Additionally, the provisions of the Regulatory Flexibility Act,[5] which apply only when notice and comment are required by the APA or other law, are not applicable.[6] These amendments do not contain any collection of information requirements as defined by the Paperwork Reduction Act of 1995.[7] Further, because these amendments impose no new burdens on private parties, the Commission does not believe that the amendments will have any impact on competition for purposes of section 23(a)(2) of the Exchange Act.[8]

II. Statutory Authority

We are adopting these technical amendments under the authority set forth in section 19(a) of the Securities Act of 1933 [15 U.S.C. 77s], section 319 of the Trust Indenture Act of 1939 [15 U.S.C. 77sss], section 23(a) of the Securities Exchange Act of 1934 [15 U.S.C. 78w(a)], section 38(a) of the Investment Company Act of 1940 [15 U.S.C. 80a–37(a)], and section 211(a) of the Investment Advisers Act of 1940 [15 U.S.C. 80b–11(a)].

List of Subjects in 17 CFR Part 200

Administrative practice and procedure, Authority delegations (Government agencies).

Text of Amendments

For reasons set forth in the preamble, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

■ 1. Add an authority citation for part 200 to read as follows:

Authority: 5 U.S.C. 552, 552a, 552b, and 557; 11 U.S.C. 901 and 1109(a); 15 U.S.C. 77c, 77e, 77f, 77g, 77h, 77j, 77o, 77q, 77s, 77u, 77z–3, 77ggg(a), 77hhh, 77sss, 77uuu, 78b, 78c(b), 78d, 78d–1, 78d–2, 78e, 78f, 78g, 78h, 78i, 78k, 78k–1, 78*l,* 78m, 78n, 78o, 78o–4, 78q, 78q–1, 78w, 78t–1, 78u, 78w, 78*ll*(d), 78mm, 78eee, 80a–8, 80a–20, 80a–24, 80a–29, 80a–37, 80a–41, 80a–44(a), 80a–44(b), 80b–3, 80b–4, 80b–5, 80b–9, 80b–10(a), 80b–11, 7202, and 7211 *et seq.;* 29 U.S.C. 794; 44 U.S.C. 3506 and 3507; Reorganization Plan No. 10 of 1950 (15 U.S.C. 78d nt); sec. 8G, Pub. L. 95–452, 92 Stat. 1101 (5 U.S.C. App.); sec. 913, Pub. L. 111–203, 124 Stat. 1376, 1827; sec. 3(a), Pub. L. 114–185, 130 Stat. 538; E.O. 11222, 30 FR 6469, 3 CFR, 1964–1965 Comp., p. 36; E.O. 12356, 47 FR 14874, 3 CFR, 1982 Comp., p. 166; E.O. 12600, 52 FR 23781, 3 CFR, 1987 Comp., p. 235; Information Security Oversight Office Directive No. 1, 47 FR 27836; and 5 CFR 735.104 and 5 CFR parts 2634 and 2635, unless otherwise noted.

Subpart A—Organization and Program Management

■ 2. Remove the authority citation for part 200, subpart A.

Subpart B—Disposition of Commission Business

■ 3. Remove the authority citation for part 200, subpart B.

Subpart C—Canons of Ethics

■ 4. Remove the authority citation for part 200, subpart C.

Subpart D—Information and Requests

■ 5. Remove the authority citation for part 200, subpart D.

Subpart F—Code of Behavior Governing Ex Parte Communications Between Persons Outside the Commission and Decisional Employees

■ 6. Remove the authority citation for part 200, subpart F.

Subpart G—Plan of Organization and Operation Effective During Emergency Conditions

■ 7. Remove the authority citation for part 200, subpart G.

Subpart H—Regulations Pertaining to the Privacy of Individuals and Systems of Records Maintained by the Commission

■ 8. Remove the authority citation for part 200, subpart H.

Subpart I—Regulations Pertaining to Public Observation of Commission Meetings

■ 9. Remove the authority citation for part 200, subpart I.

Subpart J—Classification and Declassification of National Security Information and Material

■ 10. Remove the authority citation for part 200, subpart J.

