Bulletin 737–53A1401, dated April 27, 2021, which is referred to in Boeing Alert Requirements Bulletin 737–53A1401 RB, dated April 27, 2021.

(h) Exceptions to Service Information Specifications

(1) Where the Compliance Time column of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 737–53A1401 RB, dated April 27, 2021, uses the phrase ''the original issue date of Requirements Bulletin 737–53A1401 RB,'' this AD requires using ''the effective date of this AD.''

(2) Where Boeing Alert Requirements Bulletin 737–53A1401 RB, dated April 27, 2021, specifies contacting Boeing for repair instructions: This AD requires doing the repair using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1)of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

(1) For more information about this AD, contact Courtney Tuck, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3986; email: *courtney.k.tuck@faa.gov*.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com*. You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on December 22, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–01408 Filed 1–25–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 170

[Docket No. FDA–2021–N–0403]

RIN 0910–AI01

Food Additives: Food Contact Substance Notification That Is No Longer Effective

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend its regulations relating to the procedures by which we determine that a premarket notification for a food contact substance (FCN) is no longer effective. The proposed rule, if finalized, would, among other things, ensure that manufacturers or suppliers have the opportunity to provide input before we could determine that an FCN is no longer effective. The proposed rule also would provide additional reasons that could be the basis for FDA to determine that an FCN is no longer effective. We are proposing these changes to better enable FDA to respond to new information on the safety and use of food contact substances, as well as manufacturers' business decisions, which would also improve our FCN program's efficiency.

DATES: Submit either electronic or written comments on the proposed rule by April 11, 2022. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 by March 28, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 11, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 11, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2021–N–0403 for ''Food Additives: Food Contact Substance Notification That Is No Longer Effective.'' 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.'' 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.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) at *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this proposed collection is Food Contact Substance Notification Program.

FOR FURTHER INFORMATION CONTACT: *With regard to the proposed rule:* Paulina Piotrowski, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301–796–8649, *paulina.piotrowski@fda.hhs.gov;* or Lauren Baham, Center for Food Safety and Applied Nutrition (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Proposed Rule

We are proposing to amend our regulations at § 170.105 (21 CFR 170.105) to provide additional reasons which may be the basis for FDA to determine that a FCN is no longer effective and to provide the manufacturer or supplier of the substance an opportunity to provide input before we could make such a determination. These changes to § 170.105 would create administrative mechanisms to improve the efficiency of the premarket notification program for food contact substances.

We also are proposing to clarify our confidentiality of information regulation at § 170.102 (21 CFR 170.102).

B. Summary of the Major Provisions of the Proposed Rule

FDA's current regulations at § 170.105 provide the process by which we may determine that an FCN is no longer effective based on data or other information available to us that demonstrate that the intended use of the food contact substance is no longer safe. The proposed rule, if finalized, would include reasons other than safety as the basis on which we may determine that an FCN is no longer effective and the process under which we would make determinations based on these other reasons. These reasons would include instances in which the production, supply, or use of the food contact substance for its intended use has ceased or will cease, or the use of a food contact substance identified in an FCN is authorized by a food additive regulation or covered by a threshold of regulation exemption. We also propose to provide the manufacturer or supplier who submitted an FCN the opportunity to address our safety concerns or to otherwise show why an FCN should continue to be effective before we could determine that an FCN is no longer effective, resulting in this use no longer being authorized.

C. Legal Authority

FDA is proposing to modify the procedures by which FDA determines that an FCN is no longer effective. These modifications would include additional reasons as the basis for FDA to determine that an FCN is no longer effective and to amend the regulation pertaining to confidentiality of information to address, among other things, data and information related to FDA's determination that an FCN is no longer effective. These changes are consistent with our authority in sections 201, 409, and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, 348, and 371(a)). We discuss our legal authority in greater detail in part III below.

D. Costs and Benefits

The proposed changes to § 170.105 are expected to result in cost savings and other benefits to manufacturers and suppliers of food contact substances, as well as to FDA. We expect the costs of the proposed rule to be minimal and, therefore, do not believe that the proposed rule will have a significant economic impact on a substantial number of small entities. For further discussion, see Section VI, ''Economic Analysis of Impacts.''

II. Background

A. Need for the Regulation

Our regulations at § 170.105 set forth the process by which FDA may determine that an FCN is no longer effective. This determination currently only applies when data or other information demonstrating the intended use of a food contact substance is no longer safe. Our regulations currently do not provide reasons other than safety as the basis for FDA to determine that an FCN is no longer effective, nor do our regulations provide manufacturers or suppliers the opportunity to show why an FCN should continue to be effective before we make our determination. The proposed rule would establish new procedures to address these issues, which would better enable FDA to respond to new information on the safety and use of food contact substances. The proposed rule would ensure that a manufacturer or supplier has the opportunity to provide information relevant for FDA to make a safety determination before we could make such a determination. The proposed rule would also permit FDA to make a determination that an FCN is no longer effective for reasons other than safety. For example, FDA could reduce confusion created by duplicative authorizations by removing effective FCNs for intended uses authorized by food additive regulations or covered by a Threshold of Regulation (TOR) exemption. In addition, the proposed rule would allow a manufacturer or supplier to request that an FCN be determined to no longer be effective because it has ceased (or intends to cease) producing, supplying, or using a food contact substance for the intended use. This may be less burdensome for both FDA and the manufacturer or supplier than addressing potential safety concerns. We may decline this request if we determine there is a safety issue that serves as the basis for FDA's determination. This would improve the efficiency of the FCN program, which in turn may reduce the burden on manufacturers or suppliers, as well as FDA. The proposed rule will also improve the transparency of the FCN program.

