scheduled to become available on January 23, 2016. The Commission believes that establishing an effective date less than 30 days after publication of these rules is necessary to coordinate the effectiveness of the updated Filer Manual with these system upgrades.

Statutory Basis

We are adopting the amendments to Regulation S–T under Sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933, Sections 3, 12, 13, 14, 15, 23, and 35A of the Securities Exchange Act of 1934, Section 319 of the Trust Indenture Act of 1939, and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.

List of Subjects in 17 CFR Part 232

* * * * *

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendment

In accordance with the foregoing, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

1. The authority citation for Part 232 continues to read in part as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78l, 78m, 78n, 78o(d), 78w(a), 78ll, 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, and 7201 et seq.; and 18 U.S.C. 1350.

2. Section 232.301 is revised to read as follows:


Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets out the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the updated EDGAR Filer Manual, Volume I: “General Information,” Version 24 (December 2015). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: “EDGAR Filing,” Version 35 (December 2015). Additional provisions applicable to Form N–SAR filers are set forth in the EDGAR Filer Manual, Volume III: “N–SAR Supplement.” Version 5 (September 2015). All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. The EDGAR Filer Manual is available for Web site viewing and printing; the address for the Filer Manual is http://www.sec.gov/info/edgar.shtml. You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. You can also inspect the document at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Dated: December 11, 2015.

By the Commission.

Brent J. Fields,
Secretary.

[FR Doc. 2015–32985 Filed 12–31–15; 8:45 am]
BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. FDA–2015–F–0714]

Indirect Food Additives: Paper and Paperboard Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the food additive regulations to no longer provide for the use of three specific perfluoroalkyl ethyl containing food-contact substances (FCSs) as oil and water repellants for paper and paperboard for use in contact with aqueous and fatty foods because new data are available as to the toxicity of substances structurally similar to these compounds that demonstrate there is no longer a reasonable certainty of no harm from the food-contact use of these FCSs. This action is in response to a petition filed by the Natural Resources Defense Council, the Center for Food Safety, the Breast Cancer Fund, the Center for Environmental Health, Clean Water Action, the Center for Science in the Public Interest, Children’s Environmental Health Network, Environmental Working Group, and Improving Kids’ Environment.

DATES: This rule is effective January 4, 2016. Submit either electronic or written objections and requests for a hearing by February 3, 2016. See section VIII for further information on the filing of objections.

ADDRESSES: You may submit objections and requests for a hearing as follows:

Electronic Submissions

Submit electronic objections in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection 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 objection, that information will be posted on http://www.regulations.gov.

• If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions in the following way:

• Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper objections submitted to the Division of Dockets Management, FDA will post your objection, 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–
I. Background

In a notice published in the Federal Register on March 16, 2015 (80 FR 13508), we announced that we filed a food additive petition (FAP 4B4809) submitted to the National Resources Defense Council, 1152 15th St. NW., Suite 300, Washington, DC 20005; the Center for Food Safety, 303 Sacramento St., Second Floor, San Francisco, CA 94111; Clean Water Action, 1444 Eye St. NW., Suite 400, Washington, DC 20005; the Center for Science in the Public Interest, 1220 L St. NW., Suite 300, Washington, DC 20005; Children’s Environmental Health Network, 110 Maryland Ave. NE., Suite 404, Washington, DC 20002; the Breast Cancer Fund, 1388 Sutter St., Suite 400, San Francisco, CA 94109–5400; the Center for Environmental Health, 2201 Broadway, Suite 302, Oakland, CA 94612; Environmental Working Group, 1436 U St. NW., Suite 100, Washington, DC 20009; and Improving Kids’ Environment, 1915 West 18th St., Indianapolis, IN 46202.

The petition proposed to amend § 176.170 (21 CFR 176.170) to no longer provide for the use of three perfluoroalkyl ethyl containing FCSs as oil and water repellants for paper and aimer for use in contact with aqueous and fatty foods. The three FCSs which are the subjects of this petition are as follows:

1. Diethanolamine salts of mono- and bis (1H,1H,2H,2H perfluoroalkyl) phosphates where the alkyl group is even-numbered in the range C8–C18 and the salts have a fluorine content of 52.4 percent to 54.4 percent as determined on a solids basis;
2. Pentaconic acid, 4,4-bis [(omega-0-omega-perfluoro-C4-20-alkyl)(thio)] derivatives, compounds with diethanolamine (CAS Reg. No. 71608-61-2); and
3. Perfluoroalkyl substituted phosphate ester acids, ammonium salts formed by the reaction of 2,2-bis[(omega-0-omega-perfluoro-C4-20-alkyl)(thio)] methyl-1,3-propanediol, polynphosphoric acid and ammonium hydroxide.

II. Evaluation of Safety

The three subject FCSs are regulated as food additives under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Section 409 of the FD&C Act (21 U.S.C. 348) sets forth the statutory requirements for food additives. Section 201(s) of the FD&C Act (21 U.S.C. 321(s)) includes substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food among the substances defined as food additives, provided the intended use results or is only expected to result in it becoming a component of food and those uses were not sanctioned prior to 1958 or are not generally recognized as safe among experts qualified by scientific training and experience to evaluate its safety.

