We prepared a regulatory evaluation of the estimated costs to comply with this supplemental NPRM. *See* the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

Under the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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:

CFM International, S.A.: Docket No. FAA–2009–0606; Directorate Identifier 2009–NE–11–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this airworthiness directive (AD) action by May 17, 2010.

Affected ADs

(b) None.

Applicability

(c) This AD applies to CFM International, S.A. models CFM56–3 and –3B turbofan engines with 25 degrees midspan shroud fan blades, part numbers (P/Ns) 9527M99P08, 9527M99P09, 9527M99P10, 9527M99P11, 1285M39P01, or fan blade pairs, P/Ns 335–088–901–0, 335–088–902–0, 335–088–903–0, and 335–088–904–0 installed. These engines are installed on, but not limited to, Boeing 737 series airplanes.

(d) CFM International, S.A. has added to the basic engine model number on the engine nameplate to identify minor variations in engine configuration, installation components, or reduced ratings peculiar to aircraft installation requirements.

(e) Those engines marked on the engine data plate as CFM56–3–B1 are included in this AD as CFM56–3 turbofan engines.

(f) Those engines marked on the engine data plate as CFM56–3B–2 are included in this AD as CFM56–3B turbofan engines.

Unsafe Condition

(g) This AD results from a report of a failed fan blade with severe out-of-limit wear on the underside of the blade platform where it contacts the damper. We are issuing this AD to prevent failure of multiple fan blades, which could result in an uncontained failure of the engine and damage to the airplane.

Compliance

(h) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspection for Wear

(i) Within 900 cycles-in-service after the effective date of this AD, perform an on-wing or in-shop inspection of the fan blade and damper for wear. Use paragraphs 3.A.(1) through 3.A.(5) or paragraphs 3.B.(1) through 3.B.(5) respectively, of the Accomplishment Instructions of CFM International Service Bulletin (SB) No. CFM56–3/3B/3C S/B 72–1067, dated February 15, 2007.

(j) If you find out-of-limit wear on at least one fan blade platform underside, perform the additional inspections and disposition the parts, as specified in paragraphs 3.A.(3) and 3.A.(5) or paragraphs 3.B.(3) and 3.B.(5) respectively, of the Accomplishment Instructions of CFM International SB No. CFM56–3/3B/3C S/B 72–1067, dated February 15, 2007.

(k) Thereafter, within intervals not to exceed 3,000 cycles-since-last inspection, perform an on-wing or in-shop inspection for wear. Use paragraphs 3.A.(1) through 3.A.(5) or paragraphs 3.B.(1) through 3.B.(5) respectively, of the Accomplishment Instructions of CFM International SB No. CFM56–3/3B/3C S/B 72–1067, dated February 15, 2007.

(l) If you find wear on at least one fan blade platform underside, perform additional inspections and disposition the parts, as specified in paragraphs 3.A.(3) and 3.A.(5) or paragraphs 3.B.(3) and 3.B.(5) respectively, of the Accomplishment Instructions of CFM International SB No. CFM56–3/3B/3C S/B 72–1067, dated February 15, 2007.

Installation Prohibition

(m) After the effective date of this AD, don't install any 25 degrees midspan shroud fan blades, P/Ns 9527M99P08, 9527M99P09, 9527M99P10, 9527M99P11, 1285M39P01, or fan blade pairs, P/Ns 335–088–901–0, 335–088–902–0, 335–088–903–0, and 335–088–904–0, unless they have passed an inspection specified in paragraph 3. of the Accomplishment Instructions of CFM International SB No. CFM56–3/3B/3C S/B 72–1067, dated February 15, 2007.

Optional Terminating Action

(n) Replacing the 25 degrees midspan shroud fan blade set with a 37 degrees midspan shroud fan blade set terminates the repetitive inspection requirements specified in paragraph (k) of this AD.

Alternative Methods of Compliance

(o) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Related Information

(p) Contact Antonio Cancelliere, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; *e-mail: antonio.cancelliere@faa.gov;* telephone (781) 238–7751; fax (781) 238–7199, for more information about this AD.

