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]

BILLING CODE 4164–01–P

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

ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

FORTESTA (testosterone) Gel, 10 mg/0.5 gm actuation, is the subject of NDA 021463, held by Endo Operations Ltd., and initially approved on December 29, 2020. FORTESTA is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone: primary hypogonadism (congenital or acquired), hypogonadotropic hypogonadism (congenital or acquired).

In a letter dated December 1, 2023, Endo Operations Ltd., notified FDA that FORTESTA (testosterone) gel, 10 mg/0.5 gm actuation, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Encube Ethicals Private Limited submitted a citizen petition dated May 22, 2024 (Docket No. FDA–2024–P–2515), under 21 CFR 10.30, requesting that the Agency determine whether FORTESTA (testosterone) gel, 10 mg/0.5 gm actuation, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that FORTESTA (testosterone) gel, 10 mg/0.5 gm actuation, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of FORTESTA (testosterone) gel, 10 mg/0.5 gm actuation, from sale. We have also independently evaluated relevant literature and data for possible post-marketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list FORTESTA (testosterone) gel, 10 mg/0.5 gm actuation, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 7, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–27103 Filed 11–19–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Funding; National Rural Health Information Clearinghouse Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental funding.

SUMMARY: HRSA provided supplemental funds to the National Rural Health Information Clearinghouse Program recipient, University of North Dakota, to develop toolkits and other resources that address strategies to promote rural community health and support the improvement of health care in rural areas.

FOR FURTHER INFORMATION CONTACT: Sarah Scott, Federal Office of Rural Health Policy, HRSA, at *sscott2@hrsa.gov* and 301–287–2619.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: University of North Dakota.

Amount of Non-Competitive Award: One award for $782,000.

Project Period: June 1, 2020, through May 31, 2025.

Assistance Listing (CFDA) Number: 93.223.

Award Instrument: Cooperative Agreement Supplement for Services.

Authority: Section 711 of the Social Security Act (42 U.S.C. 912).

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

Grant number	Award recipient name	City, State	Award amount
U56RH05539	University of North Dakota	Grand Forks, ND	$782,000

Justification: This supplement allows the University of North Dakota to build on past and ongoing projects to improve health care in rural areas by advancing the knowledge base regarding strategies to support and enhance rural community health. The University of North Dakota has longstanding experience developing resources like toolkits and webinars to support a broad range of rural health topics. The supplement will allow the University of North Dakota to create new toolkits and resources on important topics related to rural community health and health care.

Diana Espinosa,

Principal Deputy Administrator.

[FR Doc. 2024–27099 Filed 11–19–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Funding; Rural Health and Economic Development Analysis Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.