Under section 402(a)(2)(c)(1) of the FD&C Act (21 U.S.C. 342(a)(2)(c)(1)), food shall be deemed to be adulterated if it or if it bears or contains any food additive that is unsafe within the meaning of section 409 of the FD&C Act. A food additive shall be deemed to be unsafe under section 409 of the FD&C Act, in relevant part, unless its use conforms to a food additive regulation or an effective food contact notification.

Section 409(i) of the FD&C Act states that the procedure for amending or repealing a regulation shall conform to the procedure for the promulgation of such regulations. FDA’s regulations specific to the administrative actions for food additives provide that the Commissioner, either on his own initiative or on the petition of any interested person, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive (§ 171.150(a) (21 CFR 171.150(a))). These regulations further provide that any such petition must include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data must be furnished in the form specified in § 171.130(a) (21 CFR 171.130(a)) and 21 CFR 171.100 for submitting petitions (see § 171.130(b)). Under these regulations, a petitioner may propose that we amend a food additive regulation if the petitioner can demonstrate that new data are available as to the toxicity of the food additive that may justify amendment of the food additive regulation.

Under section 409(c)(3) of the FD&C Act we will not establish a regulation for the use of a food additive if a fair evaluation of the data fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe. Our regulations, at 21 CFR 170.3(h)(i), define safety as “a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.” In order for FDA to grant a petition that seeks an amendment to a food additive regulation based upon new data concerning the toxicity of a food additive, such data must be adequate for FDA to conclude that there is no longer


SUPPLEMENTARY INFORMATION:
a reasonable certainty of no harm for the intended use of the substance.

The petition asserts that publically available information on long-chain perfluorinated compounds as a chemical class, which has become available after the food contact use of the three FCSs was approved, demonstrates that there is no longer a reasonable certainty of no harm from the food contact use of the three FCSs as listed in § 176.170.

All three of the FCSs subject to the petition contain extended alkyl chains where all of the hydrogens are replaced by fluorine (hence the FCSs are “perfluorinated”). The toxicological profile of extended perfluorinated alkyl chains varies with chain length: On a general basis, those with extended perfluorinated alkyl chains greater than or equal to eight carbons in length demonstrate biopersistence in chronic feeding studies, while those with extended perfluorinated alkyl chains less than eight carbons in length do not (Ref. 1). Biopersistence is defined as persistence and accumulation of a material in a biological tissue due to preferential deposition of the material in the tissue combined with resistance of the material to removal from the tissue by natural clearance mechanisms (Ref. 2). As such, compounds containing extended perfluorinated alkyl chains are often classified as long- (i.e., ≥ eight carbons in length) or short-chain perfluorinated compounds, with implications for toxicology analysis including consideration of biopersistence. All three of the FCSs contain extended perfluorinated alkyl chains ≥ eight carbons in length and as such are long-chain perfluorinated compounds (PFCs).

The petition cites a 2010 FDA comprehensive review memorandum on the available literature for long-chain PFCs (Ref. 3). This memorandum noted that available data on long-chain perfluorocarboxylic acids and fluorotelomer alcohols, both of which are subsets of long-chain PFCs, demonstrate reproductive and developmental toxicity in animal models. The FDA memorandum determined that, based on structural similarity to long-chain perfluorocarboxylic acids and fluorotelomer alcohols, and in the absence of contradictory data, data demonstrating reproductive and developmental toxicity for long-chain perfluorocarboxylic acids and fluorotelomer alcohols was applicable to long-chain PFCs on a general basis. The petition ascribes to the three subject FCSs long-chain PFCs, the concern for reproductive and developmental toxicity for long-chain PFCs as determined in FDA’s 2010 comprehensive review memorandum is applicable to these three FCSs. The petition also provides the results of an updated comprehensive literature search, which the petition asserts reinforces the concern for reproductive and developmental toxicity for long-chain PFCs. The petition also asserts that the updated literature search did not discover any information which would contradict FDA’s 2010 determination that data demonstrating reproductive and developmental toxicity for long-chain perfluorocarboxylic acids and fluorotelomer alcohols was applicable to long-chain PFCs on a general basis (Ref. 4). FDA’s updated review noted that there are no available toxicological studies conducted with the three FCSs that address the endpoints of reproductive or developmental toxicity. As all three FCSs are long-chain PFCs, and in the absence of data specific to the three FCSs to address these endpoints, FDA utilized the available data demonstrating reproductive and developmental toxicity for long-chain perfluorocarboxylic acids and fluorotelomer alcohols to assess the safety of the approved food-contact use of the FCSs. FDA’s updated review noted deficiencies in the available information used to determine migration of the FCSs into food as a result of their approved food-contact use (Ref. 5). For this reason FDA was unable to calculate consumer exposure to the FCSs in a manner which would allow a quantitative assessment of the safety of that exposure in the context of the available data demonstrating reproductive and developmental toxicity for long-chain perfluorocarboxylic acids and fluorotelomer alcohols. However, FDA’s review noted that available data demonstrate that long-chain perfluorocarboxylic acids and fluorotelomer alcohols biopersist in animals and that this biopersistence also occurs in humans (Ref. 4). Although available migration information does not allow a quantitative assessment of the safety of exposure to these FCSs, the reproductive and developmental toxicity of the three FCSs can be qualitatively assessed in the context of biopersistence and the expectation that chronic dietary exposure to these FCSs would result in a systemic exposure to the FCSs or their metabolic by-products at levels higher than their daily dietary exposure (Ref. 4).