B. FDA's Current Regulatory Framework for Food Contact Substances

A food additive (see section 201(s) of the FD&C Act for the definition of a food additive) is subject to premarket review by FDA (see section 409 of the FD&C Act). The use of a food additive not in compliance with section 409 of the FD&C Act is deemed unsafe (section 409(a) of the FD&C Act). A food is deemed to be adulterated if it is or if it bears or contains an unsafe food additive (section 402(a)(2)(C) of the FD&C Act).

A food additive may be a food contact substance. A food contact substance is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food (see section 409(h)(6) of the FD&C Act and § 170.3(e)(3)). Accordingly, food contact substances that are food additives require FDA premarket authorization (id.).

Certain uses of food contact substances (often described as indirect food additives) are authorized through FDA's food additive regulations (see 21 CFR parts 173 through 177, and 180). FDA has also established procedures set forth in § 170.39 to exempt from regulation as food additives certain substances used in food-contact articles that migrate or may be expected to migrate into food at levels that are below the threshold of regulation. Manufacturers and suppliers can review our food additive regulations and TOR exemptions to determine which food contact substances are already authorized by regulation or exempted from regulation for a specific food-contact use.

Section 409 of the FD&C Act (21 U.S.C. 348) establishes a premarket FCN process as the primary method by which FDA reviews the use of food additives that are food contact substances and by which such uses are authorized as safe. Our regulations in part 170, Subpart D, set forth the procedures for the FCN process. The FD&C Act establishes that a manufacturer or supplier of a food contact substance may, at least 120 days before introducing or delivering into interstate commerce, notify us of the identity and intended use of the substance and of the manufacturer's determination that it is safe for such intended use (see section 409(h) of the FD&C Act and § 170.100). An FCN is effective only for the substance, its intended use, and the manufacturer or supplier identified in the FCN submission (see section 409(h)(1)(C) of the FD&C Act and § 170.100(a)). If another manufacturer or supplier wishes to market the same food contact substance for the same use, they must submit an FCN to FDA (see § 170.100(a)).

Our regulations, at § 170.105, establish the process by which we may determine that an FCN is no longer effective. We may determine that the FCN is no longer effective if data or other information available to us, including data not submitted by the manufacturer or supplier, demonstrate that the intended use of the food contact substance is no longer safe (see § 170.105(a)). Further, if we determine that an FCN is no longer effective, we inform the manufacturer or supplier in writing of the basis for that determination and provide a time by which the manufacturer or supplier may show why the FCN should continue to be effective (see § 170.105(b)). Finally, if the manufacturer or supplier fails to respond adequately to the safety concerns regarding the notified use, we will publish a notice of our determination that the FCN is no longer effective in the **Federal Register** (see § 170.105(c)). The notice states that a detailed summary of the basis for our determination that the FCN is no longer effective has been placed on public display and that copies are available upon request (id.). The date that the notice publishes in the **Federal Register** is the date on which the notification is no longer effective (id.). Our determination that an FCN is no longer effective constitutes final agency action that is subject to judicial review (see § 170.105(d)).

Currently, our regulations do not provide reasons other than safety as the basis for FDA to determine that an FCN is no longer effective, nor do our regulations provide manufacturers or suppliers the opportunity to show why an FCN should continue to be effective before we make our determination.

III. Legal Authority

FDA is proposing to modify the procedures by which FDA determines that an FCN is no longer effective and to include additional reasons as the basis for FDA to determine that an FCN is no longer effective. Given these proposed changes, FDA also is proposing to amend the regulation pertaining to confidentiality of information. These changes are consistent with our authority in sections 201, 409, and 701(a) of the FD&C Act.

The FD&C Act defines ''food additive,'' in relevant part, as any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component of food or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized by

experts as safe under its intended use (section 201(s) of the FD&C Act). Food additives include ''food contact substances,'' which are defined as any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food (section 409(h)(6) of the FD&C Act).

A food additive is deemed unsafe unless that substance and its use conform with a regulation issued under section 409 of the FD&C Act or unless there is an FCN submitted under section 409(h) that is effective (section 409(a) of the FD&C Act)). Section 409(h) of the FD&C Act sets forth the procedure for FCNs.

Under section 409(i) of the FD&C Act, FDA must prescribe by regulation the procedure by which FDA may deem an FCN to no longer be effective (sections 409(i) and 1003(d) of the FD&C Act) (21 U.S.C. 348(i) and 393(d)). Section 701(a) of the FD&C Act gives us the authority to issue regulations for the efficient enforcement of the FD&C Act.

