DCSJ)
Human and Animal Drug Investigations Branch 5 (DCSJ)
Division of Human and Animal Drug Inspectorate V (DCSJ)
Human and Animal Drug Investigations Branch 1 (DCSJ)
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II. Delegations of Authority

Pursuant to 21 U.S.C. 335a(d)(1), this order provides for the termination of Mr. Little’s debarment.

The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Michael Terry Little for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Little was convicted of one felony count under Federal law for introduction of unapproved new drugs in interstate commerce. The factual basis supporting Mr. Little’s conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Little was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of March 13, 2024 (30 days after receipt of the notice), Mr. Little had not responded. Mr. Little’s failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable June 3, 2024.

ADDRESSES: Any application by Mr. Little for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time as follows:

Electronic Submissions

• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or