

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 016801	XYLOCAINE PRE-SERVATIVE FREE.	Lidocaine Hydrochloride.	1%; 2%; 4%; 10%; 20%	Injectable; Injection ...	Fresenius Kabi USA, LLC.
NDA 018238	MICRO-K	Potassium Chloride ..	8 milliequivalents (mEq); 10 mEq.	Extended-Release Capsule; Oral.	Nesher Pharmaceuticals LLC.
NDA 019568	DERMATOP	Prednicarbate	0.10%	Ointment; Topical	Valeant Pharmaceuticals.
NDA 020192	LAMISIL	Terbinafine Hydrochloride.	1%	Cream; Topical	Novartis.
NDA 020482	PRECOSE	Acarbose	25 mg; 50 mg; 100 mg	Tablet; Oral	Bayer Healthcare.
NDA 020591	TARKA	Trandolapril; Verapamil Hydrochloride.	1 mg; 240 mg	Extended-Release Tablet; Oral.	AbbVie Inc.
NDA 020635	LEVAQUIN	Levofloxacin	EQ 500 mg/20 mL; EQ 750 mg/30 mL.	Injectable; Injection ...	Janssen Pharmaceuticals, Inc.
NDA 020823	EXELON	Rivastigmine Tartrate	EQ 1.5 mg Base; EQ 3 mg Base; EQ 4.5 mg Base; EQ 6 mg Base.	Capsule; Oral	Novartis.
NDA 020920	NATRECOR	Nesiritide	1.5 mg/Vial	For Solution; Intravenous.	Scios Inc.
NDA 021549	EMEND	Aprepitant	40 mg	Capsule; Oral	Merck.
NDA 021590	FAZACLO ODT	Clozapine	12.5 mg; 25 mg; 100 mg; 150 mg; and 200 mg.	Orally Disintegrating Tablet; Oral.	Jazz Pharmaceuticals PLC.
NDA 202535	PREPOPIK	Citric Acid, Magnesium Oxide, and Sodium Picosulfate.	12 grams (g)/Packet; 3.5 g/ Packet; 10 mg/Package.	For Solution; Oral	Ferring Pharmaceuticals Inc.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: January 4, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-00118 Filed 1-7-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Committee on the National Health Service Corps

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the National Advisory Committee on the National Health Service Corps (NACNHSC) will hold public meetings for the 2021 calendar year (CY). Information about NACNHSC, agendas, and materials for these meetings can be found on the NACNHSC website at <https://nhsc.hrsa.gov/about/national-advisory-council-nhsc/index.html>.

DATES: NACNHSC meetings will be held on

- March 16, 2021, 9:00 a.m.–5:00 p.m. Eastern Time (ET) and March 17, 2021, 9:00 a.m.–2:00 p.m. ET;
- June 22, 2021, 9:00 a.m.–5:00 p.m. ET and June 23, 2021, 9:00 a.m.–2:00 p.m. ET;
- November 9, 2021, 9:00 a.m.–5:00 p.m. ET and November 10, 2021, 9:00 a.m.–2:00 p.m. ET.

ADDRESSES: Meetings may be held in-person, by teleconference, and/or Adobe Connect webinar. For updates on how

the meeting will be held, visit the NACNHSC website 30 business days before the date of the meeting, where instructions for joining meetings either in-person or remotely will also be posted. In-person NACNHSC meetings will be held at 5600 Fishers Lane, Rockville, Maryland 20857. For meeting information updates, go to the NACNHSC website meeting page at <https://nhsc.hrsa.gov/nac/meetings.html>.

FOR FURTHER INFORMATION CONTACT:

Diane Fabiyi-King (DFO), Division of National Health Service Corps, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301-443-3609; or NHSCAdvisoryCouncil@hrsa.gov.