IV. Description of the Proposed Rule

Our regulations, at § 170.105, provide safety as the only basis for FDA to determine that an FCN is no longer effective and provides an opportunity for the manufacturer or supplier to respond to our safety concerns only after we have made our determination. Based on our experience in administering the FCN program, we have concluded that FDA could better respond to new information about the safety and use of food contact substances if FDA were not limited only to determining that an FCN is no longer effective based on safety. The proposed rule would amend § 170.105 by including additional reasons which may be the basis for us to determine that an FCN is no longer effective. The proposed rule also would give the manufacturer or supplier the opportunity to respond to our safety concerns or to otherwise show why an FCN should continue to be effective before we could determine that an FCN is no longer effective.

We are proposing to provide additional reasons which may be the basis for FDA to determine that an FCN is no longer effective. These additional reasons include: (1) Information available to FDA that demonstrate that the manufacturer or supplier specified in the FCN has stopped or intends to stop producing, supplying, or using a food contact substance for the intended use; (2) the intended use of the food contact substance identified in the FCN is authorized by a food additive regulation; or (3) the intended use of the food contact substance identified in the FCN is covered by a TOR exemption. After FDA has determined that an FCN is no longer effective, a manufacturer or supplier would not be precluded from submitting a new FCN for the same food contact substance, including for the same intended use, unless the intended use of the food contact substance is authorized by a food additive regulation or covered by a TOR exemption.

We also are proposing to amend our confidentiality of information regulation at § 170.102 to address the data and information that is related to a notification, including data and information related to FDA's determination that an FCN is no longer effective.

A. Data or Other Information Demonstrate That the Intended Use of the Food Contact Substance Is No Longer Safe

Our current regulations state that if data or other information available to us, including data not submitted by a manufacturer or supplier, demonstrate that the intended use of a food contact substance is no longer safe, we may determine that the FCN is no longer effective (see § 170.105(a)). This regulation also sets forth the process whereby we will inform a manufacturer or supplier of our determination and give the manufacturer or supplier an opportunity to show why the FCN should continue to be effective for that use and specifies the time for the manufacturer or supplier to respond (see § 170.105(b)).

The proposed rule would change the process for determining that an FCN is no longer effective based on safety concerns in one key respect. Under the proposed rule, we would make a determination that the FCN is no longer effective only *after* we have given the manufacturer or supplier an opportunity to provide data or other information to respond to our safety concerns. We could determine an FCN is no longer effective if a manufacturer or supplier fails to respond by the specified date, or to provide the data and information that is necessary to address the safety concerns regarding the notified use. Giving manufacturers and suppliers the opportunity to provide data and information will help inform our safety reviews before we make a determination.

In brief, the proposed rule, at § 170.105(a)(1)(i), would state that we will inform the manufacturer or supplier specified in the FCN, in writing, of our concerns regarding the safety of the intended use of the food contact substance. FDA will specify a date by which the manufacturer or supplier must provide data or other information to address the safety concerns (see proposed § 170.105(a)(1)(i)). Under proposed § 170.105(a)(1)(ii), if the manufacturer or supplier fails, by the specified date, to supply the data or other information necessary to address the safety concerns regarding the notified use, we may determine that the FCN is no longer effective because there is no longer a basis to conclude that the intended use is safe.

In response to our potential safety concerns with the intended use of a food contact substance, we have received voluntary commitment letters from certain manufacturers that they have ceased or intend to cease the introduction into interstate commerce of food contact substances for food contact use in the United States; however, these FCNs remain effective. (See ''Market Phase-Out of Certain Short-Chain PFAS'' and also at ''Market Phase-Out and Revocation of Authorization of Long-Chain PFAS'' at *https://www.fda.gov/food/chemicals/authorized-uses-pfas-food-contact-applications*.) Accordingly, we also propose allowing a manufacturer or supplier to respond to FDA, by the date specified for providing data or other information, by requesting that we determine that an FCN is no longer effective because the manufacturer or supplier no longer produces, supplies, or uses the food contact substance for the intended use in the United States, or intends to stop producing, supplying, or using a food contact substance for the intended use in the United States by a specified date (see proposed § 170.105(a)(2)(i)(A)).

Depending on the circumstances, we may deny such a request if it is insufficient to protect the public health, for example, because of the public health risk from continued exposure to the food contact substance. If FDA denies such a request, and we had previously informed the manufacturer or supplier of our concerns regarding the safety of the intended use of the food contact substance, we may determine that an FCN is no longer effective because there is no longer a basis to conclude that the intended use is safe (see proposed § 170.105(a)(1)(iii)). Alternatively, FDA may provide the manufacturer or supplier with additional time to provide us with data or other information to respond to the safety concerns (id.). If the manufacturer or supplier fails, by the specified date, to supply the data or

other information necessary to address the safety concerns regarding the notified use, we may determine that the FCN is no longer effective because there is no longer a basis to conclude that the notified use is safe (id.).

