ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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21 CFR 10.30, requesting that the Agency determine whether FORTESTA (testosterone) gel, 10 mg/0.5 gm actuation, was withdrawn from sale for reasons of safety or effectiveness.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have at this time, FDA has determined under § 314.161 that FORTESTA (testosterone) gel, 10 mg/0.5 gm actuation, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness.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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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.