III. Comments on the Filing Notice

We received very few comments on the petition. These comments stated that the use of the three FCSs as listed in § 176.170 has been abandoned. The basis for the action requested in the petition is that new data are available as to the toxicity of substances structurally similar to the subject FCSs that justify amending § 176.170. The petition is not based on abandonment of the approved food contact use of these three FCSs. We have made a determination that the information provided in the petition and other publicly available relevant data demonstrates that there is no longer a reasonable certainty of no harm for the food contact use of the three FCS.

IV. Conclusion

We reviewed the data and information in the petition and other available relevant material to evaluate whether new data are available as to the toxicity of the subject FCSs that justify amendment of § 176.170. As a result of this review, we concluded that data for subsets of long-chain PFCs (demonstrating biopersistence and reproductive and developmental toxicity) are applicable to long-chain PFCs on a general basis and that this data raises significant questions as to the safety of the authorized uses of the three FCSs subject to the petition (Ref. 4). We also concluded that there is a lack of data specific to the three subject FCSs subject to the petition to address these questions (Ref. 4). For these reasons, in the absence of data specific to the three FCSs to address reproductive and developmental toxicity, adequate migration data to determine dietary exposure to the FCSs from the food-contact use, and sufficient data to account for a consumer’s systemic exposure resulting from chronic dietary exposure to these FCSs, we conclude that there is no longer a reasonable certainty of no harm for the food contact use of these FCSs. Therefore, we are amending part 176 as set forth in this document. Upon the effective date (see DATES), these food additive uses are no longer authorized.

V. Public Disclosure

In accordance with § 171.1(h), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will
be made available for public disclosure (see FOR FURTHER INFORMATION CONTACT). As provided in § 171.1(b), we will delete from the documents any materials that are not available for public disclosure.

VI. Environmental Impact

We have considered the environmental effects of this rule. As stated in the March 16, 2015, Federal Register notice of petition for FAP 4B4809 (80 FR 13508), we have determined, under 21 CFR 25.15(c), that this action “is of a type that does not individually or cumulatively have a significant effect on the human environment” such that neither an environmental assessment nor an environmental impact statement is required, as set forth in 21 CFR 25.32(m). We have not received any new information or comments that would affect our previous determination.

VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Objections

If you will be adversely affected by one or more provisions of this regulation, you may file with the Division of Dockets Management (see ADDRESSES) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify, with particularity, the provision(s) to which you object and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on that particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov. We will publish notice of the objections that we have received or lack thereof in the Federal Register.

IX. References

The following references have been placed on display in the Division of Dockets Management (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 http://www.regulations.gov. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

3. FDA Memorandum from P. Rice to P. Honigfort, September 30, 2010.
4. FDA Memorandum from P. Rice to P. Honigfort, July 27, 2015.
5. FDA Memorandum from J. Cooper to P. Honigfort, July 23, 2015.

List of Subjects in 21 CFR Part 176

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and re-delegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

§ 176.170 [Amended]

1. Amend § 176.170 in the table in paragraph (a)(5) by removing the entries for “Diethanolamine salts of mono- and bis,” “Pentanoic acid,” and “Perfluoroalkyl substituted phosphate ester acids.”

Dated: December 29, 2015.

Susan Bernard,
Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy (DoN) is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972, as amended (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (DAJAG)(Admiralty and Maritime Law) has determined that USS ZUMWALT (DDG 1000) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

DATES: This rule is effective January 4, 2016 and is applicable beginning November 16, 2015.


This amendment provides notice that the DAJAG (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that USS ZUMWALT (DDG 1000) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with its special function as a naval ship: Annex I paragraph 2(a)(i), pertaining to the location of the forward masthead light at a height not less than 6 meters above the hull; Annex I, paragraph 2(g) pertaining to the placement of sidelights above the hull of the vessel; Annex I, paragraph 2(i)(iii), pertaining to the equally spaced vertical separation of three task lights; and Annex I, paragraph 2(k) as described in Rule 30(a)(i), pertaining to the vertical separation between anchor lights, and the location of the forward anchor light at a height of not less than 6 meters above the hull; Annex I, paragraph 3(a), pertaining to the location of the forward