

(i) Bombardier Service Bulletin 600-0770, including Appendix A, both Revision 01, both dated March 31, 2016.

(ii) Bombardier Service Bulletin 601-0643, including Appendix A, both Revision 01, both dated March 31, 2016.

(iii) Bombardier Service Bulletin 604-27-037, including Appendix A, Revision 01, both dated March 31, 2016.

(iv) Bombardier Service Bulletin 605-27-008, including Appendix A, Revision 01, both dated March 31, 2016.

(v) Bombardier Service Bulletin 650-27-002, dated June 30, 2016, including Appendix A, Revision 01, dated March 31, 2016.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone 1-866-538-1247 or direct-dial telephone 1-514-855-2999; fax 514-855-7401; email [ac.yul@aero.bombardier.com](mailto:ac.yul@aero.bombardier.com); internet <http://www.bombardier.com>.

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195.

(5) You may view this service information that is incorporated by reference 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/cfr/ibr-locations.html>.

Issued in Des Moines, Washington, on April 27, 2018.

**Michael Kaszycki,**

*Acting Director, System Oversight Division, Aircraft Certification Service.*

[FR Doc. 2018-09732 Filed 5-18-18; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2017-0874; Product Identifier 2015-SW-082-AD; Amendment 39-19282; AD 2018-10-07]

RIN 2120-AA64

#### Airworthiness Directives; Sikorsky Aircraft Corporation

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for Sikorsky Aircraft Corporation (Sikorsky) Model S-76C helicopters. This AD requires inspecting the engine collective position transducer (CPT). This AD was prompted by reports of wear of the CPT that has resulted in several One Engine

Inoperative (OEI) incidents. The actions of this AD are intended to detect and prevent an unsafe condition on these products.

**DATES:** This AD is effective June 25, 2018.

The Director of the Federal Register approved the incorporation by reference of certain documents listed in this AD as of June 25, 2018.

**ADDRESSES:** For service information identified in this final rule, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1-800-Winged-S or 203-416-4299; email [wcs\\_cust\\_service\\_eng.gr-sik@lmco.com](mailto:wcs_cust_service_eng.gr-sik@lmco.com). You may review a copy of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N-321, Fort Worth, TX 76177. It is also available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0874.

#### Examining the AD Docket

You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0874; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, any incorporated-by-reference service information, the economic evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800-647-5527) is U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:** Nick Rediess, Aviation Safety Engineer, Boston ACO Branch, Compliance & Airworthiness Division, 1200 District Avenue, Burlington, MA 01803; telephone (781) 238-7159; email [nicholas.rediess@faa.gov](mailto:nicholas.rediess@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Discussion

On September 14, 2017, at 82 FR 43195, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 by adding an AD that would apply to Sikorsky Model S-76C helicopters with a Turbomeca, S.A., Arriel 2S1 or Arriel 2S2 engine with an engine CPT part number (P/N) 76900-01821-104 installed. The NPRM was prompted by 20 reports of OEI incidents resulting from wear of a CPT. One of

these incidents resulted in a rejected takeoff to an unprepared site.

The NPRM proposed to require initial and recurring inspections of each CPT by measuring resistance, linearity resistance movement, and differential voltage, and depending on the outcome of the inspections, replacing the CPT. The proposed requirements were intended to detect wear of a CPT prior to it causing an OEI condition and possible emergency landing.

#### Comments

After our NPRM was published, we received comments from Sikorsky.

#### Request To Include an Additional Part to the AD

Sikorsky requested the AD also apply to engine CPT P/N 76900-01821-105. In support of this request, Sikorsky stated that engine CPT P/N 76900-01821-105 is a new replacement for engine CPT P/N 76900-01821-104, which does not differ substantially from engine CPT P/N 76900-01821-104 and therefore should be subject to the periodic inspections.

We partially agree. While engine CPT P/N 76900-01821-105 may be subject to the same unsafe condition because of design similarity, adding this part would increase the scope of the AD. Therefore, we plan to publish another NPRM for P/N 76900-01821-105 to give the public an opportunity to comment on those requirements.

#### Request To Remove a Test Box From the AD

Sikorsky requested we remove Test Box P/N 76700-40009-042 and only allow the use of Test Box P/N 76700-40009-043 to comply with the AD. In support of this request, Sikorsky stated it considers Test Box P/N 76700-40009-042 obsolete because Test Box P/N 76700-40009-043 is easier to use and provides less subjective results.

