(i) Collects, analyzes, or maintains information that solely relates to transactions or experiences between the person and a consumer; and

(ii) Provides the information described in paragraph (i)(2)(i) of this section to an affiliate.

(3) *Exception for furnishing information to a consumer reporting entity.* Consumer reporting does not include the activities of a person to the extent that a person provides information that solely relates to transactions or experiences between a consumer and the person, or the affiliate of such person, to another person that is engaged in consumer reporting.

(4) *Exception for providing information to be used solely in a decision regarding employment, government licensing, or residential leasing or tenancy.* Consumer reporting does not include the activities of a person to the extent that a person provides consumer report or other account information that is used or expected to be used solely in any decision regarding the offering or provision of a product or service that is not a consumer financial product or service, including a decision for employment, government licensing, or a residential lease or tenancy involving a consumer.

(j) *Larger participant* means a nonbank covered person that meets a test under § 1090.102, and for the period provided in § 1090.103 of this part.

(k) *Nonbank covered person* means, except for persons described in sections 1025(a) and 1026(a) of the Act:

(1) Any person that engages in offering or providing a consumer financial product or service; and

(2) Any affiliate of a person described in paragraph (k)(1) of this section if such affiliate acts as a service provider to such person.

(l) *Person* means an individual, partnership, company, corporation, association (incorporated or unincorporated), trust, estate, cooperative organization, or other entity.

(m) *Supervision or supervisory activity* means the Bureau's exercise, or intended exercise, of supervisory authority by initiating or undertaking an examination, or requiring a report of a person pursuant to section 1024 of the Act.

§ 1090.102 Covered markets and tests for determining larger participants of those markets.

(a) *Consumer debt collection.* A nonbank covered person that offers or provides consumer debt collection is a larger participant of the consumer debt collection market if the person's annual receipts resulting from consumer debt collection are more than $10 million.

(b) *Consumer reporting.* A nonbank covered person that offers or provides consumer reporting is a larger participant of the consumer reporting market if the person's annual receipts resulting from consumer reporting are more than $7 million.

§ 1090.103 Status as larger participant subject to supervision.

A person qualifying as a larger participant under § 1090.102 shall not cease to be a larger participant under this part until two years from the first day of the tax year in which the person last met the applicable test under § 1090.102.

§ 1090.104 Determination of status as a larger participant.

(a) If a nonbank covered person receives a written communication from the Bureau initiating a supervisory activity, such person may respond by asserting that the person does not meet the definition of a larger participant of a market covered by this part within 30 days of the date of the communication. Such response must be sent to the Assistant Director by electronic transmission at the address included in the communication and must include an affidavit setting forth an explanation of the basis for the person's assertion that it does not meet the definition of larger participant of a market covered by this part and therefore is not subject to the Bureau's supervisory authority under section 1024 of the Act. In addition, a person may include with the response copies of any records, documents, or other information on which the person relied to make the assertion.

(b) A person shall be deemed to have waived the right, at any time that it may dispute that it qualifies as a larger participant, to rely on any argument, records, documents, or other information that it fails to submit to the Assistant Director under paragraph (a) of this section. A person who fails to respond to the Bureau's written communication within 30 days will be deemed to have acknowledged that it is a larger participant.

(c) The Assistant Director shall review the affidavit, any attached records, documents, or other information submitted pursuant to paragraph (a) of this section, and any other information the Assistant Director deems relevant, and thereafter send by electronic transmission to the person a statement setting forth the Bureau's conclusion as to whether the person meets the definition of a larger participant of a market covered by this part.

(d) At any time, including prior to issuing the written communication referred to in paragraph (a) of this section, the Assistant Director may require that a person provide to the Bureau such records, documents, and information as the Assistant Director may deem appropriate to determine whether a person qualifies as a larger participant. Persons must provide the requisite records, documents, and other information to the Bureau within the time period specified in the request.

(e) The Assistant Director, in her or his discretion, may modify any timeframe prescribed by this section on his or her own initiative or for good cause shown.

Dated: February 8, 2012.

Richard Cordray,

Director, Consumer Financial Protection Bureau.

[FR Doc. 2012–3775 Filed 2–16–12; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. FDA–2012–F–0031]

American Chemistry Council; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the American Chemistry Council (ACC) has filed a petition proposing that the food additive regulations be amended to no longer provide for the use of polycarbonate (PC) resins in infant feeding bottles and spill-proof cups designed to help train babies to drink from cups because these uses have been abandoned. PC resins are formed by the condensation of 4,4′-isopropylenediphenol (i.e., Bisphenol A (BPA)), and carbonyl chloride or diphenyl carbonate.

DATES: Submit either electronic or written comments by April 17, 2012.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2012–F–0031 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 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 No. FDA–2012–F–0031. 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 of 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(s), 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vanee Komolprasert, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1217.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(b)(5)), notice is given that a food additive petition (FAP 1B4783) has been filed by the American Chemistry Council (ACC), 700 Second St. NE., Washington, DC 20002. The petition proposes to amend the food additive regulations in 21 CFR 177.1580 to no longer permit the use of PC resins in infant feeding bottles (''baby bottles'') and spill-proof cups designed to help train babies to drink from cups (''sippy cups'') because these uses have been abandoned. Polycarbonate resins are formed by the condensation of 4,4′-isopropylenediphenol (i.e., BPA), and carbonyl chloride or diphenyl carbonate.

