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Dated: November 12, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–27070 Filed 11–19–24; 8:45 am]

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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, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA), Office of the Commissioner (OC), Office of Digital Transformation (ODT) has modified their organizational structure. The new organizational structure was approved by the Secretary of Health and Human Services on September 20, 2024.

FOR FURTHER INFORMATION CONTACT: William Tootle, Director, Office of Budget; 10903 New Hampshire Avenue, WO–2, #3313, Silver Spring, MD 20990.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is revised to reflect FDA, OC's ODT.

The changes to ODT's organizational structure consolidate similar functions and resources across multiple areas and align the organizational structure with federal and industry standards. This will create a more agile organization, improve resource management, enhance customer service, and better align the name of organizational components with current functions. The reorganization will maintain a reasonable span of control and clear and appropriate lines of authority and responsibilities between organizations. This will also ensure optimal resource utilization and leveraging of existing staff talent and will allow ODT more efficiency and effectiveness in the advancement of continuous improvement efforts.

DCAD. ORGANIZATION: ODT is headed by the Chief Information Officer and includes:

Office of Digital Transformation (DCAD)
Office of Information Management and Technology (DCADA)
  Enterprise Architecture Staff (DCADA2)
Office of Technology and Delivery (DCADAA)
  Division of Infrastructure Services (DCADAAA)
  Network Services Support Staff (DCADAAA10)
  Systems Operations Support Staff (DCADAAA11)
  Operations and Planning Staff (DCADAAA12)
  Data Center Facilities Branch (DCADAAA13)
  Quality Assurance Branch (DCADAAA14)
  Network Communications Branch (DCADAAA15)
  Server Operations Services Branch (DCADAAA16)
  Enterprise Management Operations Branch (DCADAAA17)
  Cloud Operations Branch (DCADAAA18)
  Division of Application Services (DCADAAB)
  Operations Support Staff (DCADAAB10)
  Enterprise Business and Post-Market Staff (DCADAAB11)
  Scientific Support Staff (DCADAAB12)
  Human Food Support Branch (DCADAAB13)
  Regulatory Science Support Branch (DCADAAB14)
  Compliance and Enforcement Branch (DCADAAB15)
  Application Services Support Branch (DCADAAB16)
  Platform Management Support Branch (DCADAAB17)
  Digital Solutions Partners Branch (DCADAAB18)
  Business Intelligence Data Branch (DCADAAB19)
  Products Review and Approval Branch (DCADAAB20)
  Digital Solution Delivery Branch (DCADAAB21)
  Registration Listing Services Branch (DCADAAB22)
  User Fee Support Branch (DCADAAB23)
  Division of Engineering (DCADAAD)

Engineering Services Support Staff (DCADAAD1)
Implementation Branch (DCADAAD2)
Engineering Branch (DCADAAD3)
Data Governance Branch (DCADAAD4)
Cloud Services Branch (DCADAAD5)
Infrastructure Engineering Branch (DCADAAD6)
Database and Content Services Branch (DCADAAD7)
Division of Technology Quality Management (DCADAAE)
Contract Budget and IT Strategy Branch (DCADAAE1)
Project and Program Portfolio Branch (DCADAAE2)
Resources Management Branch (DCADAAE3)
Office of Customer Experience (DCADAB)
Division of Collaboration Services (DCADABH)
Collaboration Support Branch (DCADABH1)
Collaboration Administration Branch (DCADABH2)
Collaboration System Administration Branch (DCADABH3)
Division of Endpoint Management (DCADABI)
Property and Deployment Branch (DCADABI1)
Endpoint Management Branch (DCADABI2)
Division of Service Desk and Support (DCADABJ)
Service Desk Operations Branch (DCADABJ1)
Service Management Branch (DCADABJ2)
Specialized Support Branch (DCADABJ3)
Global Support Branch (DCADABJ4)
Division of End User Services (DCADABK)
Operations Support Branch Zone 1 (DCADABK1)
Operations Support Branch Zone 2 (DCADABK2)
Operations Support Branch Zone 3 (DCADABK3)
Division of ERIC Administration (DCADABL)
Performance, Growth and Enablement Branch (DCADABL1)
Help Desk Service Branch (DCADABL2)
Operations and Desk Services Branch (DCADABL3)
Office of Information Security (DCADB)
Cybersecurity Program Staff (DCADB2)
Division of Counterintelligence and Insider Threat (DCADBE)
Counterintelligence/Cyber Hunt Branch (DCADBE1)
Division of Cybersecurity Operations (DCADBF)
Division of Cybersecurity Risk and Compliance (DCADBG)
Division of Cybersecurity Capabilities and Integrations (DCADBH)
Office of Data, Analytics, and Research (DCADC)
Advanced Data Analytics and Innovation Staff (DCADC1)
Data & Analytics Governance Staff (DCADC2)
Master Data Management Staff (DCADC6)
Data Ecosystem Services Staff (DCADC7)
Data and Insights Services Staff (DCADC8)
Office of Enterprise Portfolio Management (DCADF)
Division of Acquisition Innovation (DCADFA)
Acquisition Operations Branch (DCADFA1)
Acquisition Governance Branch (DCADFA2)
IT Asset Management Branch (DCADFA3)
Division of Technology Business Management (DCADFB)
IT Governance Staff (DCADFB1)
IT Policy Branch (DCADFB2)
Business Intelligence Branch (DCADFB3)
Division of IT Finance (DCADFC)
Budget Formulation Branch (DCADFC1)
Budget Execution Branch (DCADFC2)
Office of Organizational Excellence (DCADG)
Division of Management (DCADGA)
Administrative Services Branch (DCADGA1)
Employee Experience Branch (DCADGA2)
Talent Strategy Branch (DCADGA3)
Division of Strategy, Education, and Communications (DCADGB)
Learning and Development Branch (DCADGB1)
Strategic Initiatives Branch (DCADGB2)
Strategic Communications Branch (DCADGB3)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete SMG can find it on FDA's website at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

Authority: 44 U.S.C. 3101.

Dated: November 14, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–27011 Filed 11–19–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–2515]

Determination That FORTESTA (Testosterone) Gel, 10 Milligrams/0.5 Gram Actuation, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that FORTESTA (testosterone) gel, 10 milligrams (mg)/0.5 gram (gm) actuation, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Swati Rawani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6221, Silver Spring, MD 20993–0002, 240–402–9917, *Swati.Rawani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or