B. Manufacturer or Supplier No Longer Produces, Supplies, or Uses the Food Contact Substance for the Intended Use

Our current regulations do not provide a basis for determining that an FCN is no longer effective for reasons other than safety. Based on our experience, manufacturers have stopped manufacturing certain food contact substances that are authorized for use under effective FCNs; however, there is no provision for the manufacturers to request that an FCN be determined to be no longer effective based on reasons other than safety. For example, a manufacturer may choose, for business reasons, to stop production of the food contact substance to the specifications in the FCN and sale of the food contact substance into food contact applications, while continuing to sell the same substance for use in non-food contact applications.

The proposed rule would provide that a manufacturer or supplier may request in writing that FDA determine that an FCN is no longer effective on the basis that it has stopped, or intends to stop by a specified date, producing, supplying, or using a food contact substance for the intended food contact use in the United States (see proposed § 170.105(a)(2)(i)(A)). As detailed above, the manufacturer or supplier also may provide this information when given the opportunity to respond to our safety concerns (see proposed § 170.105(a)(1)(ii)). We would then notify the manufacturer or supplier whether we are granting this request (see proposed § 170.105(a)(2)(i)(A)).

If FDA grants the request, we may determine that the FCN is no longer effective on the basis that the manufacturer or supplier has stopped producing, supplying, or using a food contact substance for the intended use in the United States or that it intends to stop producing, supplying, or using a food contact substance for the intended use in the United States by a specified date (see proposed § 170.105(a)(2)(i)(B)). When such a request is based on the intent to stop producing, supplying, or using a food contact substance for the intended use in the United States at a future date, FDA will include the date specified in the request (*i.e.,* the date by which the manufacturer or supplier intends to stop producing, supplying, or using a food contact substance) as the compliance date to stop producing, supplying, or using the food contact substance for the intended use in the United States (id.).

The proposed rule also would provide that if other data or information available to FDA demonstrate that a manufacturer or supplier no longer produces, supplies, or uses a food contact substance for the intended use in the United States, we will inform, in writing, the manufacturer or supplier specified in the FCN before we could determine that the FCN is no longer effective (see proposed § 170.105(a)(2)(ii)(A)). For example, we may learn from persons other than the manufacturer or supplier listed in the FCN that the manufacturer or supplier is no longer producing, supplying, or using the food contact substance for its intended use in the United States, such as when the listed manufacturer or supplier has ceased operations and has not been acquired by another company. The proposal also would state that we will include a specified time period by which the manufacturer or supplier must provide us with data or other information that demonstrate that the manufacturer or supplier continues to produce, supply, or use a food contact substance for the intended use in the United States (id.).

If the manufacturer or supplier fails, by the specified date, to provide data or other information that demonstrate that the manufacturer or supplier continues to produce, supply, or use a food contact substance for the intended use in the United States, or if the manufacturer or supplier confirms that it has stopped producing, supplying, or using the food contact substance for the intended food contact use in the United States, FDA may determine that the FCN is no longer effective (see proposed § 170.105(a)(2)(ii)(B)).

C. The Intended Use of the Food Contact Substance Is Authorized by a Food Additive Regulation

The proposed rule would create a new provision by which we may determine that an FCN is no longer effective because the intended use of the food contact substance is authorized by a food additive regulation (see proposed § 170.105(a)(3)). Issuing a food additive regulation can be more efficient than reviewing multiple FCNs for the same food contact substance and for the same use. FCNs are effective only for a specific manufacturer or supplier to produce, supply, or use the subject food contact substance for the intended use described in the FCN notification. Multiple manufacturers or suppliers often request FCNs for the same intended use of a food contact substance. In contrast, a food additive regulation can authorize the use of a food contact substance for any manufacturer or supplier who meets the provisions of the relevant food additive regulation (see section 409(a)(3) of the FD&C Act).

Therefore, if a food additive regulation exists for a substance that is the subject of an FCN for the same intended use, proposed § 170.105(a)(3) would enable us to determine that this FCN is no longer effective because the food contact substance is authorized by a food additive regulation. This would enable us to remove the duplicative authorization specific to the manufacturer or supplier listed in each FCN. Removing these FCNs from the inventory of effective FCNs when such authorization is unnecessary because the intended use of the food contact substance is authorized under a food additive regulation may avoid confusion by other manufacturers and suppliers on whether they would also need to obtain authorization through an FCN for that use.

The proposed rule also would state that, before we could determine that an FCN is no longer effective, we would inform the manufacturer or supplier specified in the FCN, in writing, that the intended use of the food contact substance identified in the FCN is authorized by a food additive regulation (see proposed § 170.105(a)(3)(i)). FDA would include a specified time period by which the manufacturer or supplier must provide FDA with data or other information about whether the intended use of the food contact substance is authorized by a food additive regulation, and we would not make a determination until after the time period expires (id). If the manufacturer or supplier fails, by the specified date, to supply data or other information that demonstrate that the intended use of the food contact substance is not authorized by a food additive regulation, FDA may determine that the FCN is no longer effective (see proposed § 170.105(a)(3)(ii)).