(q) Contact CFM International, S.A., Technical Publication Department, 1 Neumann Way, Cincinnati, OH 45215; telephone (513) 552–2800; fax (513) 552–2816, for a copy of the service information referenced in this AD.

(r) European Aviation Safety Agency AD 2009–0036, dated February 20, 2009, also addresses the subject of this AD.

Issued in Burlington, Massachusetts, on March 19, 2010.

Peter A. White,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2010–7343 Filed 3–31–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 165

[Docket No. FDA 1993–N–0259] (formerly Docket No. 1993N–0085)

Beverages: Bottled Water; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until June 1, 2010 the comment period for the proposed rule, published in the **Federal Register** of August 4, 1993 (58 FR 41612), amending the quality standard for bottled water (currently in 21 CFR 165.110(b)). In the 1993 proposed rule, FDA proposed to revise the bottled water quality standard to establish or modify the allowable levels for 5 inorganic chemicals and 18 synthetic organic chemicals, and to maintain the existing allowable level for the inorganic chemical sulfate. In a final rule published March 26, 1996 (61 FR 13258), FDA maintained the existing allowable level for sulfate and adopted the proposed allowable levels for the 5 inorganic chemicals and 17 of the synthetic organic chemicals, but deferred final action on the proposed allowable level for the chemical di(2-ethylhexyl)phthalate (DEHP). FDA is reopening the comment period on the 1993 proposed rule to seek further comment on finalizing the allowable level for DEHP in the bottled water quality standard.

DATES: Submit written or electronic comments by June 1, 2010.

ADDRESSES: You may submit comments, identified by Docket No. FDA 1993–N–0259, by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

• *FAX:* 301–827–6870.

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

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the "Comments" heading in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://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 Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm.1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lauren Posnick Robin, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1639.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 4, 1993 (58 FR 41612), FDA published a proposal ("the 1993 proposed rule") to revise the bottled water standard of quality regulations in 21 CFR part 103 (now 21 CFR 165.110(b)) to establish or modify the allowable levels in bottled water for 5 inorganic chemicals and 18 synthetic organic chemicals, and to maintain the existing allowable level for the inorganic chemical sulfate. FDA proposed these revisions in response to the publication by the Environmental Protection Agency (EPA) of a final rule (57 FR 31776; July 17, 1992) that established national primary drinking water regulations consisting of maximum contaminant levels (MCLs) for the same 23 chemicals and establishing an MCL for sulfate in public drinking water. In a final rule published March 26, 1996 (61 FR 13258), FDA maintained its existing allowable level for sulfate and adopted the proposed allowable levels for the 5 inorganic chemicals and 17 of the synthetic organic chemicals, but deferred final action on the proposed allowable level of 0.006 milligrams/liter (mg/L) for the chemical di(2-ethylhexyl)phthalate (DEHP). FDA deferred action on DEHP in response to a comment stating that the proposed allowable level conflicted with an existing prior sanction for this substance in § 181.27 (21 CFR 181.27). The comment stated that DEHP is prior sanctioned in § 181.27 for use as a plasticizer when migrating from food-packaging material into foods with high water content and, as such, is approved for use in contact with food in § 177.1210 (21 CFR 177.1210) *Closures with sealing gaskets for food containers*. The comment also stated that DEHP is routinely used as a plasticizer in gaskets used in metal and plastic closures for the packaging of bottled water in accord with this approval, and that such use may result in levels of this chemical migrating into water that exceed the proposed allowable level. Thus, the comment maintained that finalizing the proposed allowable level for DEHP would result in a limit on the level of this chemical in bottled water that conflicts with this chemical's permitted use under the existing food additive regulation for closures with sealing gaskets, and that taking such action would effectively ban the use of this plasticizer. The comment further stated that gaskets containing DEHP are permitted for use in packaging food and bottled water under relevant European national regulations.