SUPPLEMENTARY INFORMATION:

NACNHSC provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under Subpart II, Part D of Title III of the Public Health Service Act (42 U.S.C. 254d–254k). NACNHSC designates areas of the United States with health professional shortages and assigns National Health Service Corps clinicians to improve the delivery of health services in health professional shortage areas. Since priorities dictate meeting times and agenda items, be advised that start times, end times, and agenda items are subject to change. For CY 2021 meetings, agenda items may include, but are not limited to, the identification of NACNHSC priorities for future

program issues and concerns; propose policy changes using the varying levels of expertise represented on the Council to advise on specific program areas; updates from clinician workforce experts; and education and practice improvement in the training development of primary care clinicians. More general items may include: Presentations and discussions on the current and emerging needs of health workforce; public health priorities; healthcare access and evaluation; NACNHSC-approved sites; HRSA priorities and other federal health workforce and education programs that impact the NACNHSC.

Refer to the NACNHSC website listed above for all current and updated information concerning the CY 2021 NACNHSC meetings, including draft agendas and meeting materials that will be posted 30 calendar days before the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting(s). Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the NACNHSC should be sent to Diane Fabiyi-King using the contact information above at least 5 business days before the meeting date(s).

Individuals who need special assistance or another reasonable accommodation should notify Diane Fabiyi-King using the contact information listed above at least 10 business days before the meeting(s) they wish to attend.

If a meeting is held in-person, it will occur in a federal government building and attendees must go through a security check to enter. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at an in-person meeting at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021-00093 Filed 1-7-21; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Council on Graduate Medical Education

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Council on Graduate Medical Education (COGME or Council) will hold public meetings for the 2021 calendar year (CY). Information about COGME, agendas, and materials for these meetings can be found on the COGME website at <https://www.hrsa.gov/advisory-committees/graduate-medical-edu/index.html>.

DATES: COGME meetings will be held on

- April 14, 2021, 8:30 a.m.–5:00 p.m. Eastern Time (ET) and April 15, 2021, 8:30 a.m.–2:00 p.m. ET;
- August 19, 2021, 10:00 a.m.–5:00 p.m. ET.

ADDRESSES: Meetings may be held in-person, by teleconference, and/or Adobe Connect webinar. For updates on how the meeting will be held, visit the COGME website 30 business days before the date of the meeting where instructions for joining meetings either in-person or remotely will also be posted. In-person meetings will be held at 5600 Fishers Lane, Rockville, Maryland 20857. For meeting information updates, go to the COGME website meeting page at <https://www.hrsa.gov/advisory-committees/graduate-medical-edu/meetings/index.html>.

FOR FURTHER INFORMATION CONTACT:

Shane Rogers, Designated Federal Official, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Room 15N142, Rockville, Maryland 20857; 301-443-5260; or SRogers@hrsa.gov.

SUPPLEMENTARY INFORMATION: COGME makes recommendations to the Secretary of HHS (Secretary) and Congress on policy, program development, and other matters of significance as specified by section 762 of Title VII of the Public Health Service (PHS) Act. Issues addressed by COGME include the supply and distribution of the physician workforce in the United States, including any projected shortages or excesses; foreign medical school graduates; the nature and financing of undergraduate and graduate

medical education; appropriation levels for certain programs under Title VII of the PHS Act; and deficiencies in databases of the supply and distribution of the physician workforce and postgraduate programs for training physicians. COGME submits reports to the Secretary of HHS; the Senate Committee on Health, Education, Labor and Pensions; and the House of Representatives Committee on Energy and Commerce. Additionally, COGME encourages entities providing graduate medical education to conduct activities to voluntarily achieve the recommendations of the Council. Since priorities dictate meeting times, be advised that start times, end times, and agenda items are subject to change. For CY 2021 meetings, agenda items may include, but are not limited to, discussion on topics surrounding rural health workforce and training. Refer to the COGME website listed above for all current and updated information concerning the CY 2021 COGME meetings, including draft agendas and meeting materials that will be posted 30 calendar days before the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting(s). Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to COGME should be sent to Shane Rogers using the contact information above at least 5 business days before the meeting date(s).

Individuals who need special assistance or another reasonable accommodation should notify Shane Rogers using the contact information listed above at least 10 business days before the meeting(s) they wish to attend.

If a meeting is held in-person, it will occur in a federal government building and attendees must go through a security check to enter. Non-U.S. citizen attendees must notify HRSA of their planned attendance at an in-person meeting at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021-00058 Filed 1-7-21; 8:45 am]

BILLING CODE 4165-15-P