Subpart K—Regulations Pertaining to the Protection of the Environment

■ 11. Remove the authority citation for part 200, subpart K.

Subpart L—Enforcement of Nondiscrimination on the Basis of Handicap in Programs or Activities Conducted by the Securities and Exchange Commission

■ 12. Remove the authority citation for part 200, subpart L.

Subpart M—Regulation Concerning Conduct of Members and Employees and Former Members and Employees of the Commission

■ 13. Remove the authority citation for part 200, subpart M.

Subpart N—Commission Information Collection Requirements Under the Paperwork Reduction Act: OMB Control Numbers

■ 14. Remove the authority citation for part 200, subpart N.

By the Commission.

Dated: December 15, 2022.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–27636 Filed 12–20–22; 8:45 am]

BILLING CODE 8011–01–P

affect the rights or obligations of non-agency parties'').

[5] 5 U.S.C. 601 *et seq.*

[6] *See* 5 U.S.C. 601(2).

[7] *See* 5 CFR 1320.3.

[8] 15 U.S.C. 78w(a)(2).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 170 and 570

[Docket No. FDA–2017–D–0085]

Best Practices for Convening a GRAS Panel; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''Best Practices for Convening a GRAS Panel.'' This guidance document is intended for any person who is responsible for a conclusion that a substance may be used in food on the basis of the generally recognized as safe (GRAS) provision of the Federal Food, Drug, and Cosmetic Act (FD&C Act) when that person convenes a panel of experts (''GRAS panel'') to independently evaluate whether the available scientific data, information, and methods establish that the substance is safe under the conditions of its intended use in human food or animal food. This guidance provides our current thinking on best practices to identify GRAS panel

members who have appropriate and balanced expertise; to take steps to reduce the risk that bias (or the appearance of bias) will affect the credibility of the GRAS panel's output (often called a ''GRAS panel report''), including the assessment of potential GRAS panel members for conflict of interest and the appearance of conflict of interest; and to limit the data and information provided to a GRAS panel to public information (*e.g.,* by not providing the GRAS panel with information such as trade secret information).

DATES: The announcement of the guidance is published in the **Federal Register** on December 21, 2022.

ADDRESSES: You may submit either electronic or written comments on FDA guidances at any time 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 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–2017–D–0085 for ''Best Practices for Convening a GRAS Panel.'' Received comments 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.'' We will review this copy, including the claimed confidential information, in our 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–200), 5001 Campus Dr., College Park, MD 20740, or to the Office of Surveillance and Compliance (HFV–200), Center for Veterinary Medicine, 12225 Wilkins Ave., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: *Regarding substances that would be used in human food:* Paulette M. Gaynor, Office of Food Additive Safety (HFS–255), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1192. *Regarding substances that would be used in animal food:* Geoffrey K. Wong, Office of Surveillance and Compliance (HFV–225), Center for Veterinary Medicine, Food and Drug Administration, 12225 Wilkins Ave., Rockville, MD 20855, 240–402–5838. *Regarding other questions about this document:* Alexandra Jurewitz, Office of Regulations and Policy (HFS–024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

Section 201(s) of the FD&C Act (21 U.S.C. 321(s)) defines a ''food additive'' as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use. Under this definition, a substance that is GRAS under the conditions of its intended use is not a ''food additive'' and is therefore not subject to mandatory premarket review by FDA under section 409 of the FD&C Act (21 U.S.C. 348). In this document, we refer to a person who is responsible for a conclusion that a substance may be used in human food or animal food on the basis of the GRAS provision of the FD&C Act, without premarket review by FDA under section 409 of the FD&C Act, as the ''proponent'' of that substance.

We have established regulations implementing the GRAS provision of section 201(s) of the FD&C Act in part 170 (21 CFR part 170) for human food

and in part 570 (21 CFR part 570) for animal food. Those regulations include a voluntary procedure (''GRAS notification procedure'') through which a proponent may notify us of a conclusion that a substance is GRAS under the conditions of its intended use in human food (part 170, subpart E) or animal food (part 570, subpart E).

