

ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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21 CFR 10.30, requesting that the Agency determine whether FORTESTA (testosterone) gel, 10 mg/0.5 gm actuation, was withdrawn from sale for reasons of safety or effectiveness.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§ 314.161 that FORTESTA (testosterone) gel, 10 mg/0.5 gm actuation, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness.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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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

ACTION: Notice of supplemental funding.
SUMMARY: HRSA provided supplemental funds to the sole award recipient of the Rural Health and Economic Development Analysis Program to support a research project that quantifies the relationships between health care and economic factors in rural communities.

FOR FURTHER INFORMATION CONTACT: Karis Tyner, Federal Office of Rural Health Policy, HRSA, at kytyner@hrsa.gov and 240-645-5756.

SUPPLEMENTARY INFORMATION:
Intended Recipient of the Award: University of Kentucky.
Amount of Non-Competitive Award: One award for \$175,000.

Project Period: September 1, 2022, through August 31, 2025.
Assistance Listing (CFDA) Number: 93.155.
Award Instrument: Cooperative Agreement Supplement for Research.
Authority: Section 711 of the Social Security Act (42 U.S.C. 912).

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

| Grant No. | Award recipient name | City, state | Award amount |
|------------------|------------------------------|---------------------|--------------|
| U1ZRH33331 | University of Kentucky | Lexington, KY | \$175,000 |

Justification: The University of Kentucky, the sole recipient of the Rural Health and Economic Development Analysis Program funding, possesses specialized experience in rural health care research and economic analysis that positions it to be the most qualified entity to perform this work. The funding allows the University of Kentucky to collect and analyze additional data on health care and economic impacts, building on the planned research project and providing more information to inform policy makers and other rural stakeholders. Its research may focus on emerging issues at the intersection of rural health care improvement and rural economic analysis.

Diana Espinosa,
Principal Deputy Administrator.
 [FR Doc. 2024-27109 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; National Rural Health Policy, Community, and Collaboration 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 sole award recipient of the National Rural Health Policy, Community, and Collaboration Program to enhance rural health state partnerships, support ongoing work with technical assistance recipients, and

work to support a toolkit designed to assist rural health networks.

FOR FURTHER INFORMATION CONTACT: Alexa Ofori, Senior Advisor, Federal Office of Rural Health Policy, HRSA, at aofori@hrsa.gov and 301-945-3986.

SUPPLEMENTARY INFORMATION:
Intended Recipient of the Award: National Rural Health Association.
Amount of Non-Competitive Award: One award for \$710,000.

Project Period: August 1, 2024, through July 31, 2029.
Assistance Listing (CFDA) Number: 93.155.
Authority: Section 711 of the Social Security Act (42 U.S.C. 912).

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

| Grant No. | Award recipient name | City, State | Award amount |
|------------------|---|-------------------|--------------|
| U16RH03702 | National Rural Health Association | Leawood, KS | \$710,000 |

Justification: The purpose of the National Rural Health Policy, Community, and Collaboration Program is to identify, engage, educate, and collaborate with rural stakeholders on national rural health policy issues and promising practices to improve health care in rural areas nationwide. These activities build on past and ongoing National Rural Health Association projects supported by HRSA and align with the goals of the program to educate rural stakeholders about national policy issues and promising practices for rural health and to facilitate collaboration with key stakeholders to improve the

exchange of information and promising practices that support rural health.

Diana Espinosa,
Principal Deputy Administrator.
 [FR Doc. 2024-27088 Filed 11-19-24; 8:45 am]
BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting. This meeting is open to the public.

Name: National Committee on Vital and Health Statistics (NCVHS) Meeting.
DATES: Tuesday, December 3, 2024: 10 a.m.–5 p.m. EST, and Wednesday, December 4, 2024: 10 a.m.–3 p.m. EST.

ADDRESSES: Virtual open meeting. The public is welcome to obtain a link to attend this meeting by following the instructions posted on the Committee website: <https://ncvhs.hhs.gov/meetings/full-committee-meeting-22/>.

FOR FURTHER INFORMATION CONTACT: Substantive program information may be obtained from Naomi Michaelis,