We disagree. The proposed AD provided procedures for both test boxes for the repetitive inspections. While Test Box P/N 76700-40009-043 may be more efficient, the use of Test Box P/N 76700-40009-042 also addresses the unsafe condition. We do not find justification for requiring operators who have Test Box P/N 76700-40009-042 to upgrade or replace their test box. However, we have revised the initial inspection requirements of the AD to allow the use of Test Box P/N 76700-40009-043 as an option. We have also revised the repetitive inspection procedures to allow the use of updated testing procedures for Test Box P/N 76700-40009-043, which had not been

issued at the time we published the proposed AD, as an option.

Lastly, Sikorsky requested we revise the unsafe condition to more accurately describe that it would be a momentary OEI condition. In support, Sikorsky stated that the unsafe condition statement in the proposed AD could be misinterpreted as an in-flight shutdown or engine failure. For this particular CPT failure, Sikorsky stated normal engine operation is restored within approximately two seconds without the need for any specific action by the pilot.

We agree and have made the requested change accordingly.

#### FAA's Determination

We have reviewed the relevant information, considered the comments received, and determined that an unsafe condition exists and is likely to exist or develop on other products of the same type design and that air safety and the public interest require adopting the AD requirements as proposed with the changes described previously and minor editorial changes. These changes are consistent with the intent of the proposals in the NPRM and will not increase the economic burden on any operator nor increase the scope of the AD.

#### Interim Action

We consider this AD to be an interim action. The design approval holder is currently developing a modification that will address the unsafe condition identified in this AD. Once this modification is developed, approved, and available, we might consider additional rulemaking.

#### Related Service Information Under 1 CFR Part 51

We reviewed Sikorsky S-76 Helicopter Alert Service Bulletin (ASB) 76-73-8, Revision A, dated December 4, 2015 (ASB 76-73-8A), which specifies a one-time inspection of total resistance, linearity resistant movement, excitation voltage, and differential voltage of the CPTs using CPT Text Box P/N 76700-40009-042.

We reviewed Sikorsky Maintenance Manual, SA 4047-76C-2, Temporary Revision No. 73-07, dated August 17, 2016 (TR 73-07), which specifies procedures for removing, installing, and adjusting the CPTs, and inspections of total resistance, linearity resistant movement, excitation voltage, and differential voltage of the CPTs. TR 73-07 also divides the procedures by CPT Test Box P/N by providing separate procedures for test boxes modified by Sikorsky Special Service Instructions (SSI) No. 76-96, dated August 19, 2016,

which is not incorporated by reference in this AD.

We also reviewed Sikorsky Maintenance Manual, SA 4047-76C-2, Temporary Revision No. 73-08, dated September 20, 2017 (TR 73-08), which updates the procedures in TR 73-07. TR 73-08 does not divide the procedures by CPT Test Box P/N as it eliminates the procedures for CPT Text Box P/N 76700-40009-042. TR 73-08 omits obsolete figures and it provides inspection results as pass or fail.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

#### Other Related Service Information

We reviewed Sikorsky S-76 Helicopter ASB 76-73-8, Basic Issue, dated August 21, 2015 (ASB 76-73-8). ASB 76-73-8 contains the same procedures as ASB 76-73-8A; however, ASB 76-73-8A updates Sikorsky's contact information for submitting a purchase order.

We also reviewed Sikorsky SA 4047-76C-2-1, Temporary Revision No. 5-181, dated August 21, 2015 (TR 5-181); Task 5-20-00 of Sikorsky Airworthiness Limitations and Inspection Requirements, Publication No. SA 4047-76C-2-1, Revision 24, dated December 15, 2015 (Task 5-20-00); and Section 73-22-04 of Chapter 73 Engine Fuel and Control, of Sikorsky Maintenance Manual, SA 4047-76C-2, Revision 31, dated December 15, 2015 (Section 73-22-04). TR 5-181 specifies adding CPT inspections referenced in Section 73-22-04 to the 300-hour inspection checklist contained in Task 5-20-00.

We reviewed Sikorsky Safety Advisory No. SSA-S76-11-0002, dated May 17, 2011. This service information provides precautionary instructions to minimize hazardous situations that might result from an unreliable CPT.

We also reviewed Sikorsky SSI No. 76-96, dated August 19, 2016, which specifies procedures to modify CPT Test Box P/N 76700-40009-042 and re-identify it as P/N 76700-40009-043. This one-time modification reduces the instructions to inspect the CPT and improves the inspection accuracy.

