based on his determination that the drug's clinical risks, device-related deficiencies, and product quality and manufacturing deficiencies had not been satisfactorily resolved, reaffirming the reasoning in OCHEN's denial of the prior FDRR. Intarcia submitted a third FDRR on November 27, 2020, for review of the OND denial and requested an advisory committee meeting. Douglas Throckmorton, Deputy Director for Regulatory Programs, CDER, denied the third FDRR and the request for an advisory committee meeting on behalf of CDER by correspondence dated February 12, 2021, based on his determination that the drug's clinical risks and device-related deficiencies had not been satisfactorily resolved, reaffirming the reasoning in OND's denial of the prior FDRR, and determined that an advisory committee would be premature because of these unresolved safety issues.

On March 16, 2021, Intarcia submitted a request for an opportunity for a hearing under § 314.110(b)(3) on whether there are grounds under section 505(d) of the FD&C Act for denying approval of NDA 209053.

II. Notice of Opportunity for a Hearing

For the reasons stated above and as explained in further detail in the March 9, 2020, complete response letter and the February 12, 2021, November 27, 2020, and July 30, 2020, FDRR denials, notice is given to Intarcia and all other interested persons that the Center Director proposes to issue an order refusing to approve NDA 209053 on the grounds that the application fails to meet the criteria for approval under section 505(d) of the FD&C Act, including the following: (1) Data submitted in the application do not show that the product would be safe under the proposed conditions of use (section 505(d)(2) of the FD&C Act) and (2) the methods used in, and the facilities and controls used for, the manufacture, processing, or packing of the product are not shown to be adequate to preserve its identity, strength, quality, and purity (section 505(d)(3) of the FD&C Act).

Intarcia may request a hearing before the Commissioner of Food and Drugs (the Commissioner) on the Center Director's proposal to refuse to approve NDA 209053. If Intarcia decides to seek a hearing, it must file: (1) A written notice of participation and request for a hearing (see the **DATES** section) and (2) the studies, data, information, and analyses relied upon to justify a hearing (see the **DATES** section), as specified in § 314.200 (21 CFR 314.200).

As stated in § 314.200(g), a request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing to resolve. We note in this regard that because CDER proposes to refuse to approve NDA 209053 based on the multiple deficiencies summarized above, any hearing request from Intarcia must address all of those deficiencies. Failure to request a hearing within the time provided and in the manner required by § 314.200 constitutes a waiver of the opportunity to request a hearing. If a hearing request is not properly submitted, FDA will issue a notice refusing to approve NDA 209053.

The Commissioner will grant a hearing if there exists a genuine and substantial issue of fact or if the Commissioner concludes that a hearing would otherwise be in the public interest (§ 314.200(g)(6)). If a hearing is granted, it will be conducted according to the procedures provided in 21 CFR parts 10 through 16 (21 CFR 314.201).

Paper submissions under this notice of opportunity for a hearing should be filed in one copy, except for those submitted as ''Confidential Submissions'' (see ''Written/Paper Submissions'' and ''Instructions''). Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, submissions may be seen in the Dockets Management Staff Office between 9 a.m. and 4 p.m., Monday through Friday, and on the internet at *https://www.regulations.gov.* This notice is issued under section 505(c)(1)(B) of the FD&C Act and §§ 314.110(b)(3) and 314.200.

Dated: August 27, 2021.

Jacqueline Corrigan-Curay,

Principal Deputy Center Director, Center for Drug Evaluation and Research.

[FR Doc. 2021–18928 Filed 9–1–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration; Delegation of Authority

Notice is hereby given that I have delegated to the Food and Drug Administration (FDA) Commissioner of Food and Drugs (Commissioner), the authority vested in the Secretary to issue all regulations of the FDA. This includes authority to issue regulations pursuant to the Federal Food, Drug, and Cosmetic Act (FD&C Act), applicable portions of the Public Health Service Act (PHS Act), and other authorities governing functions of the FDA. This authority may be re-delegated by the Commissioner.

On September 15, 2020, the Secretary of Health and Human Services (HHS) issued a memorandum (''September 15 Memorandum'') to the HHS Heads of Operating and Staff Divisions that reserved to the Secretary ''the authority to sign and issue any rule for which notice and comment would normally be required, irrespective of whether notice and comment is waived.'' The September 15 Memorandum further stated that it rescinded ''any prior delegation of rulemaking authority'' to the Operating Divisions, including FDA. This delegation revokes the September 15 Memorandum as it applies to FDA and reinstates any delegations to FDA rescinded by the September 15 Memorandum.