In the 1996 final rule, FDA stated that it was not aware of the potential conflict between the proposed allowable level for DEHP and the existing prior sanction for this substance in § 181.27 at the time it published the proposal. FDA also stated that the agency needed additional time to evaluate this matter and to determine an appropriate course of action with respect to the proposed allowable level for DEHP and, therefore, FDA was deferring final action on the proposed allowable level for DEHP at that time.

II. Request for Comments

FDA is now considering finalizing the allowable level of 0.006 mg/L for DEHP in the quality standard for bottled water in § 165.110(b). Because of the length of time that has elapsed since the 1993 proposed rule, FDA is seeking additional comments on establishing an allowable level for DEHP. Comments previously submitted to the Division of Dockets Management on the issue of establishing an allowable level for DEHP do not need to be and should not be resubmitted. All comments on DEHP previously submitted to the docket number found in brackets in the heading of this document, and comments on DEHP submitted in response to this reopening of the comment period, will be considered in any final rule finalizing the allowable level for DEHP in the quality standard for bottled water.

In this document, FDA is addressing the issue of the prior sanction for the use of DEHP under § 181.27, which resulted in deferral of final action in 1996. FDA is also providing updates on the use of DEHP in bottled water bottles and lid gaskets, and on international standards for DEHP in bottled water. Finally, FDA is providing information on analytical methods for measuring DEHP that were adopted by EPA after the 1993 proposed rule, and is seeking comment on the possible inclusion of these methods in the final regulation.

A. Prior Sanction for Use of DEHP

FDA has determined that the prior sanction for the use of DEHP in § 181.27, which exempts the use listed in § 181.27 from the food additive provisions of the Federal Food, Drug, and Cosmetic Act (the act), does not preclude the agency from establishing an allowable level for DEHP in the standard of quality for bottled water under § 165.110(b). The existence of a prior sanction exempts "sanctioned uses from the food additive provisions of the [a]ct but not from the other adulteration or the misbranding provisions of the [a]ct." 21 CFR 181.5(b). Therefore, while a food product containing DEHP consistent with its prior sanction could not be considered adulterated within the meaning of section 402(C)(i) of the act, it could be considered adulterated or misbranded under other adulteration or the misbranding provisions of the act.

Under section 403(h)(1) of the act (21 U.S.C. 343(h)(1)), bottled water that is of a quality below the prescribed standard in § 165.110(b) is required by § 165.110(c) to be labeled with a statement of substandard quality or it is deemed misbranded. Thus, if an allowable level for DEHP is finalized under the quality standard for bottled water, finished bottled water products with DEHP levels above the finalized level will be misbranded if the products do not bear label statements of substandard quality. FDA also notes that under the adulteration provisions of the

act, bottled water containing DEHP at a level considered injurious to health under section 402(a)(1) of the act is deemed to be adulterated.

B. Use of DEHP in Bottled Water Bottles and Lid Gaskets

The comment on the 1993 proposal stated that: (a) DEHP is routinely used as a plasticizer in gaskets used in metal and plastic closures for the packaging of bottled water in accord with the prior sanction, and that such use may result in levels of DEHP migrating into water that exceed the proposed allowable level, and that (b) gaskets containing DEHP are permitted for use in packaging food and bottled water under relevant European national regulations. However, based on information from industry, it appears that DEHP currently is not used in caps or closures for bottled water in the U.S (Ref. 1). Furthermore, FDA notes that current European Commission (EC) regulations limit the use of DEHP as a plasticizer in food contact materials to repeated use materials (Ref. 2). DEHP use is not permitted under EC regulations for plastic caps or plastic lid gaskets in metal caps.

C. International Standards for DEHP in Bottled Water

FDA also notes that several international organizations have adopted standards for DEHP that are the same or similar to FDA's proposed allowable level of 0.006 mg/L. The International Bottled Water Association (IBWA), a trade association representing a large segment of the U.S. bottled water industry, had adopted EPA's 0.006 mg/l standard for DEHP in its Model Code by 1995, suggesting that U.S. manufacturers already are able to meet the proposed level (Refs. 3 and 4). In addition, the World Health Organization (WHO) has established a guideline value for DEHP in drinking water of 0.008 mg/L (Ref. 5). The Codex Alimentarius General Standard for Bottled/Packaged Drinking Waters (Other than Natural Mineral Waters) requires that bottled/packaged drinking waters comply with WHO's guideline values (Ref. 6).