We reviewed Sikorsky SSI No. 76-87, dated July 24, 2015, and SSI No. 76-87A, Revision A, dated August 21, 2015. These SSIs specify a one-time inspection of total resistance, linearity resistant movement, excitation voltage, and differential voltage of the CPTs using CPT Text Box P/N 76700-40009-042.

#### Differences Between This AD and the Service Information

Sikorsky ASB 76-73-8A, TR 73-07, and TR 73-08 specify using and returning Sikorsky's CPT data sheet and any failed CPT to Sikorsky. This AD does not.

#### Costs of Compliance

We estimate that this AD affects 90 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD. Labor costs are estimated at \$85 per work-hour.

The inspections will take about 3.75 work-hours for an estimated cost of \$319 per helicopter and \$28,710 for the U.S. fleet per inspection cycle. Replacing a CPT will take about 6 work-hours and parts will cost \$3,072 for an estimated replacement cost of \$3,582.

#### Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

#### Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866;
- (2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
- (3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

#### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

#### Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

### PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

#### § 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

**2018–10–07 Sikorsky Aircraft Corporation:**  
Amendment 39–19282; Docket No. FAA–2017–0874; Product Identifier 2015–SW–082–AD.

#### (a) Applicability

This AD applies to Sikorsky Aircraft Corporation Model S–76C helicopters, certificated in any category, with a Turbomeca, S.A., Arriel 2S1 or Arriel 2S2 engine with an engine collective position transducer (CPT) part number 76900–01821–104 installed.

#### (b) Unsafe Condition

This AD defines the unsafe condition as failure of a CPT. This condition could result in a reduction in power to one engine resulting in an annunciated momentary One Engine Inoperative (OEI) condition and subsequent emergency landing.

#### (c) Effective Date

This AD becomes effective June 25, 2018.

#### (d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

#### (e) Required Actions

(1) Within 130 hours time-in-service (TIS):

(i) Measure resistance of each engine CPT and replace the CPT if the measured resistance is not within tolerance by following the Accomplishment Instructions, paragraphs 3.C.(1) through 3.C.(8)(b), of Sikorsky S–76 Helicopter Alert Service Bulletin ASB 76–73–8, Revision A, dated December 4, 2015 (ASB 76–73–8A), if using Test Box P/N 76700–40009–042 or by

following paragraph 3.B.(11) of Sikorsky Maintenance Manual, SA 4047–76C–2, Temporary Revision No. 73–08, dated September 20, 2017 (TR 73–08), if using Test Box P/N 76700–40009–043. You are not required to use Sikorsky's CPT data sheet or submit a data sheet to Sikorsky.

(ii) Measure the linearity resistance movement of each engine CPT and replace the CPT if there is a linear abnormality or change in resistance that is not within tolerance by following the Accomplishment Instructions, paragraphs 3.D.(1) through 3.D.(14)(b), of ASB 76–73–8A, if using Test Box P/N 76700–40009–042 or by following paragraph 3.B.(12) of TR 73–08, if using Test Box P/N 76700–40009–043. You are not required to use Sikorsky's CPT data sheet or submit a data sheet to Sikorsky.

(iii) Measure the differential voltage of each engine CPT and replace the CPT if the measured voltage is not within tolerance by following the Accomplishment Instructions, paragraphs 3.E. through 3.G.(1) of ASB 76–73–8A, if using Test Box P/N 76700–40009–042 or by following paragraph 3.B.(13) of TR 73–08, if using Test Box P/N 76700–40009–043. You are not required to use Sikorsky's CPT data sheet or submit a data sheet to Sikorsky.

(2) Thereafter, at intervals not to exceed 300 hours TIS:

(i) If using Test Box P/N 76700–40009–042:  
(A) Measure resistance of each engine CPT and replace the CPT if the resistance is not within tolerance by following paragraph 4.B.(11) of Sikorsky Maintenance Manual, SA 4047–76C–2, Temporary Revision No. 73–07, dated August 17, 2016 (TR 73–07), except you are not required to use Sikorsky's CPT data sheet or return a failed CPT to Sikorsky.

(B) Measure the linearity resistance movement of each engine CPT and replace the CPT if the movement exceeds tolerance by following paragraphs 4.B.(12)(a) through 4.B.(13)(f) of TR 73–07, except you are not required to use Sikorsky's CPT data sheet or return a failed CPT to Sikorsky.

