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Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
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Re: Petition Seeking Amendment of Food Additive Regulations to Remove Approval for the Use of Bisphenol A in Reusable Food and Beverage Containers.

The undersigned ("Petitioner") submits this petition, pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 C.F.R. § 171.130, and 21 C.F.R. Part 10. The Petitioner requests that the Food and Drug Administration (FDA) amend 21 C.F.R. § 177.1580 and 177.1585 to remove small reusable household food and beverage containers¹ (i.e. sport bottles, insulated beverage containers, pitchers, tumblers, food storage containers, etc.) from the scope of permitted food contact applications for polycarbonate and polyestercarbonate resins containing bisphenol A (BPA).

Recently, the FDA opened a comment period for an American Chemistry Council (ACC) petition that requests removal of infant feeding bottles and spill-proof "sippy" cups from the scope of permitted food contact applications for polycarbonate resins containing BPA on the grounds that these uses have been abandoned by major manufacturers of baby bottles and sippy cups.² Although the Petitioner concurs with the goals of this petition, the Petitioner also believes the rationale used in the ACC petition can be extended to support a prohibition on BPA in other small reusable household food and beverage containers.

Provided below is full information on the proposed amendment.

¹ According to state laws (for example Connecticut Public Act No. 09-103) "reusable food or beverage container" means a receptacle for storing food or beverages, including, but not limited to, baby bottles, spill-proof cups, sports bottles and thermoses, and excluding food or beverage containers intended for disposal after initial use.

² See <http://plastics.americanchemistry.com/Product-Groups-and-Stats/PolycarbonateBPA-Global-Group/FDA-Petition-Letter-ACC.pdf>.

I. Background on FDA Regulation of BPA

Polycarbonate and polyestercarbonate resins are approved for use in food contact articles under 21 C.F.R. § 177.1580 and 177.1585, respectively. Polycarbonate and polyestercarbonate are polymers made with BPA (4,4'-isopropylidenediphenol; CAS Reg. No. 80-05-7). Section 177.1580 and 177.1585 broadly permit these resins to be used as “articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food,” provided that the resins are produced in accordance with the regulation and meet applicable specifications and extractives limitations.³ Historically, BPA has been used in the manufacture of shatter resistant polycarbonate for use in reusable food and beverage containers, such as sport bottles, insulated beverage containers, tumblers, pitchers, microwavable containers sippy cups and other household food service items.

The same consumer preferences for alternatives to BPA that have driven the elimination of BPA from baby bottles and sippy cups as described in the ACC petition have also led to elimination of its use in many other similar products. Since there is no material difference between sippy cups and other reusable beverage bottles, the complete elimination of BPA from baby bottles and sippy cups demonstrates that elimination from other reusable food and beverage containers could easily and economically be accomplished. Consequently, major manufacturers of small reusable household food and beverage service items have phased out the use of BPA in constructing these items. Pursuant to 21 C.F.R § 171.130, I petition the Commissioner to amend Section 177.1580 and 177.1585 to remove all small reusable household food and beverage containers from the scope of permitted food contact applications for polycarbonate and polyestercarbonate resins.

II. Product Manufacturers have Eliminated the Use of Resins Containing BPA in Reusable Food and Beverage Containers

Under 21 C.F.R. § 171.130, any interested person is permitted to file a petition to “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.” The petition may be based on “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.”⁴

Because BPA is an unstable polymer and is also lipophilic (fat-seeking), it can leach from packaging into canned foods,⁵ infant formula, and other food products.⁶ Once in food,

³ 21 C.F.R. § 177.1580

⁴ 21 C.F.R. § 171.130(b)

⁵ Noonan GO, Ackerman LK, Begley TH (2011). Concentration of bisphenol A in highly consumed canned foods on the U.S. market. *Journal of Food and Agricultural Chemistry* (in press): DOI: 10.1021/jf201076f. See also Brotons JA, Olea-Serrano MF, Villalobos M, et al. (1995). Xenoestrogens released from lacquer coatings in food cans. *Environ Health Perspect*, 103:608-612.

