Comment: Several Tribal organizations wrote comments objecting to the modification. They suggested that all Tribal lands be defined as rural and that funds be set aside solely for awards to Tribal health providers.

Response to Comment: The statutory authority for rural health grant programs directs services at rural areas and populations. FORHP understands the unique challenges faced by Tribal entities. Rural health grants can be and have been awarded to Tribal organizations located in rural areas. With the changes in the authorization for 330A programs, urban Tribal providers can also apply for rural health grants to serve rural populations. FORHP cannot change rural health funding to direct it to urban populations, even if they are underserved, or specify funding set-asides for Tribal organizations.

Comment: Different commenters suggested that FORHP use a combination of population density, travel time or distance, geographic isolation, and access to resources to designate rural areas, or that FORHP use Frontier and Remote Area (FAR) Codes to determine rurality.

Response to Comment: Commenters did not suggest data sources that would combine population density, travel time or distance, geographic isolation, and access to resources to provide a consistent, nationally standard definition of rural areas. FAR Codes utilize population density and travel time to designate different levels of ''frontier'' or remoteness. However, much of the rural U.S. that is currently eligible for rural health grants is not designated as frontier and remote and would lose eligibility if only FAR codes were used.

FORHP thanks the public for their comments. After consideration of the public comments we received, FORHP is implementing the modification as proposed to expand its list of rural areas. FORHP will add MSA counties that contain no UA population to the areas eligible for rural health grant programs. Using the March 2020 update of MSA delineations released by OMB, 295 counties will meet this criteria as outlying MSA counties with no UA population. The expanded eligibility will go into effect for new rural health grants awarded in fiscal year 2022. FORHP will ensure information about the expanded eligibility is available to the public and update the Rural Health Grants Eligibility Analyzer at *https://data.hrsa.gov/tools/rural-health* for fiscal year 2022 funding opportunities. These changes reflect FORHP's desire to accurately identify areas that are rural in character using a data-driven methodology that relies on existing geographic identifiers and utilizes standard, national level data sources.

Thomas J. Engels,

Administrator.

[FR Doc. 2021–00443 Filed 1–11–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. FDA–2020–N–2246]

Notice That Persons That Entered the Over-the-Counter Drug Market To Supply Hand Sanitizer During the COVID–19 Public Health Emergency Are Not Subject to the Over-the-Counter Drug Monograph Facility Fee

AGENCY: Food and Drug Administration (FDA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services is issuing this Notice to clarify that persons that entered into the over-the-counter drug industry for the first time in order to supply hand sanitizers during the COVID–19 Public Health Emergency are not persons subject to the facility fee the Secretary is authorized to collect under section 744M of the Food, Drug, and Cosmetic Act.

DATES: January 12, 2021.

FOR FURTHER INFORMATION CONTACT: David Haas, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402 4585.

SUPPLEMENTARY INFORMATION: On December 29, 2020, FDA published a Notice in the **Federal Register** entitled *Fee Rates Under the Over-the-Counter Monograph User Fee Program for Fiscal Year 2021.* 85 FR 85646. The Department since withdrew that Notice because it was not approved by the Secretary. For the reasons provided below, the Department is clarifying that persons that entered the over-the-counter drug market to supply hand sanitizer products in response to the COVID–19 Public Health Emergency are not subject to the facility fee the Secretary is authorized to collect under section 744M of the Food, Drug, and Cosmetic Act (FD&C Act).

In March 2020, FDA issued a temporary policy to enable increased production of alcohol-based hand sanitizers.[1] The agency acknowledged ''that some consumers and health care personnel are currently experiencing difficulties accessing alcohol-based hand sanitizers,'' and that some were relying on home-made hand sanitizers as a result.[2] FDA issued the guidance in response to requests from ''certain entities that are not currently regulated by FDA as drug manufacturers'' that nevertheless rose up to meet this public health need.[3] FDA stated it ''does not intend to take action against firms that'' produce hand sanitizer products during the COVID–19 Public Health Emergency, provided the firm's activities are consistent with the guidance.[4]

The guidance, which FDA amended after the Coronavirus Aid, Relief, and Economic Security Act (''CARES Act''), Public Law 116–136, 134 Stat. 281 (March 27, 2020) became law, contains no mention of user or facility fees. FDA's website on Hand Sanitizers and COVID–19, contains a sub-bullet under the link to the guidance announcing that ''the facility fee applies to all OTC hand sanitizer manufacturers registered with FDA, including facilities that manufacture or process hand sanitizer products under this temporary policy,'' but that language was added about the same time as the aforementioned withdrawn Notice was published in the **Federal Register**.[5] Entities that began producing hand sanitizers in reliance on the guidance were understandably surprised when FDA contacted them to collect an establishment fee in excess of $14,000.[6]