(C) Measure the differential voltage of each CPT by following paragraphs 4.B.(14) through 4.B.(15)(h) of TR 73–07, except you are not required to use Sikorsky's CPT data sheet. If the maximum voltage is greater than 100 millivolts or the minimum voltage is less than –100 millivolts, replace the CPT.

(ii) For helicopters using Test Box P/N 76700–40009–043:

(A) Measure resistance of each engine CPT and replace the CPT if the resistance is not within tolerance by following paragraph 5.B.(11) of TR 73–07 or paragraph 3.B.(11) of TR 73–08, except you are not required to use Sikorsky's CPT data sheet or return a failed CPT to Sikorsky.

(B) Measure the resistance linearity of each engine CPT and replace the CPT if the resistance is not within tolerance by following paragraph 5.B.(12) of TR 73–07 or paragraph 3.B.(12) of TR 73–08, except you are not required to use Sikorsky's CPT data sheet or return a failed CPT to Sikorsky.

(C) Measure the differential voltage of each engine CPT and replace the CPT if the resistance is not within tolerance by following paragraphs 5.B.(13)(a) through 5.B.(13)(k) of TR 73–07 or paragraph 3.B.(13)

of TR 73–08, except you are not required to use Sikorsky's CPT data sheet or return a failed CPT to Sikorsky.

#### (f) Credit for Previous Actions

Actions accomplished before the effective date of this AD in accordance with the procedures specified in Sikorsky S–76 Helicopter Alert Service Bulletin ASB 76–73–8, Basic Issue, dated August 21, 2015; Sikorsky Special Service Instruction SSI No. 76–87, dated July 24, 2015; or Sikorsky Special Service Instruction SSI No. 76–87, Revision A, dated August 21, 2015, are considered acceptable for compliance with the corresponding actions specified in paragraph (e)(1) of this AD.

#### (g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston ACO Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Nick Rediess, Aviation Safety Engineer, Boston ACO Branch, Compliance & Airworthiness Division, 1200 District Avenue, Burlington, MA 01803; telephone (781) 238–7159; email [nicholas.rediess@faa.gov](mailto:nicholas.rediess@faa.gov).

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

#### (h) Additional Information

Sikorsky S–76 Helicopter Alert Service Bulletin ASB 76–73–8, Basic Issue, dated August 21, 2015; Sikorsky SA 4047–76C–2–1, Temporary Revision No. 5–181, dated August 21, 2015; Task 5–20–00 of Sikorsky Airworthiness Limitations and Inspection Requirements, Publication No. SA 4047–76C–2–1, Revision 24, dated December 15, 2015; Section 73–22–04 of Chapter 73 Engine Fuel and Control, of Sikorsky Maintenance Manual, SA 4047–76C–2, Revision 31, dated December 15, 2015; Sikorsky Safety Advisory No. SSA–S76–11–0002, dated May 17, 2011; Sikorsky Special Service Instruction (SSI) No. 76–96, dated August 19, 2016; Sikorsky SSI No. 76–87, dated July 24, 2015; and Sikorsky SSI No. 76–87, Revision A, dated August 21, 2015, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–Winged-S or 203–416–4299; email [wcs\\_cust\\_service\\_eng\\_gr-sik@lmco.com](mailto:wcs_cust_service_eng_gr-sik@lmco.com). You may review a copy of this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

#### (i) Subject

Joint Aircraft Service Component (JASC) Code: 7600, Engine Controls.

#### (j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of

the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Sikorsky S-76 Helicopter Alert Service Bulletin ASB 76-73-8, Revision A, dated December 4, 2015.

(ii) Sikorsky Maintenance Manual, SA 4047-76C-2, Temporary Revision No. 73-07, dated August 17, 2016.

(iii) Sikorsky Maintenance Manual, SA 4047-76C-2, Temporary Revision No. 73-08, dated September 20, 2017.

(3) For Sikorsky service information identified in this AD, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1-800-Winged-S or 203-416-4299; email [wcs\\_cust\\_service\\_eng\\_grsik@lmco.com](mailto:wcs_cust_service_eng_grsik@lmco.com).

(4) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110.

(5) You may view this service information that is incorporated by reference 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/cfr/ibr-locations.html>.

Issued in Fort Worth, Texas, on May 9, 2018.