D. The Intended Use of the Food Contact Substance Is Covered by a Threshold of Regulation Exemption

The proposed rule would create a new provision by which we may determine that an FCN is no longer effective because the intended use of the food contact substance is covered by a TOR exemption (see proposed § 170.105(a)(4)). As noted earlier, FCNs are effective only for a specific manufacturer or supplier, and multiple manufacturers or suppliers often request FCNs for the same intended use of a

food contact substance. In contrast, a TOR exemption can cover the use of a food contact substance for any manufacturer or supplier who meets the requirements of the TOR. FDA will grant a TOR exemption only if the likelihood or extent of migration to food of a substance used in a food-contact article (*e.g.,* food-packaging or food-processing equipment) is so trivial as not to require regulation of the substance as a food additive (see § 170.39). As such, the substance used in a food-contact article becomes a component of food at levels that are below the threshold of regulation. FDA may grant a TOR exemption only if: (1) The substance is not, or is not suspected to be, a carcinogen in humans or animals; (2) the substance presents no other health or safety concern because the use results in a dietary concentration of 0.5 parts per billion or less or a dietary exposure of 1 percent or less of the acceptable daily intake for the substance and the substance is currently regulated for direct addition to food; (3) the substance has no technical effect in or on the food itself; and (4) the substance use has no significant adverse impact on the environment (see § 170.39(a)). We list current TOR exemptions on our website (see *https://www.fda.gov/food/packaging-food-contact-substances-fcs/threshold-regulation-exemptions-substances-used-food-contact-articles*).

If there is an FCN for a use of a food contact substance that is also covered by a TOR exemption, the proposed rule would enable us to remove an FCN for that same substance for the same intended use. Removing these FCNs from the inventory of effective FCNs may avoid confusion by other manufacturers and suppliers on whether they need to obtain authorization under the FCN process for the use of a food contact substance that is covered under a TOR exemption. Therefore, if a TOR exemption exists for a substance that is the subject of an FCN for the same intended use, proposed § 170.105(a)(4) would enable us to determine that this FCN is no longer effective because the use of the food contact substance is covered by a TOR exemption. This process would enable us to remove the duplicative authorization specific to the manufacturer or supplier listed in each FCN and would increase efficiency for the food industry and FDA.

The proposed rule also would state that, before we determine that an FCN is no longer effective, we would inform the manufacturer or supplier specified in the FCN, in writing, that the intended use of the food contact substance identified in the FCN is covered by a TOR exemption (see proposed § 170.105(a)(4)(i)). FDA would include a specified time period by which the manufacturer or supplier must provide FDA with data or other information about whether the intended use of the food contact substance is covered by a TOR exemption, and we would not make a determination until after the time period expired (id).

If a manufacturer or supplier fails, by the specified date, to supply data or other information that demonstrate that the intended use of the food contact substance identified in the FCN is not covered by a TOR exemption, FDA may determine that the FCN is no longer effective on the basis that the intended use of the food contact substance is covered under a threshold of regulation exemption (see proposed § 170.105(a)(4)(ii)).

E. Publication of FDA's Determination That an FCN Is No Longer Effective

Our current regulation states that, if the manufacturer or supplier fails to respond adequately to the safety concerns regarding the notified use, FDA will publish a notice of its determination that the FCN is no longer effective (see § 170.105(c)). FDA will publish the notice in the **Federal Register**, stating that a detailed summary of the basis for FDA's determination that the FCN is no longer effective has been placed on public display and that copies are available upon request (id). The date that the notice publishes in the **Federal Register** is the date on which the FCN is no longer effective (see § 170.105(c)).

The proposed rule would retain the provision but renumber it as § 170.105(b) and extend this provision to the proposed provisions in this proposed rule under which FDA will determine an FCN is no longer effective. FDA may include a separate compliance date for the use of the food contact substance in food contact articles, if FDA determines it would be protective of public health, for the time-limited use of the food contact substance (see proposed § 170.105(b)). For example, food contact articles that contain the food contact substance for its intended use may still be in the supply chain after a manufacturer has stopped manufacturing the food contact substance. FDA may set a compliance date in the future for the continued use of the food contact substance if FDA determines that its intended use during this timeframe would not pose a risk to public health.

Additionally, our current regulation, at § 170.105(d), states that our determination that an FCN is no longer effective constitutes final agency action and is subject to judicial review. The proposed rule would renumber the provision as proposed § 170.105(b).

F. Future Submissions Following Determination That an FCN Is No Longer Effective

Currently, § 170.105 does not state that a manufacturer or supplier may submit a new FCN for the same food contact substance for the same intended use. The proposed rule would state that our determination that an FCN is no longer effective does not preclude any manufacturer or supplier from submitting a new FCN for the same food contact substance, including for the same intended use, after we have determined that an FCN is no longer effective, unless the intended use of the food contact substance is authorized by a food additive regulation or is covered by a TOR exemption (see proposed § 170.105(c)). The new submission would be made under §§ 170.100 and 170.101 (id.).