This delegation shall be exercised in accordance with the Department's applicable policies, procedures, and guidelines. For internal Department management purposes, this delegation is subject to certain reservations of authority for the Secretary to approve FDA regulations. Specifically, the Secretary reserves the authority to approve regulations of FDA, except regulations to which sections 556 and 557 of Title 5 U.S.C. apply, which (1) establish procedural rules applicable to a general class of foods, drugs, cosmetics, medical devices, tobacco products, or other subjects of regulation; or (2) present highly significant public issues involving the quality, availability, marketability, or cost of one or more foods, drugs, cosmetics, medical devices, tobacco products, or other subjects of regulation. The delegation does not preclude the Secretary from approving a regulation, or being notified in advance of an action, to which section 556 and 557 of Title 5 U.S.C. apply, which meets one of the above-referenced criteria. This reservation of authority is intended only to improve the internal management of the Department of Health and Human Services, and it is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, the Department of Health and Human Services, the FDA, any Agency, officer, or employee of the United States, or any person. Regulations issued by FDA without the approval of the Secretary are to be conclusively viewed as falling outside the scope of this reservation of authority.

This delegation became effective upon the date of signature. In addition, I hereby affirm and ratify any actions

taken by the Commissioner or the Commissioner's subordinates which involved the exercise of the authorities delegated herein, or substantially similar authorities, prior to the effective date of the delegation.

Dated: August 30, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–18985 Filed 9–1–21; 8:45 am]

BILLING CODE 4164–28–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: Center for Scientific Review Special Emphasis Panel; Shared Instrumentation: NMR and X-Ray (S10).

Date: October 6, 2021.

Time: 10:00 a.m. to 9:00 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: Shan Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 858–735–0788, *shan.wang@nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Behavioral Neuroendocrinology, Neuroimmunology, Rhythms, and Sleep Study Section.

Date: October 7–8, 2021.

Time: 8:00 a.m. to 7:00 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: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, 301–435–1119, *selmanom@csr.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Psychosocial Development, Risk and Prevention Study Section.

Date: October 7–8, 2021.

Time: 9:00 a.m. to 8:00 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: Anna L. Riley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7759, Bethesda, MD 20892, 301–435–2889, *rileyann@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Synthetic and Biological Chemistry B Study Section.

Date: October 7–8, 2021.

Time: 9:00 a.m. to 8:00 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: Michael Eissenstat, Ph.D., Scientific Review Officer, BCMB IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, MSC 7806, Bethesda, MD 20892, 301–435–1722, *eissenstatma@csr.nih.gov.*

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group; Enabling Bioanalytical and Imaging Technologies Study Section.

Date: October 7–8, 2021.

Time: 9:00 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: Kenneth Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7717, Bethesda, MD 20892, 301–435–0229, *kenneth.ryan@nih.hhs.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function C Study Section.

Date: October 7–8, 2021.

Time: 9:00 a.m. to 8:00 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: William A. Greenberg, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4168, MSC 7806, Bethesda, MD 20892, (301) 435–1726, *greenbergwa@csr.nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Cardiovascular Differentiation and Development Study Section.

Date: October 7, 2021.

Time: 9:30 a.m. to 7:30 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: Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 4136, Bethesda, MD 20817–7814, 301–435–0904, *sara.ahlgren@nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Surgery, Anesthesiology and Trauma Study Section.

Date: October 7–8, 2021.

Time: 9:30 a.m. to 8:00 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: Weihua Luo, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, (301) 435–1170, *luow@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Sensory-Motor Neuroscience Study Section.

Date: October 7–8, 2021.

Time: 10:00 a.m. to 7:00 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: John Bishop, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408–9664, *bishopj@csr.nih.gov.*

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Tumor Cell Biology Study Section.

Date: October 7–8, 2021.

Time: 10:00 a.m. to 8:00 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: Charles Morrow, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6202, MSC 7804, Bethesda, MD 20892, 301–408–9850, *morrowcs@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 30, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–18980 Filed 9–1–21; 8:45 am]

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