FDA's purported authority for these facility fees comes from the CARES Act. In section 3862 of the CARES Act, Congress provided the Secretary with the authority to assess user and facility fees from ''each person that owns a facility identified as an OTC drug monograph facility on December 31 of the fiscal year or at any time during the preceding 12-month period.'' FD&C Act 744M(a)(1)(A), 21 U.S.C. 379j–

[1] FDA, Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19) Guidance for Industry (Mar. 2020; updated Aug. 7, 2020).

[2] *Id.* at 3.

[3] *Id.*

[4] *Id.*

[5] An archived version of the website shows the language at issue was not on the website as late as December 29, 2020. See: *https://web.archive.org/web/20201229105739/https://www.fda.gov/drugs/coronavirus-covid-19-drugs/hand-sanitizers-covid-19.*

[6] This surprise, coupled with the guidance's silence on facility fees, raises reliance interests concerns under the Supreme Court's decision in *Department of Homeland Security* v. *Regents of the University of California,* 140 S. Ct. 1891 (2020).

72(a)(1)(A). An ''OTC drug monograph facility'' is defined, in relevant part, as ''a foreign or domestic business or other entity that is under one management, either direct or indirect; and at one geographic location or address engaged in manufacturing or processing the finished dosage form of an OTC monograph drug.'' FD&C Act 744L(10)(A)(i)(I)–(II), 21 U.S.C. 379j–71(10)(A)(i)(I)–(II).

The Department has concluded that persons that entered the over-the-counter drug market in order to produce hand sanitizers in reliance on the guidance cited above are not ''identified as . . . OTC drug monograph facilit[ies]'' and are thus not subject to the facility fees authorized under section 744M of the FD&CT Act, 21 U.S.C. 379j–72. The Department reached this conclusion for two reasons. First, as the guidance itself acknowledges, the parties at issue are not in the drug manufacturing business. Many of them produce alcoholic beverages. These entities do not hold themselves out to the public as drug makers nor does the public generally encounter them as such. Under the extraordinary circumstances presented by the COVID–19 pandemic, the Department declines to identify these entities as OTC drug manufacturing facilities.

Second, imposing facility fees on these entities is inconsistent with Congress' stated intent elsewhere in the CARES Act. Section 2308 of the Act provides a temporary exemption from excise taxes for distilled spirits ''use[d] in or contained in hand sanitizer produced and distributed in a manner consistent with any guidance issued by the Food and Drug Administration that is related to the outbreak of virus SARS–CoV–2 or coronavirus disease 2019 (COVID–19).'' It is unlikely Congress intended to save these entities from excise taxes only to impose tens of thousands of dollars in facility fees from an unfamiliar regulator. The Department declines to discern such a design under these circumstances.

In conclusion, the Department clarifies that persons that were not registered with FDA as drug manufacturers prior to the COVID–19 Public Health Emergency, which then later registered with FDA for the purpose of producing hand sanitizers, are not ''identified'' as ''OTC drug manufacturing facilit[ies]'' under section 744M of the FD&C Act, 21 U.S.C. 379j–72, and are thus not subject to the facility fee contained therein. The Department's conclusion does not apply to such persons which (1) manufacture, distribute, and sell over-the-counter drugs in addition to hand sanitizer or (2) continue to manufacture (as opposed to hold, distribute, or sell existing inventories) hand sanitizer products as of December 31 of the year immediately following the year during which the COVID–19 Public Health Emergency is terminated. In those cases, the Department may identify such persons as OTC drug manufacturing facilities.

Dated: January 5, 2021.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–00237 Filed 1–8–21; 1:30 pm]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; Clinical Trials Review Committee.

Date: February 25–26, 2021.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Keary A. Cope, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 209–A, Bethesda, MD 20892–7924, (301) 827–7912, *copeka@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 6, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–00344 Filed 1–11–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cell Biology Integrated Review Group; Development—1 Study Section.

Date: February 8–9, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Zubaida Saifudeen, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, *zubaida.saifudeen@nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Brain Injury and Neurovascular Pathologies Study Section.

Date: February 8–9, 2021.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alexander Yakovlev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5206, MSC 7846, Bethesda, MD 20892, 301–435–1254, *yakovleva@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Nuclear and Cytoplasmic Structure/Function and Dynamics Study Section.

Date: February 8–9, 2021.

Time: 11:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.