D. Analytical Methodology

In the 1993 proposal, FDA proposed adopting EPA Method 506 (Ref. 7) and EPA Method 525.1, Revision 3.0, (Ref. 8) for analysis of selected chemicals, including DEHP (58 FR 41612). In the 1996 document, FDA adopted EPA Methods 506 and 525.1, Rev. 3.0, for all the chemicals with the exception of DEHP (61 FR 13258). EPA has since updated its methods for DEHP (Refs. 9 and 10). In this document, FDA is making EPA's updated methods for DEHP analysis (Refs. 9 and 10) available for comment on their possible inclusion in the final regulation.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. References

FDA has placed the following references on display in FDA's Division of Dockets Management (see **ADDRESSES**). You may see them between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**.)

1. John Rost, Crown Packaging Technology, 2010, personal communication, January 5, 2010.

2. European Commission, 2007, Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs, *Official Journal of the European Union*, 31.3.2007, L 91/17–36.

3. International Bottled Water Association, 2007, IBWA Model Code, Version October 2007, accessed online at *http://www.bottledwater.org/files/IBWA%20Bottled%20Water%20Code%20of%20Practice.pdf.*

4. International Bottled Water Association, 2007, personal communication, August 30, 2007.

5. World Health Organization, 2008, Guidelines for drinking-water quality, third edition, incorporating first and second addenda, World Health Organization: Geneva, accessed online at *http://www.who.int/water_sanitation_health/dwq/fulltext.pdf.*

6. Codex Alimentarius, 2001, General Standard for Bottled/Packaged Drinking Waters (Other than Natural Mineral Waters), CODEX STAN 227–2001, accessed online at *www.codexalimentarius.net/download/standards/369/CXS_227e.pdf.*

7. U.S. Environmental Protection Agency (EPA), EPA Method 506—"Determination of Phthalate and Adipate Esters in Drinking Water by Liquid-Liquid Extraction or Liquid-Solid Extraction and Gas Chromatography with Photoionization Detection, " In "Methods for the Determination of Organic Compounds in Drinking Water, Supplement I," July 1990.

8. U.S. EPA, EPA Method 525.1, Revision 2.2—"Determination of Organic Compounds in Drinking Water by Liquid-Solid Extraction and Capillary Column Gas Chromatography/Mass Spectrometry." In "Methods for the Determination of Organic Compounds in Drinking Water, Supplement I," May 1991, accessed online at *http://www.epa.gov/waterscience/methods/method/files/525_1.pdf*

9. U.S. EPA, EPA Method 506, Rev. 1.1—"Determination of phthalate and adipate esters in drinking water by liquid/liquid extraction or liquid/solid extraction and gas chromatography with photoionization detection," In "Analytical Methods Approved for Drinking Water Compliance Monitoring of Organic Contaminants," June 2008, accessed online at *http://www.epa.gov/ogwdw000/methods/pdfs/methods/organic_080521b.pdf.*

10. U.S. EPA, EPA Method 525.2, Rev. 2.0—"Determination of organic compounds in drinking water by liquid-solid extraction and capillary column gas chromatography/mass spectrometry, " In "Analytical Methods Approved for Drinking Water Compliance Monitoring of Organic Contaminants," June 2008, accessed online at *http://www.epa.gov/ogwdw000/methods/pdfs/methods/organic_080521b.pdf.*

Dated: March 24, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–7292 Filed 3–31–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. FDA–2009–N–0458]

RIN 0910–AG29

Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended to Treat, Diagnose, or Cure

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulations on premarket approval of medical devices to include requirements relating to the submission of information on pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure. Elsewhere in this issue of the **Federal Register**, we are publishing a companion direct final rule. This