**Lance T. Gant,**

*Director, Compliance & Airworthiness Division, Aircraft Certification Service.*

[FR Doc. 2018-10581 Filed 5-18-18; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 172

[Docket No. FDA-2013-N-1317]

#### Final Determination Regarding Partially Hydrogenated Oils

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification; declaratory order; extension of compliance date.

**SUMMARY:** Based on the available scientific evidence and the findings of expert scientific panels, the Food and Drug Administration (FDA or we) made a final determination that there is no longer a consensus among qualified experts that partially hydrogenated oils (PHOs), which are the primary dietary source of industrially produced *trans* fatty acids (IP-TFA), are generally recognized as safe (GRAS) for any use in

human food. In a declaratory order announcing our final determination, we set a compliance date of June 18, 2018. We are now extending the compliance date for certain uses of PHOs.

**DATES:** *Compliance dates:* See sections II and III of this document.

**FOR FURTHER INFORMATION CONTACT:** Ellen Anderson, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1309, email: [ellen.anderson@fda.hhs.gov](mailto:ellen.anderson@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of June 17, 2015 (80 FR 34650), we issued a final determination that there is no longer a consensus among qualified experts that PHOs are GRAS for any use in human food. Because PHOs are the primary dietary source of IP-TFA, FDA's evaluation of the GRAS status of PHOs centered on the *trans* fatty acid component of these fats and oils. We based our determination on available scientific evidence and the findings of expert scientific panels establishing the health risks associated with the consumption of *trans* fat. FDA's determination identified significant human health risks, namely an increased risk of coronary heart disease, associated with the consumption of *trans* fat (78 FR 67169 at 67172; 80 FR 34650 at 34659).

The order established a 3-year compliance date, to June 18, 2018, to allow time for food manufacturers using PHOs to identify suitable replacement ingredients for PHOs and to reformulate and modify labeling of affected products. The 3-year compliance date was also intended to allow time for submission and review and, if applicable requirements were met, approval of food additive petitions for uses of PHOs for which industry or other interested individuals believe that safe conditions of use may be prescribed. Finally, this compliance date was also intended to give manufacturers time to exhaust existing inventories and give distributors and retailers time to distribute products with PHOs (80 FR 34650 at 34669). We based the compliance date on the information available, including comments on the proposed order (80 FR 34650 at 34668 to 34669).

In the 2015 final order, we stated that food that is adulterated may be subject to seizure and distributors, manufacturers, and other parties responsible for such food may be subject to injunction. We also reminded

distributors and other members of the food industry that they have an obligation to ensure that the food they manufacture, distribute, sell, or otherwise market complies with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (80 FR 34650 at 34655).

In the **Federal Register** of October 28, 2015 (80 FR 65978), we published a document announcing that we had filed a food additive petition submitted by the Grocery Manufacturers Association (GMA) seeking approval for certain uses of PHOs in or on select foods. We initially filed the food additive petition on October 1, 2015. GMA subsequently amended their food additive petition, and it was re-filed on March 7, 2017. The amended food additive petition requested that the food additive regulations be amended to provide for the safe use of PHOs in certain food applications. Elsewhere in this issue of the **Federal Register**, we have published a document announcing our denial of this food additive petition.

For purposes of this document extending the compliance date for certain uses of PHOs, we refer to the specified uses of PHOs in GMA's food additive petition as the "petitioned uses" and all other uses of PHOs not authorized by FDA as "non-petitioned uses." We refer to "manufacturing" in this document as making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. See 21 CFR 1.227.

On March 23, 2018, the Consolidated Appropriations Act, 2018, (Pub. L. 115-141) was enacted into law. Section 738 of the Consolidated Appropriations Act, 2018, provided that no PHOs, as defined in our declaratory order, shall be deemed unsafe within the meaning of section 409(a) of the FD&C Act (21 U.S.C. 348(a)) and no food that is introduced or delivered for introduction into interstate commerce that bears or contains a partially hydrogenated oil shall be deemed adulterated under sections 402(a)(1) or (a)(2)(C)(i) of the FD&C Act (21 U.S.C. 342(a)(1) or (a)(2)(C)(i)) by virtue of bearing or containing a partially hydrogenated oil, until June 18, 2018.

##### II. Extension of the Compliance Date for Certain Uses

We have been informed by a number of trade associations representing many segments of the food industry that they have replaced the PHO uses that are not covered by the food additive petition (the non-petitioned uses) and thus will be able to stop using PHOs by the June 18, 2018, compliance date (Ref. 1). However, the trade associations also