(identifying the transgenic mutation assay as appropriate for followup for any positive bacterial mutagenicity test as opposed to other tests, which are recommended under more limited circumstances). When such in vivo testing is warranted, industry collaboration on the testing to develop robust data and share results among themselves could enhance scientific analyses and could facilitate regulatory decision-making. Similarly, we have encouraged applicants to publish scientific research and test results to further scientific knowledge on NDSRIs and facilitate regulatory decision-making, as appropriate.

II. Issues for Consideration and Request for Comments

FDA is requesting comments from the public regarding the identification, assessment, and control of NDSRIs in drug product development and regulatory review to provide interested parties an opportunity to comment on scientific and regulatory considerations, including areas that may benefit from collaborative efforts. FDA is also interested in any challenges preventing industry from identifying, assessing, and controlling NDSRIs that may assist FDA in its analysis.

The questions posed below are not meant to be exhaustive. FDA is interested in other pertinent information that stakeholders would like to provide on issues and challenges related to addressing NDSRIs. FDA is particularly interested in comments on the following topics:

A. General Questions

1. What additional topics related to the evaluation of nitrosamines should be a priority for the Agency to address through guidance documents?
2. What factors should FDA consider in prioritizing its evaluation of NDSRIs on a compound-specific basis?
3. What additional mitigation strategies should be considered for reducing NDSRI formation or eliminating these impurities (where feasible)?

B. NDSRI Risk Assessment

1. What scientific and technical factors should FDA consider in developing best practices for conducting testing for NDSRIs (*e.g.,* Ames test, enhanced Ames test, followup in vitro mutagenicity, in vivo transgenic gene mutation test) in support of establishing AI limits?

a. Are there other tests recommended for assessing mutagenic potential of NDSRIs, and how supportable are these methods?

b. Would ''short-term'' carcinogenicity testing (*e.g.,* 6-month transgenic mouse model) be informative to evaluate the risk associated with NDSRIs?

c. If so, what are the advantages and disadvantages to such testing?

d. Are there other types of studies that may further inform FDA about the risk associated with NDSRI (*e.g.,* in vitro/in vivo metabolism, DNA biomarkers, identification of reactive intermediates)?

2. FDA recommended in the Nitrosamine Guidance that confirmatory testing of drug products and submission of required changes in drug applications be concluded on or before October 1, 2023 (see Ref. 3 at 17). Would an extension of the recommended timeline for submission of changes in drug applications as described in the guidance to June 1, 2024, allow for additional assessment of NDSRIs and enable collaborative efforts among affected applicants? How can FDA further support manufacturers' efforts toward completion of confirmatory testing?

C. Collaborative Efforts To Develop NDSRI Data and Establish and Implement Recommended AI Limits

1. How can FDA facilitate collaborative efforts to generate reliable compound-specific data on NDSRIs and reduce the need for additional and potentially duplicative testing?
2. Are there obstacles that industry has encountered when engaging in collaborative efforts that could allow companies to share data to assess the safety of NDSRIs, particularly with the intent of reducing redundant testing and integrating the 3R principles? Such examples of collaboration may include enhancing (Q)SAR methods and models, conducting in vitro mutagenicity testing and/or in vivo transgenic gene mutation tests. If there are such obstacles, are there ways that FDA could facilitate collaboration?

D. Establishing and Implementing Recommended AI Limits and Access to Medications

1. In implementing recommendations for controlling nitrosamines, including NDSRIs, have manufacturers or suppliers experienced difficulties with meeting recommended AI limits that has led to discontinuation of manufacturing or distribution?

III. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Food and Drug Administration (FDA) guidance for industry ''ANDAs: Impurities in Drug Substances,'' June 2009, available at *https://www.regulations.gov/document/FDA-1998-D-0021-0008.*

2. FDA guidance for industry ''ANDAs: Impurities in Drug Products,'' November 2010, available at *https://www.fda.gov/media/71351/download.*

3. FDA guidance for industry ''Control of Nitrosamine Impurities in Human Drugs,'' February 2021, available at *https://www.fda.gov/media/141720/download.*

4. FDA, ''Updates on Possible Mitigation Strategies To Reduce the Risk of Nitrosamine Drug Substance-Related Impurities in Drug Products,'' available at *https://www.fda.gov/drugs/drug-safety-and-availability/updates-possible-mitigation-strategies-reduce-risk-nitrosamine-drug-substance-related-impurities.* Last accessed April 14, 2023.

5. FDA and International Council for Harmonisation guidance for industry ''M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk,'' March 2018, available at *https://www.fda.gov/media/85885/download.*

6. FDA and International Council for Harmonisation guidance for industry, ''M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals'' January 2010, available at *https://www.fda.gov/media/71542/download.*

Dated: May 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09526 Filed 5–3–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–N–1894; FDA–2018–N–3303; FDA–2022–N–0576; FDA–2022–N–1794; FDA–2011–N–0902; FDA–2009–N–0545; FDA–2016–N–2474; FDA–2010–D–0350; FDA–2012–D–0530; FDA–2016–N–2683; FDA–2013–N–0403; FDA–2013–N–0134; FDA–2022–N–2440; FDA–2013–N–0879; and FDA–2014–N–1048]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a

list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation B12 Pediatric Device Survey	0910–0912	3/31/2024
Electronic Products Requirements	0910–0025	2/28/2026
Investigational Device Exemptions	0910–0078	2/28/2026
General Drug Labeling Provisions and OTC Monograph Drug User Fee Submissions	0910–0340	2/28/2026
Prescription Drug Product Labeling; Medication Guide Requirements	0910–0393	2/28/2026
Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Product Deviations in Manufacturing	0910–0458	2/28/2026
Designation of New Animal Drugs for Minor Use or Minor Species	0910–0605	2/28/2026
Tobacco Retailer Training Programs	0910–0745	2/28/2026
Q-Submission and Early Payor Feedback Request Programs for Medical Devices	0910–0756	2/28/2026
Data To Support Social and Behavioral Research as Used by the Food and Drug Administration	0910–0847	2/28/2026
Protection of Human Subjects and Institutional Review Boards	0910–0130	3/31/2026
Mammography Standards Quality Act Requirements	0910–0309	3/31/2026
Biologics License Applications; Procedures & Requirements	0910–0338	3/31/2026
Procedures for the Safe Processing and Importing of Fish and Fishery Products	0910–0354	3/31/2026
Medical Device Labeling Regulations; Unique Device Identification	0910–0485	3/31/2026

Dated: April 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09401 Filed 5–3–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1553]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. On June 15, 2023, the committee will meet in open session to discuss and make recommendations on the selection of strain(s) to be included in the periodic updated COVID–19 vaccines for the 2023–2024 vaccination campaign. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on June 15, 2023, from 8:30 a.m. to 5 p.m. Eastern Time.

ADDRESSES: Please note that all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. The online web conference meeting will be available at the following link on the day of the meeting: *https://youtube.com/live/gBOyPREXGh8.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2023–N–1553. The docket will close on June 14, 2023. Either electronic or written comments on this public meeting must be submitted by June 14, 2023. 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 June 14, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before June 7, 2023, will be provided to the committee. Comments received after June 7, 2023, and by June 14, 2023, will be taken into consideration by FDA. In the event that the meeting is canceled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate. You may submit comments as follows:

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