G. Confidentiality of Information

Currently, our regulation at § 170.102 discusses the confidentiality of information in a premarket notification for a food contact substance. The proposed rule would amend our regulation to address the confidentiality of data and information that is related to a notification, including data and information related to FDA's determination that an FCN is no longer effective. Specifically, the proposed rule would amend § 170.102(e) to address the disclosure of certain information related to a notification, including information related to FDA's determination that an FCN is no longer effective. The proposed rule would amend § 170.102(e)(1) to include all safety and functionality data and information submitted with or incorporated by reference into the notification, or submitted in reference to an effective FCN. The proposed rule also would amend § 170.102(e)(5) to include all correspondence and written summaries of oral discussions relating to the notification or to FDA's determination that an FCN is no longer effective.

V. Proposed Effective Date

We intend that any final rule resulting from this rulemaking become effective 60 days after the date of publication of the final rule in the **Federal Register**.

VI. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order

12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612) and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits (both quantitative and qualitative) of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive economic analysis of impacts that assesses the impacts of the proposed rule. We believe that the proposed rule will not be an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because of the minimal costs to manufacturers and suppliers that would be affected by this proposed rule, we propose to certify that this proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. We do not expect this proposed rule to result in any 1-year expenditure that will meet or exceed this amount.

B. Summary of Benefits and Costs of the Proposed Rule

The proposed rule is expected to lead to benefits in the form of cost savings to manufacturers and suppliers who have effective food contact notifications and to FDA. The proposed rule would revise FDA's current process of determining whether an FCN is no longer effective. The proposed rule would give manufacturers and suppliers the opportunity to demonstrate why an FCN should continue to be effective before we could make a determination. Additionally, the proposed rule would amend § 170.105 to include reasons other than safety as the basis for FDA to determine that an FCN is no longer effective. This would include instances in which the production, supply, or use of the food contact substance for its intended use has ceased or will cease by a specified date, or the use of a food contact substance identified in an FCN is authorized by a food additive regulation or TOR exemption. Cost savings would be accrued by manufacturers and suppliers who may wish to cease manufacturing a food contact substance and to request that FDA determine that an FCN is no longer effective for reasons other than safety. This may enable manufacturers to resolve the regulatory status of a food contact substance without acquiring and submitting data or other information addressing the safety of the intended use. We also would realize cost savings as we would be able to act more efficiently upon an FCN request by the manufacturer or supplier to determine that an FCN is no longer effective for reasons other than safety. Because the proposed rule would reduce the burden for both industry and FDA and would not require significant additional action to be taken, we expect the costs of the proposed rule to be minimal.

The estimated total cost savings of the proposed rule are estimated in 2020 U.S. dollars and range from zero to $0.5 million, with a central estimate of $0.1 million, annualized at 7 percent over 10 years. Discounted at 3 percent, annualized cost savings range from zero to $0.4 million, with a central estimate of $0.1 million. We estimate that the costs of the proposed rule are minimal. The estimated cost savings and costs of the proposed rule are summarized in table 1.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (percent)	Period covered (years)	
Cost Savings:							
One-time Monetized millions/year							
Annualized	$0.1M	$0	$0.5M	2020	7	10	
Quantified	0.1M	0	0.4M	2020	3	10	
Qualitative							
Costs:							
Annualized							
Monetized millions/year							
Annualized							
Quantified							
Qualitative		0		2020		10	
Transfers:							
Federal Annualized							
Monetized $millions/year							
	From:			To:			
Other Annualized							
Monetized $millions/year							
	From:			To:			

Effects:
State, Local or Tribal Government:
Small Business: Increased cost savings of zero to $144.25 per affected small entity
Wages:
Growth:

The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 1) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This proposed rule 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). A description of these provisions is given in the *Description* section of this document below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Food Contact Substance Notification System; OMB Control Number 0910–0495—Revision

Description: Section 409(h) of the FD&C Act establishes a premarket notification process for food contact substances. Section 409(h)(6) of the FD&C Act defines a ''food contact substance'' as any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food. Section 409(h)(3) of the FD&C Act requires that the notification process be used for authorizing the marketing of food contact substances except when: (1) The Secretary determines that the submission and premarket review of a food additive petition (FAP) under section 409(b) of the FD&C Act is necessary to provide adequate assurance of safety or (2) the Secretary and the manufacturer or supplier agree that an FAP should be submitted. Section 409(h)(1) of the FD&C Act requires that a notification include: (1) Information on the identity and the intended use of the food contact substance and (2) the basis for the manufacturer's or supplier's determination that the food contact substance is safe under the intended use. FDA regulations at part 170 specify the information that a notification must contain.

The proposed rule would amend the procedure by which we determine that an FCN is no longer effective. The information collection would cover situations that entail the potential reporting of additional data or other information by manufacturers or suppliers of food contact substances. This proposal would augment the existing information collection that covers the food contact substance notification program at part 170, subpart D.

Description of Respondents: Respondents to the information collection are manufacturers and suppliers of food contact substances sold in the United States. Respondents are from the private sector (for-profit businesses).

