a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• 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.'' FDA 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 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 the 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Candace Nalls, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993–0002, 301–636–0510, *Candace.Nalls@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION: *Agenda:* On November 7, 2024, the Committee will discuss, make recommendations, and vote on clinical information related to a *De Novo* request for the ProSense Cryoablation System sponsored by IceCure Medical Ltd. The discussion will focus on the sponsor's proposed indication: ''for use in the treatment of patients with early stage, low-risk breast cancer for the treatment of breast cancer with adjuvant endocrine therapy.''

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material will be available at the location of the advisory committee meeting and at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before October 17, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled on November 7, 2024, between approximately 1:45 p.m. and 2:45 p.m. eastern time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 10, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 15, 2024. Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Ann Marie Williams at *Annmarie.Williams@fda.hh.gov* or 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*).

Dated: September 10, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20889 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–3878]

New Drugs Regulatory Program Modernization: Integrated Assessment of Marketing Applications and Integrated Review Documentation; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is seeking public comments on the ''New Drugs Regulatory Program Modernization: Integrated Assessment of Marketing Applications and Integrated Review Documentation.'' The purpose is to seek public comments/feedback on the Integrated Review documentation generated by the Integrated Assessment of Marketing Applications for new drug products developed as part of the New Drugs Regulatory Program Modernization. The Agency hopes to receive public feedback on how this Integrated Review documentation can continue supporting our stakeholders' needs.

DATES: Submit either electronic or written comments on the notice by December 12, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. eastern time at the end of December 12, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. 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–2024–N–3878 for ''New Drugs Regulatory Program Modernization: Integrated Assessment of Marketing Applications and Integrated Review Documentation; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Rhonda M. Hearns-Stewart, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6460, Silver Spring, MD 20993–0002, 240–402–3180, *Rhonda.Hearns-Stewart@fda.hhs.gov,* with the subject line ''Collecting Public Feedback on the Integrated Review.''

SUPPLEMENTARY INFORMATION:

I. Background

The Integrated Assessment of Marketing Applications, which is part of FDA's New Drugs Regulatory Program Modernization, includes a new review template for the assessment and documentation of new drug product marketing applications (*e.g.,* new drug applications (NDAs) or biologics license applications (BLAs)) in the Center for Drug Evaluation and Research. The resultant Integrated Review is the product of an interdisciplinary team assessment process that provides collaborative discussions of key review issues that span multiple disciplines and includes resolution of important issues pertinent to benefit-risk assessments. This interdisciplinary approach facilitates clarity of decision making and ensures input from relevant disciplines in the consideration of scientific issues. FDA believes the format and content of the Integrated Review documentation will provide sufficient detail concerning the evidence of efficacy and assessment of risk and risk management as well as a clearer description of FDA's analysis of the scientific issues raised by the application and the scientific reasoning supporting the benefit-risk determination. The overall objective is to more effectively communicate the basis for FDA's decision on applications.

This new Integrated Review document replaces the previous documentation, which included a separate review document authored by each discipline. It also replaces the multidisciplinary review (*i.e.,* Unireview) in which each discipline provided a separate review section but within a single review document. FDA implemented the Integrated Review documentation for new molecular entities, original BLAs, and select efficacy supplements. FDA plans to expand the scope to other marketing application types in the near future.

The following guiding principles informed the Integrated Review documentation:

- The importance of conducting an issue-focused assessment,
- Enhanced communication within the review team, and
- Strong interdisciplinary collaboration.

The Integrated Review documentation template has three main components:

- *Executive Summary:*
  - Represents FDA's conclusions regarding key scientific and regulatory issues while describing any differences of scientific opinion or perspective,

- 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