BPA can move quickly into people—a particular concern for women of childbearing age and for young children. Despite the fact that BPA has been largely removed from baby bottles and sippy cups, the chemical's pervasive presence in food and beverage packaging and ability to readily leach into food results in estimates of 93 percent of the U.S. population having detectable levels of BPA in their bodies.⁷ Studies have suggested that BPA in food packaging is the most significant sources of exposure to this chemical.⁸

BPA is a well-documented endocrine-disrupting chemical that can mimic action of the hormone estrogen.⁹ Recent scientific data also shows that BPA can interfere with the thyroid hormone, which is important for neurodevelopment in fetuses, infants and children.¹⁰ Over 200 scientific studies show that exposure to BPA, particularly during prenatal development and early infancy, are associated with a wide range of adverse health effects in later life. Studies have found that BPA is associated with an increased risk for cardiovascular disease, miscarriages, breast and prostate cancer, reproductive dysfunction, metabolic dysfunction, and neurological and behavioral disorders.¹¹ These scientific findings led both the National Toxicology Program at the National Institutes of Health and the FDA to express some concern about the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children.¹² BPA has been found in blood¹³ and urine¹⁴ of pregnant women and in breast milk soon after women gave birth.¹⁵ BPA also has been found in blood samples from developing fetuses as well as the surrounding amniotic fluid,¹⁶ and it has been measured in placental tissue

⁶ Schechter A, Malik N, Haffner D et al. (2010). Bisphenol A (BPA) in U.S. Food. *Environmental Science and Technology* 44: 9425-9430.

⁷ 2003-2004 National Health and Nutrition Examination Survey (NHANES III) conducted by the Centers for Disease Control and Prevention (CDC) found detectable levels of BPA in 93% of 2517 urine samples from people six years of age and older.

⁸ Rudel R, Gray J, Engel C, et al. (2011). Food Packaging and Bisphenol A and Bis(2-Ethyhexyl) Phthalate Exposure: Findings from a Dietary Intervention. *Environ Health Perspect.* 119: 914-919.

⁹ NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A, NIH Publication No. 08 – 5994 (9/2008) (<http://cerhr.niehs.nih.gov/chemicals/bisphenol/bisphenol.pdf>).

¹⁰ Kaneko M, et al. Bisphenol A acts differently from and independently of thyroid hormone in suppressing thyrotropin release from the bullfrog pituitary. *Gen Comp Endocrinol.* 2008 155(3):574-80. Zoeller RT. Environmental chemicals impacting the thyroid: targets and consequences. *Thyroid.* 2007. 17(9):811-7.

¹¹ Braun JM, Yolton K, Dietrich KN, et al. (2009). Prenatal bisphenol A exposure and early childhood behavior. *Environ Health Perspect.* 117:1945-1952; Lang IA, Galloway TS, Scarlett A, et al. (2008). Association of urinary bisphenol A concentration with medical disorders and laboratory abnormalities in adults. *J Am Med Assoc.* 300:1303-1310; Prins GS, et al. Developmental exposure to bisphenol A increases prostate cancer susceptibility in adult rats: epigenetic mode of action is implicated. *Fertil Steril.* 2008 Feb;89(2 Suppl) e 41, doi:10.1093/humrep/dep381.

¹² See <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm197739.htm>

¹³ Padmanabhan V, Siefert K, Ransom S, et al. (2008). Maternal bisphenol-A levels at delivery: A looming problem? *J Perinatol.* 28:258-263.

¹⁴ Ye X, Bishop AM, Reidy JA, et al. (2006a). Parabens as urinary biomarkers of exposure in humans. *Environ Health Perspect.* 114: 843-1846.

¹⁵ Kuruto-Niwa R, Tateoka Y, Usuki Y, et al. (2006). Measurement of bisphenol A concentration in human colostrum. *Chemosphere.* 66: 1160-1164.

¹⁶ Ikezuki Y, Tsutsumi O, Takai Y, et al. (2002). Determination of bisphenol A concentrations in human biological fluids reveals significant early prenatal exposure. *Hum Reprod.* 17:2839-2841.

and umbilical cord blood at birth¹⁷ as well as in the urine of premature infants housed in neonatal intensive care units.¹⁸ These data indicate that pregnant women exposed to BPA can easily pass this chemical to their children during pregnancy or breastfeeding and further illustrates the necessity for permanently abandoning BPA use in all reusable food and beverage containers.

As asserted by the ACC,¹⁹ companies that collectively represent more than 97 percent of global polycarbonate resin production capacity are no longer selling polycarbonate to be used in the manufacture of baby bottles or sippy cups in the U.S. Similarly, major manufacturers and retailers who make and sell small reusable household food and beverage containers have made public statements indicating that they have shifted away from the use of BPA, opting for alternative materials. For example:

- Rubbermaid[®] states: “we recognized consumer concerns around the BPA issue, and identified new materials which do not contain BPA that allow us to retain the consumer-desired, stain-resistance benefits. In fall 2009, we introduced new versions of our stain-resistant Premier food storage containers and Refill Reuse water bottles that are BPA-free.”²⁰
- The retailer REI stated that “All water bottles (and food containers) offered at REI are constructed without the use of bisphenol A (BPA), a chemical that has raised health safety questions.”²¹
- Since 2008, Glad[®] issued an official statement:²² “Glad food containers, wraps, storage bags and other food contact products are not made of phthalates or polycarbonate. Nor is Bisphenol A (BPA) used as a raw material in their production.”
- Thermos[®] states “Bisphenol A (BPA) is a controversial chemical that can be found in the lining of food cans, certain water bottles and more. Some researchers have linked the hormone-mimicking chemical to a host of issues including behavioral and developmental effects in kids. Thermos plays it safe, and has made a commitment to only manufacture products that are BPA-free.”²³
- Sterilite[®] states that “all Sterilite[®] food storage and kitchen items are BPA-free and phthalates-free.”²⁴

¹⁷ Schonfelder G, Wittfoht W, Hopp H, et al. (2002). Parent Bisphenol A accumulation in the human maternal-fetal-placental unit. *Environ Health Perspect*, 110:A703-707; Environmental Working Group (2009) Pollution in minority newborns (www.ewg.org/minoritycordblood/home).

¹⁸ Calafat AM, Weuve J, Ye X, et al. (2009). Exposure to bisphenol A and other phenols in neonatal intensive care unit premature infants. *Environ Health Perspect*, 117:639-644.

¹⁹ See <http://plastics.americanchemistry.com/Product-Groups-and-Stats/PolycarbonateBPA-Global-Group/FDA-Petition-Letter-ACC.pdf>.

²⁰ <http://www.rubbermaid.com/pages/LearnAboutBPA.aspx#bpa>

²¹ <http://www.rei.com/expertadvice/articles/water+bottles.html>

²² http://www.glad.com/pdf/Glad-Bisphenol_A_Declaration.pdf

²³ <http://www.thermos.com/bpa.aspx>

²⁴ http://www.sterilite.com/food_storage.html

This public data was further substantiated when in December 2011 a survey was taken by the Petitioner of all the major identifiable manufacturers of small reusable household food and beverage containers (see Attachment 1 for manufacturers' responses). The Petitioner learned from:

- Sterilite[®] that the information provided on their website is indeed affirmative and that the company has “never used polycarbonate in our food and beverage containers and does not use any plastic resins which contain BPA in any of our products.”
- The Clorox Company, which produces Glad[®] and Brita[®] products that “none of its reusable food and beverage containers use BPA in their construction.”
- S.C. Johnson “does not use BPA in its food storage products, including ZIPLOC[®] brand bags and containers and SARAN[™] brand wraps.”
- Tupperware[®] Brands Corporation “made the decision in 2009 to cease use of polycarbonate plastic in its U.S. products” and none of its food or beverage containers are made with substances that contain BPA.
- Newell Rubbermaid that “none of (their) reusable food and beverage containers sold for consumer use are made of plastic that contains BPA.”

In today's marketplace, small reusable household food and beverage containers made from polycarbonate or polyestercarbonate containing BPA have been actively removed from major brands in the U.S. market. Much like other choices to remove BPA from products intended for infants (sippy cups and bottles), there is nothing to suggest that the phase out of BPA from small reusable household food and beverage containers is a temporary condition. Rather, the industry, in response to consumer preference, has made an affirmative decision to discontinue the use of BPA in these products and transition to materials that are BPA-free.

III. Conclusion and Proposed Amendment

In light of the abandonment of the use of BPA in baby bottles and sippy cups, and the adoption of BPA-alternative materials for other reusable food and beverage containers, the Petitioner respectfully requests that FDA amend 21 C.F.R. § 177.1580 and 177.1585 to prohibit the use of BPA in all small household reusable food and beverage containers (i.e. sport bottles, insulated beverage containers, pitchers, tumblers, home food containers, blenders and other food service items).

Amend 21 C.F.R. § 177.1580 as follows (new language underlined):

“Polycarbonate resins may be safely used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:...”

(d) Polycarbonate resins may be used in accordance with this Section except in small reusable household food and beverage containers (including, but not limited

to sport bottles, insulated beverage containers, pitchers, tumblers, and food storage containers.)

Amend 21 C.F.R. § 177.1585 as follows (new language underlined):

“Polyestercarbonate resins may be safely used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, or holding food, in accordance with the following prescribed conditions:...”

(d) Polyestercarbonate resins may be used in accordance with this Section except in small reusable household food and beverage containers (including, but not limited to sport bottles, insulated beverage containers, pitchers, tumblers, and food storage containers.)

This amendment would have the effect of precluding the use of BPA containing polycarbonate or polyestercarbonate in these products and reflect actions and decisions taken by major manufacturers to abandon such use.

IV. Environmental Impact

This petition requests action to prohibit the use of a substance in food packaging and is therefore categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement under 21 C.F.R. § 25.32(m).

Respectfully submitted,



Edward J. Markey