We estimate the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
170.105(a); Manufacturer or supplier responds to FDA by providing additional data or information to demonstrate that the FCN should continue to be effective	2	1	2	75	150
170.105 (a)(2)(i); Manufacturer or supplier requests that FDA determine that the FCN should no longer be effective based on non-safety reasons	5	1	5	2	10
Total					160

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates in table 2 are based on our experience with our Food Contact Substance Notification Program.

We will inform the affected manufacturers or suppliers of the specified FCN about data or other information that their food contact substance may: (1) Not be safe for its intended use; or (2) have stopped being produced, supplied, or used as a food contact substance for its intended use; or (3) be authorized by a food additive regulation; or (4) be covered by a TOR exemption. As such, we may determine that the specified FCN may no longer be effective for its intended use unless the affected manufacturer or supplier provides additional data or other information to demonstrate that the FCN should continue to be effective. In row 1, we estimate that, annually, 2 respondents will each spend about 75 hours preparing a response for a total of 150 hours (2 respondents × 75 hours). In the existing information collection for our Food Contact Substance Notification Program (OMB control number 0910–0495; 84 FR 3468), we estimate that it may take up to 150 hours to prepare and submit an FCN depending on the complexity of the submittal. We assume the time to prepare a response will take about half the time of the initial submittal because the manufacturer or supplier should already have compiled and have access to most, if not all the information demonstrating that their FCN should continue to be effective and remains safe for its intended use.

The proposed rule would allow a manufacturer or supplier to request that FDA determine that their FCN is no

longer effective on the basis that the manufacturer or supplier no longer produces, supplies, or uses the food contact substance for the intended use. We believe a manufacturer or supplier will not need much time to prepare such a request as it should already have access to information that it has or intends to no longer produce, supply, or use the food contact substance for the intended use. Based on the Preliminary Regulatory Impact Analysis, we estimate that 5 respondents will voluntarily request that FDA determine that their FCN is no longer effective (Ref. 1). Accordingly, in row 2, we estimate that 5 respondents will each submit 1 request to us per year with each request taking 2 hours to prepare for a total of about 10 hours (2 respondents × 5 hours).

To ensure that comments on information collection are received, OMB recommends that written comments be submitted through *reginfo.gov* (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the proposed rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the proposed rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. We invite comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XI. Reference

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

1. FDA, ''Food Additives: Food Contact Substance Notification That Is No Longer Effective, Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis.'' Also available at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects in 21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 170 be amended as follows:

PART 170—FOOD ADDITIVES

■ 1. The authority citation for part 170 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

■ 2. Amend § 170.102 by revising the section title, paragraph (e) introductory text and paragraphs (e)(1) and (5) to read as follows:

§ 170.102 Confidentiality of information related to premarket notification for a food contact substance (FCN).

* * * * *

(e) The following data and information are available for public disclosure, unless extraordinary circumstances are shown, on the 121st day after receipt of the notification by FDA, except that no data or information are available for public disclosure if the FCN is withdrawn under § 170.103. Data and information related to FDA's determination that an FCN is no longer effective are available for public disclosure as of the date of publication in the **Federal Register** of FDA's determination.

(1) All safety and functionality data and information submitted with or incorporated by reference into the notification, or submitted in reference to an effective FCN. Safety and functionality data include all studies and tests of a food contact substance on animals and humans and all studies and tests on a food contact substance for establishing identity, stability, purity, potency, performance, and usefulness.

* * * * *

(5) All correspondence and written summaries of oral discussions relating to the notification or to FDA's determination that an FCN is no longer effective, except information that is exempt under § 20.61 of this chapter.

* * * * *

■ 3. Revise § 170.105 to read as follows:

§ 170.105 The Food and Drug Administration's (FDA's) determination that a premarket notification for a food contact substance (FCN) is no longer effective.

(a) FDA may determine that an FCN is no longer effective if:

(1) Data or other information available to FDA, including data not submitted by the manufacturer or supplier, demonstrate that the intended use of a food contact substance is no longer safe.

(i) FDA will inform the affected manufacturer or supplier specified in the FCN, in writing, of FDA's concerns regarding the safety of the intended use of the food contact substance. FDA will specify the date by which the manufacturer or supplier must provide FDA with data or other information to respond to FDA's safety concerns.

(ii) If the manufacturer or supplier fails, by the specified date, to supply either the data or other information necessary to address the safety concerns regarding the notified use or a request described in paragraph (a)(2)(i) of this section, FDA may determine that the FCN is no longer effective because there is no longer a basis to conclude that the intended use is safe.

(iii) If FDA denies a request described in paragraph (a)(2)(i) of this section, and FDA had previously informed the manufacturer or supplier of FDA's concerns regarding the safety of the intended use of the food contact substance as described in paragraph (a)(1)(i) of this section, FDA may determine that a FCN is no longer effective because there is no longer a basis to conclude that the intended use is safe. Alternatively, FDA may provide the manufacturer or supplier with additional time to provide FDA with data or other information to respond to FDA's safety concerns. If the manufacturer or supplier fails, by the specified date, to supply the data or

other information necessary to address the safety concerns regarding the notified use, FDA may determine that the FCN is no longer effective because there is no longer a basis to conclude that the intended use is safe.

