- Provides a summary of FDA's decision and assessment of the application, including FDA's benefit-risk determination (as currently employed in marketing application reviews), and
- Provides an overall Agency assessment, including an overview of the major decisions made during the review process, and a brief discussion of the basis for the decisions.

- *Interdisciplinary Assessment:*
  - Includes succinct, integrated, focused analyses of the evidence of benefit, risk and risk management, and therapeutic individualization (*e.g.,* special populations, drug interactions).
  - Highlights key review issues (including analyses specific to key issues) the review team thinks are pertinent to the decision-making process. Issues are presented and assessed in an interdisciplinary manner.
  - Includes any dissenting data interpretations.
- *Additional Analyses and Information:*
  - Includes Discipline-Specific Appendices
  - Contains assessments and analyses that are supportive and/or important to key facts/data or conclusions included in the overall review and, in certain instances, may include discipline-specific content (*e.g.,* relevant pharmacology/toxicology information),
  - May contain work that did not directly impact the overall assessment of benefit-risk, regulatory action, labeling, or risk-mitigation plans, and
  - Includes separate reviews of reviewers who disagree with significant elements of the Executive Summary and Interdisciplinary Assessment sections or the decision of the Signatory Authority.

In general, the first two parts of the Integrated Review document are expected to provide a complete explanation of FDA's action and supporting analyses, with the third component (the additional analyses and information) providing additional detail on the comprehensive analyses FDA conducted in its review of the drug application. The target audiences for this document are diverse and include those with a specific interest in the application, such as the lay public, drug sponsors, researchers, and others who are seeking to understand the basis for FDA's decision.

II. Integrated Review Documentation

As part of FDA's ongoing evaluation of the Integrated Review documentation, the Agency welcomes comments and any relevant information specific to the Integrated Review that stakeholders wish to share in a submission to the docket. However, we emphasize that the focus is to seek input that prioritizes feedback specifically on characteristics of the Integrated Review document. Please see information and examples relevant to the Integrated Review at *https://www.fda.gov/drugs/news-events-human-drugs/new-drugs-regulatory-program-modernization-integrated-assessment-marketing-applications-and.*

Furthermore, we anticipate that the most informative suggestions would not be specific to an indication, a therapeutic area, or a disease but rather apply across multiple indications, therapeutic areas, or diseases. The Agency is interested in receiving responses to the following questions/topics, in addition to any general comments the public might have. For convenience, it would be helpful if commenters refer to the numbered question and topic when submitting responses and comments.

1. We are interested in preserving for stakeholders what they find most useful in FDA reviews.

a. Comparing the Integrated Review to previous review documentation, is there any information you are having difficulty locating?

b. Are you able to use the Integrated Review for the same purpose that you used previous reviews? If not, please provide specific examples.

2. We are interested in specific recommendations about any areas of the Integrated Review documentation of the Integrated Assessment that can be improved to meet the needs of stakeholders.

3. We are interested in stakeholders' views regarding the advantages and disadvantages of an interdisciplinary assessment presentation of key review issues and the resultant integration of the assessments of multiple disciplines into a single Integrated Review document.

4. We would like to know whether the new format of the Integrated Review documentation for the Integrated Assessment provides clarity of benefit-risk assessments and informs your knowledge of FDA's basis for making decisions.

5. Based on the integrated review, were the issues that concerned the review team clear and understandable? If so, what helped achieve this? If not, what can be improved?

Dated: September 10, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20891 Filed 9–12–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2803]

Sandoz Inc., et al.; Withdrawal of Approval of 20 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on June 21, 2024. The document announced the withdrawal of approval of 20 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of July 22, 2024. The document indicated that FDA was withdrawing approval of the ANDA 076648 for nitrofurantoin (monohydrate/macrocrystals) capsules, 75 milligrams (mg) and 25 mg, held by Aurobindo Pharma USA Inc., 279 Princeton-Hightstown Rd., East Windsor, NJ 08520; and the ANDA 090723 for duloxetine hydrochloride capsules, delayed-release pellets, Equivalent to (EQ) 20 mg base, EQ 30 mg base, and EQ 60 mg base, held by Marksans Pharma, Inc., U.S. Agent for Marksans Pharma Ltd., 150 Motor Pkwy., Suite 401, 4th Floor, Rm. 430, Hauppauge, NY 11788. Before FDA withdrew the approval of these ANDAs, Aurobindo Pharma USA Inc., and Marksans Pharma, Inc., U.S. Agent for Marksans Pharma Ltd., informed FDA that they did not want the approval of the ANDAs withdrawn. Because Aurobindo Pharma USA Inc. and Marksans Pharma, Inc., U.S. Agent for Marksans Pharma Ltd., timely requested that approval of their respective ANDAs not be withdrawn, the approvals are still in effect. This notice corrects these errors.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, June 21, 2024 (89 FR 52057), appearing on page

52058 in FR Doc. 2024–13660, the following correction is made:

On page 52058, in the table, the entries for ANDA 076648 and ANDA 090723 are removed.

Dated: September 10, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20873 Filed 9–12–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 1009 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: National Institute of Mental Health Initial Review Group; Effectiveness of Mental Health Interventions Study Section.

Date: October 17–18, 2024.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: North Bethesda Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852 (Hybrid Meeting).

Contact Person: Claudio Dario Ortiz, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Rockville, MD 20892, (240) 869–9245, email: *claudio.ortiz@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: September 10, 2024.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–20884 Filed 9–12–24; 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 Meeting

Pursuant to section 1009 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: Center for Scientific Review Special Emphasis Panel; PAR Panel: Innovative Research in Cancer Nanotechnology.

Date: October 10–11, 2024.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: AC Hotel Bethesda, 4646 Montgomery Avenue, Bethesda, MD 20814.

Contact Person: Raj K Krishnaraju, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6190, MSC 7804, Bethesda, MD 20892, (301) 435–1047, *kkrishna@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: September 9, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–20788 Filed 9–12–24; 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 1009 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: Brain Disorders and Clinical Neuroscience Integrated Review Group; Pathophysiology of Eye Disease—2 Study Section.

Date: October 9–10, 2024.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle NW, Washington, DC 20005.

Meeting Format: In person.

Contact Person: Cibu Paul Thomas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1011–H, Bethesda, MD 20894, (301) 402–4341, *thomascp@mail.nih.gov.*

Name of Committee: Social and Community Influences on Health Integrated Review Group; Psychosocial Development, Risk and Prevention Study Section.

Date: October 10–11, 2024.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency, Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Meeting Format: In person.

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: Center for Scientific Review Special Emphasis Panel; RFA–NS–24–021: HEAL Initiative: Individual Differences in Human Pain Conditions.

Date: October 10–11, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin Georgetown, 2350 M Street NW, Washington, DC 20037.

Meeting Format: In person.

Contact Person: Abu Saleh Mohammad Abdullah, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1003–L, Bethesda, MD 20892, (301) 827–4043, *abuabdullah.abdullah@nih.gov.*

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

Date: October 10–11, 2024.

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.

Meeting Format: Virtual Meeting.

Contact Person: John N. Stabley, Ph.D., Scientific Review Officer, Center for