II. Abandonment

Under section 409(i) of the FD&C Act, FDA ''shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations.'' FDA's regulations specific to administrative actions for food additives provide as follows: ''The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive.'' (21 CFR 171.130(a)). These regulations further provide: ''Any such petition shall 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 appeal. New data shall be furnished in the form specified in 21 CFR 171.1 and 171.100 for submitting petitions.'' (21 CFR 171.130(b)). Under these regulations, a petitioner may propose that FDA amend a food additive regulation if the petitioner can demonstrate that there are ''old uses abandoned'' for the relevant food additive. Such abandonment must be complete for any intended uses in the U.S. market. While section 409 of the FD&C Act and § 171.130 also provide for amending or revoking a food additive regulation based on safety, an amendment or revocation based on abandonment is not based on safety, but is based on the fact that regulatory authorization is no longer necessary for the use of that food additive.

Abandonment may be based on the abandonment of certain authorized food additive uses for a substance (e.g., if a substance is no longer used in certain product categories), or on the abandonment of all authorized food additive uses of a substance (e.g., if a substance is no longer being manufactured). If a petition seeks an amendment to a food additive regulation based on the abandonment of certain uses of the food additive, such uses must be adequately defined so that both the scope of the abandonment and any amendment to the food additive regulation are clear.

The ACC petition contains public information and information collected from companies that produce PC resins to support the claim that baby bottles and sippy cups containing PC resins are no longer being introduced into the U.S. market and that manufacturers of baby bottles and sippy cups have abandoned the use of PC resins in making these products. The petition contains the results of an industry poll showing that the PC resin manufacturers, which represent over 97 percent of worldwide, global PC resin production capacity, are no longer, to their knowledge, selling PC resins to be used in the manufacture of baby bottles and sippy cups intended for import into the United States or sale in the U.S. market.

FDA expressly requests comments on ACC's proposal that FDA amend the food additive regulations to no longer permit the use of PC resins in baby bottles and sippy cups. For the purposes of this petition, FDA considers ''sippy cups'' to mean spill-resistant training cups, including their closures and lids, intended for use by babies or toddlers. As noted, the basis for the proposed amendment is that the use of PC resins in the manufacture of baby bottles and sippy cups has been abandoned. Accordingly, FDA requests comments that address whether these uses of PC resins have been abandoned, such as information on whether baby bottles or sippy cups containing PC resins are currently being introduced or delivered for introduction into the U.S. market. Further, FDA requests comments on whether the uses that are the subject of ACC's petition (baby bottles and sippy cups) have been adequately defined. FDA is not currently aware of information that would suggest continued use of PC resins in the manufacture of baby bottles and sippy cups. FDA is providing the public 60 days to submit comments.

The Agency is not requesting comments on the safety of these uses of PC resins because, as discussed previously in this document, such information is not relevant to abandonment, which is the basis of the proposed action. Any comments addressing the safety of PC resins or containing safety information on these resins will not be considered in FDA's evaluation of this petition. Separate from FDA's consideration of this petition, FDA is actively assessing the safety of BPA (see 75 FR 17145, April 5, 2010). Interested persons with safety information that has not previously been submitted to FDA on the use of PC resins may provide that information to Docket No. FDA–2010–N–0100. Although this docket is no longer accepting electronic comments, written comments will be accepted by FDA's Division of Dockets Management (see **ADDRESSES**).

The Agency has determined under 21 CFR 25.32(m) 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.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments 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.

Dated: February 13, 2012.

Dennis M. Keefe,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2012–3744 Filed 2–16–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2012–M–0076]

Gastroenterology-Urology Devices; Reclassification of Sorbent Hemoperfusion Devices for the Treatment of Poisoning and Drug Overdose; Effective Date of Requirement for Premarket Approval for Sorbent Hemoperfusion Devices To Treat Hepatic Coma and Metabolic Disturbances

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the sorbent hemoperfusion system, a preamendments class III device, into class II (special controls) for the treatment of poisoning and drug overdose, and to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the treatment of hepatic coma and metabolic disturbances. FDA is identifying the proposed special controls that the Agency believes will reasonably ensure the safety and effectiveness of the device for the treatment of poisoning and drug overdose. The Agency is also summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. In addition, FDA is announcing the opportunity for interested persons to request that the Agency change the classification of any of the devices mentioned in this document based on new information. This action implements certain statutory requirements.

DATES: Submit either electronic or written comments by May 17, 2012. Submit requests for a change in classification by March 5, 2012. See section XVIII of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2012–M–0076, 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 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 No. FDA–2012–M–0076 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 of 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1646, Silver Spring, MD 20993, 301–796–5616, *melissa.burns@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

A. Requirement for Premarket Approval Application

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device Amendments (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101–629), Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), and the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) establish a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807.

A preamendments device that has been classified into class III may be