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.