(2) Data or other information available to FDA demonstrate that the manufacturer or supplier specified in the FCN has stopped or intends to stop producing, supplying, or using a food contact substance for the intended use. Such data or other information includes but is not limited to:

(i) A request from the manufacturer or supplier.

(A) The manufacturer or supplier specified in the FCN may request in writing that FDA determine that an FCN is no longer effective on the basis that it has stopped producing, supplying, or using a food contact substance for the intended food contact use in the United States or that it intends to stop producing, supplying, or using a food contact substance for the intended food contact use in the United States by a specified date. FDA will notify the manufacturer or supplier whether FDA is granting the request.

(B) If FDA grants the request, FDA may determine that the FCN is no longer effective on the basis that the manufacturer or supplier has stopped producing, supplying, or using a food contact substance for the intended use in the United States or that it intends to stop producing, supplying, or using a food contact substance for the intended food contact use in the United States by a specified date. When such a request is based on the intent to stop producing, supplying, or using a food contact substance for the intended food contact use in the United States at a future date, FDA will include in the notice described in paragraph (b) of this section the date specified in the request as the compliance date by which the manufacturer or supplier will stop producing, supplying, or using the food contact substance for the intended food contact use in the United States.

(ii) Other data or information available to FDA.

(A) If other data or information available to FDA demonstrate that a food contact substance is no longer produced, supplied, or used for an intended food contact use in the United States, FDA will inform the affected manufacturer or supplier specified in the FCN, in writing. FDA will include a specified time period by which the manufacturer or supplier must provide FDA with data or other information that demonstrate that the manufacturer or supplier continues to produce, supply, or use a food contact substance for the intended use in the United States.

(B) If the manufacturer or supplier fails, by the specified date, to provide data or other information that demonstrate that the manufacturer or supplier continues to produce, supply, or use a food contact substance for the intended use in the United States; or if the manufacturer or supplier confirms that it has stopped producing, supplying, or using the food contact substance for the intended food contact use in the United States, FDA may determine that the FCN is no longer effective.

(3) The intended use of the food contact substance identified in the FCN is authorized by a food additive regulation.

(i) FDA will inform the manufacturer or supplier specified in the FCN in writing that the intended use of the food contact substance identified in the FCN is authorized by a food additive regulation. FDA will include a specified time period by which the manufacturer or supplier must respond to FDA with data or other information about whether the intended use of the food contact substance is authorized by a food additive regulation.

(ii) If a manufacturer or supplier fails, by the specified date, to supply data or other information that demonstrate that the intended use of the food contact substance identified in the FCN is not authorized by a food additive regulation, FDA may determine that the FCN is no longer effective on the basis that the intended use of the food contact substance is authorized under a food additive regulation.

(4) The intended use of the food contact substance identified in the FCN is covered by a threshold of regulation exemption.

(i) FDA will inform the manufacturer or supplier specified in the authorizing FCN in writing that the intended use of the food contact substance identified in the FCN is covered by a threshold of regulation exemption. FDA will include a specified time period by which the manufacturer or supplier must respond to FDA with data or other information about whether the intended use of the food contact substance is covered by a threshold of regulation exemption.

(ii) If a manufacturer or supplier fails, by the specified date, to supply data or other information that demonstrate that the intended use of the food contact substance identified in the FCN is not covered by a threshold of regulation exemption, FDA may determine that the FCN is no longer effective on the basis that the intended use of the food contact substance is covered under a threshold of regulation exemption.

(b) If FDA determines that an FCN is no longer effective, FDA will publish a notice of its determination in the **Federal Register** stating that a detailed summary of the basis for FDA's determination that the FCN is no longer effective has been placed on public display and that copies are available upon request. If FDA determines it would be protective of public health, FDA may include a separate compliance date for the use of the food contact substance in food contact articles, including food contact substances that were produced, supplied, or used by the manufacturer or supplier before publication of the notice in the **Federal Register** or before the compliance date described in paragraph (a)(2)(i)(B) of this section. The date that the notice publishes in the **Federal Register** is the date on which the notification is no longer effective. FDA's determination that an FCN is no longer effective is final agency action subject to judicial review.

(c) FDA's determination that an FCN is no longer effective does not preclude any manufacturer or supplier from submitting a new FCN for the same food contact substance, including for the same intended use, after FDA has determined that an FCN is no longer effective, unless the intended use of the food contact substance is authorized by a food additive regulation or covered by a threshold of regulation exemption. The new submission must be made under §§ 170.100 and 170.101.

Dated: January 20, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2022–01527 Filed 1–25–22; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2021–0932; FRL–9461–01–R7]

Air Plan Approval; Iowa; Determination of Attainment by the Attainment Date for the 2010 1-Hour Sulfur Dioxide Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to determine that the Muscatine sulfur dioxide (SO_2) nonattainment area attained the 2010 1-