Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions)*: Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–1640 for ''Draft Guidance for Cannabidiol.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' will be publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Mara Miller, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4709C, Silver Spring, MD 20993–0002, 301–796–0683.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and to provide a meaningful opportunity for the public to consider and comment on the guidances. This notice announces the availability of a draft guidance on a generic cannabidiol oral solution.

FDA initially approved new drug application 210365 for EPIDIOLEX (cannabidiol) in September 2018. We are now issuing draft guidance for industry on BE recommendations for generic cannabidiol oral solution (''Draft Guidance for Cannabidiol'').

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the information and data to demonstrate BE to support ANDAs for cannabidiol oral solution. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: September 17, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–20968 Filed 9–22–20; 8:45 am]

BILLING CODE 4164–01–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; correction.

SUMMARY: The Council on Graduate Medical Education (COGME) meeting scheduled on Tuesday, December 8, 2020, and Wednesday, December 9,

2020, has changed its format and time. The meeting will now be a 2-day webinar and conference call only on Tuesday, December 8, 2020, from 10:00 a.m.–5:00 p.m. Eastern Time (ET) and Wednesday, December 9, 2020, from 10:00 a.m.–2:00 p.m. ET. The webinar link, conference dial in number, meeting materials, and updates will be available on the COGME website: *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, 15N142, Rockville, Maryland 20857; 301–443–5260; or *BHWCOGME@hrsa.gov.*

Correction: Meeting will be a 2-day webinar and conference call only rather than in-person as previously announced.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–20940 Filed 9–22–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants

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

ACTION: Request for public comment.

SUMMARY: HRSA's Federal Office of Rural Health Policy (FORHP) has sought to identify clear, consistent, and data-driven methods of defining rural areas in the United States. FORHP uses the Office of Management and Budget (OMB)'s list of counties designated as part of a Metropolitan Statistical Area (MSA) as the basis for determining eligibility to apply for or receive services funded by its rural health grant programs. FORHP designates all counties that are not part of a MSA as ''rural'' and eligible for rural health grant funding or services. In addition, FORHP designates census tracts within MSAs as rural for grant purposes using Rural-Urban Commuting Area (RUCA) codes. FORHP is proposing modifications to how it designates areas to be eligible for its rural health grant programs so that community organizations serving rural populations within MSAs will be able to apply for resources and allow more of the rural populations within MSAs to access services provided using grant funds. This notice seeks comments on the proposed methodology for designating areas eligible for rural health grant programs.

DATES: Submit written comments no later than October 23, 2020.

ADDRESSES: Written comments should be submitted to *ruralpolicy@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Steve Hirsch, Public Health Analyst FORHP, HRSA, 5600 Fishers Lane, Rockville, MD 20857, Phone number: (301) 443–0835 or Email: *ruralpolicy@hrsa.gov.*

SUPPLEMENTARY INFORMATION: FORHP was authorized by Congress in the Omnibus Budget Reconciliation Act of 1987, Public Law 100–203, codified at 42 U.S.C. 912, and located in HRSA. Congress charged FORHP with informing and advising the Department of Health and Human Services on matters affecting rural hospitals and health care and coordinating activities within the Department that relate to rural health care. Since the 1990s, FORHP has also issued grants for programs of innovative models of health care delivery in rural areas. Historically, applicant organizations for these grants, authorized under Section 330A of the Public Health Service Act, were required to be located in rural areas. However, when the programs were recently reauthorized under Section 4214 of the Coronavirus Aid, Relief, and Economic Security Act the requirement was amended to allow organizations to apply that are located in urban areas but serve rural areas.

Historically, there have been two principal definitions of ''rural'' that were in use by the Federal Government: the Census Bureau definition (*https://www.census.gov/programs-surveys/geography/guidance/geo-areas/urban-rural.html*) and the OMB definition (*https://www.census.gov/programs-surveys/metro-micro.html*). Neither definition defined ''rural'' directly, but rather defined ''urban'' areas and then designated locations that do not meet the ''urban'' definition as ''rural.''

In the early 1990s, the Census Bureau defined ''rural'' as all areas that were not part of an urbanized area (UA) or were not part of an incorporated area of at least 2,500 persons. UAs were defined as densely settled areas with a total population of at least 50,000 people. The building block of UAs is the census block, a sub-unit of census tracts. The Census Bureau introduced the urban cluster (UC) concept for the 2000 Census. UCs are defined based on the same criteria as UAs, but represent areas containing at least 2,500 but fewer than 50,000 people. Both UAs and UCs use 500 persons per square mile as their minimum density criterion.

The other major federal definition was based on the OMB's list of counties that are designated as part of a MSA. All counties that were not designated as a part of a MSA were considered ''rural'' or, more accurately, non-metropolitan. MSAs, in 1990, had to include ''a city of 50,000 or more population,'' or ''a Census Bureau defined urbanized area of at least 50,000 population, provided that the component county/counties of the MSA have a total population of at least 100,000.'' At that time, around three quarters of all counties in the United States were non-metropolitan and not classified as parts of MSAs.

After the 2000 Census, OMB also began to classify counties using a smaller urban core. The concept of a Micropolitan statistical area closely parallels that of the MSA, but a Micropolitan statistical area is based on an urban core with a population of 10,000 through 49,999 and Micropolitan counties are still considered non-metropolitan.

As currently classified, OMB builds both MSAs and Micropolitan Statistical Areas around a central county, or counties, which contains an urban core. Surrounding counties can be designated as part of the Core Based Statistical Area (CBSA) based on the presence of core population and/or the commuting patterns of the working population. A county may be included in only one CBSA.

A county qualifies as a central county of a CBSA if it meets the following requirements:

(a) Has at least 50 percent of the population in urban areas of at least 10,000 population; or

(b) Has within the boundaries a population of at least 5,000 located in a single urban area of at least 10,000 population.

Since urban areas are not defined by administrative boundaries, such as city limits or county borders, they can extend into one or more counties as long as the population density criterion (a minimum of 500 people per square mile) is met.

A county qualifies as an outlying county of a CBSA if it meets the following commuting requirements:

(a) At least 25 percent of the workers living in the county work in the central county or counties of the CBSA; or

(b) At least 25 percent of the employment in the county is accounted