In some cases, the process whereby the proponent evaluates whether the available data and information support a conclusion that a substance is GRAS under the conditions of its intended use includes considering the opinion of a ''GRAS panel'' of qualified experts who independently evaluate whether the available scientific data, information, and methods establish that a substance is safe under the conditions of its intended use in human food or animal food. Depending on the outcome of the GRAS panel's analysis, the proponent could either reach a conclusion regarding the safety of the substance under the conditions of its intended use or be advised of one or more issues (such as gaps in the data and information or alternative interpretations of the available data and information) that warrant investigation before a conclusion can be drawn about whether the substance is safe under the conditions of its intended use. When the outcome of the GRAS panel's analysis supports the proponent's conclusion that a substance is safe under the conditions of its intended use, in essence the proponent then relies on the members of the GRAS panel to act as a proxy for the larger scientific community knowledgeable about the safety of substances directly or indirectly added to food and, in so doing, relies on the outcome of the GRAS panel's analysis to support the proponent's conclusion that the safety of the intended use is ''generally recognized'' by qualified experts. Whether a GRAS panel is a sufficient proxy for the larger scientific community depends on a number of factors, such as the subject matter expertise of the members of the GRAS panel and whether the members of the GRAS panel would be considered representative of experts qualified by scientific training and experience to evaluate the safety of the substance under the conditions of its intended use.

A GRAS panel is one mechanism that proponents have used to demonstrate that the safety of a substance under the conditions of its intended use is generally recognized by qualified experts. However, the use of a GRAS panel is not the only mechanism for doing so, and the use of a GRAS panel does not necessarily mean that the GRAS criteria have been met (81 FR 54960 at 54974 through 54975, August 17, 2016).

We are announcing the availability of a guidance for industry entitled ''Best Practices for Convening a GRAS Panel.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of November 16, 2017 (82 FR 53433), we made available a draft guidance for industry entitled ''Best Practices for Convening a GRAS Panel'' (''draft guidance''), which was intended for any proponent who convenes a GRAS panel and provided our current thinking on best practices to identify GRAS panel members who have appropriate and balanced expertise; to take steps to reduce the risk that bias (or the appearance of bias) will affect the credibility of a GRAS panel report, including the assessment of potential GRAS panel members for conflict of interest and the appearance of conflict of interest; and to limit the data and information provided to a GRAS panel to public information (*e.g.,* by not providing the GRAS panel with information such as trade secret information). We gave interested parties until May 15, 2018, to submit comments for us to consider before beginning work on the final version of the guidance.

We received 13 comments on the draft guidance. Most comments supported the draft guidance and offered ideas on how to improve the guidance. One comment discussed FDA's analysis of the proposed collection of information, and another comment involved issues not related to the draft guidance. We have modified the final guidance where appropriate. Changes to the guidance include:

- Emphasizing that, in many cases, a GRAS panel is not necessary, in response to comments suggesting the GRAS notification process may become too burdensome;
- Providing additional background information regarding the value of a GRAS panel in providing evidence to support the ''general acceptance'' aspect of the criteria for eligibility for GRAS status through scientific procedures;
- Clarifying the GRAS panel policy discussions around evaluating and managing conflicts of interest and appearance issues, as well as honoraria;
- Removing one reference, as it has been withdrawn since publication of the draft guidance; and
- Removing a mistaken reference to a section V.J.

The guidance announced in this notice finalizes the draft guidance dated November 2017.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in this guidance have been approved under OMB control number 0910–0911.

This guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR parts 170 and 570 have been approved under OMB control number 0910–0342.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA websites listed in the previous sentence to find the most current version of the guidance.

Dated: December 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27714 Filed 12–20–22; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2018–0746; FRL–6494.1–02–OAR]

RIN 2060–AV54

Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action; reconsideration of the final rule.

SUMMARY: On August 12, 2020, the U.S. Environmental Protection Agency (EPA) published the final risk and technology review (RTR) for the Miscellaneous Organic Chemical Manufacturing NESHAP (2020 MON final rule) pursuant to Clean Air Act (CAA).