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Re: Petition Seeking Amendment of Food Additive Regulations to Remove Approval for the Use of Bisphenol A in Infant Formula Packaging and Baby and Toddler Food Packaging.

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. § 175.300, 177.1580, and 177.1585 and other applicable regulations¹ to remove canned infant formula and baby and toddler food from the scope of permitted food contact applications for polymeric coatings and polycarbonate resins containing bisphenol A (BPA) because these uses have been intentionally and permanently abandoned by major product manufacturers.

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 canned infant formula and baby and toddler food.

Provided below is full information on the proposed amendment.

¹ Based on a pre-petition discussion with the FDA the Petitioner believes the primary regulations governing the use of BPA as a component of coatings found in cans of infant formula and in lids of baby food is 21 CFR § 175.300. Additionally, some baby and toddler foods are packaged in small plastic containers, which are primarily made with polyethylene and polypropylene rather than the more expensive BPA-containing polycarbonate (PC). However, the use of polycarbonate in these small plastic containers is regulated by 21 CFR § 177.1580 and 177.1585. Any other potentially applicable regulations should be amended to appropriately reflect the permanent abandonment of BPA in packaging for infant formula packaging and baby and toddler food packaging.

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

BPA (4,4'-isopropylidenediphenol; CAS Reg. No. 80-05-7) is regulated for use as a monomer in the manufacture of polycarbonate and epoxy-based enamels and coatings used in food contact applications. Specific regulations which mention BPA as a monomer used in the production of food additives include 21 C.F.R. § 172.105 (anoxomer), § 175.300 (resinous and polymeric coatings), § 177.1580 (polycarbonate resins), § 177.1585 (polyestercarbonate resins), § 177.2600 (rubber articles intended for repeated use), § 177.2280 (4,4'-isopropylidenediphenol-epichlorohydrin thermosetting epoxy resins), § 177.2420 (cross-linked polyester resins), § 177.1655 (polysulfone resins), and § 177.1440 (4,4'-isopropylidenediphenol-epichlorohydrin resins with a minimum molecular weight of 10,000).

The regulations detailed above permit any manufacturer or processor to manufacture and market a food contact surface or article made from BPA as long as the conditions of use and specifications, such as identity and extractable limitations, in the applicable regulation(s) are met. For example, section 175.300 broadly permits resins and polymeric coatings to be used “as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food,” provided that the resins and coatings are produced in accordance with the regulation and meet applicable specifications and extractives limitations.³ Historically, epoxy resins and coatings made with BPA have been used in the lining of metal food and beverage containers, including cans of infant formula and baby food.

21 C.F.R. § 175.300, 177.1580, 177.1585 and other relevant regulations governing the use of BPA resins as indirect food additives in infant formula and baby food packaging should be amended, as requested below, to reflect new information showing that product manufacturers have intentionally and permanently abandoned the use of food contact surfaces or articles containing BPA in linings of cans of infant formula and in packaging of baby and toddler food. Pursuant to 21 C.F.R. § 171.130, I petition the Commissioner to revoke regulations permitting the use of an indirect food additive or food contact surface or article that results in BPA becoming a component of infant formula or food for infants and young children. This request is based on the grounds that these uses have been intentionally and permanently abandoned by all major product manufacturers.

II. Product Manufacturers Have Abandoned the Use of BPA in Cans of Infant Formula and Baby and Toddler Food Packaging

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

³ 21 C.F.R. § 175.300

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, 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 source 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

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.

⁶ Schecter 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.

women gave birth.¹⁵ BPA has also been found in blood samples from developing fetuses as well as the surrounding amniotic fluid,¹⁶ and it has been measured in placental tissue and umbilical cord blood at birth¹⁷ as well as in the urine of premature infants housed in neonatal intensive care units.¹⁸

As asserted by the ACC,¹⁹ manufacturers are no longer producing or selling BPA-containing bottles and infant feeding cups for the U.S. market. Similarly, many manufacturers of infant formula and baby and toddler food have “abandoned” (i.e., have affirmatively and intentionally chosen to permanently discontinue) the use of resins and polymeric coatings containing BPA in making these products.

Infant formula

The infant formula market is highly concentrated among manufacturers. In fact there are only four companies that are registered with the FDA and that are currently manufacturing infant formula. In 2008, three of these companies accounted for 98 percent of all dollar sales: Abbott, maker of the Similac product line, accounted for 43 percent of sales; Mead Johnson, maker of the Enfamil line, accounted for 40 percent of sales; and Nestlé, maker of the Gerber Good Start line, accounted for another 15 percent of sales.²⁰

Information collected from FDA, as of October 13, 2011, indicated that more than 90 percent of infant formula packaging no longer contained BPA.²¹ Additionally, manufacturers have issued numerous public statements indicating that they have removed it from their products. For example:

- Enfamil (Mead Johnson) shifted to an alternative to BPA in October 2011. The company now states that “[t]he cans and can liners of Enfamil® products do not include BPA as a component.”²²

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.

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 See <http://www.ers.usda.gov/Publications/ERR124/ERR124.pdf>.

²¹ Private communications between FDA staff and Representative Markey staff October 2011. Estimate based on information from notifications for changes in infant formula packaging and notifications for BPA replacement materials.

²² Call to Enfamil help center on November 16, 2011: 1-800-BABY123.

- In September 2011, Abbott Labs announced that it “achieved ‘BPA free’ status in all of its Similac[®] brand. No BPA was used in the manufacturing of these containers.”²³
- In September 2011, Nestlé-Gerber announced new “Tetra Pak packaging that is not made with BPA” for its ready to feed liquid infant formulas. Additionally, “there is no BPA in cans used to package the Nestlé GOOD START[®] Supreme Milk and Soy based powdered infant formulas, which account for more than 80 percent of the type of infant formula we sell.”²⁴

This anecdotal data was more recently substantiated when in November 2011 a survey was taken by the Petitioner of all active infant formula manufacturers.²⁵ (100 percent of the current infant formula market) to determine the extent of the use of BPA as liners in their cans of infant formula. From this survey (see Attachment 1 for the manufacturers’ responses) it was found that none of the four currently registered manufacturers of infant formula use BPA in the food contact packaging of their liquid or powdered infant formula.²⁶

Thus, BPA has already been eliminated from 100 percent of powdered infant formula cans and 100 percent of liquid formula cans. Similar to the ACC’s characterization of the removal of BPA from baby bottles and sippy cups as permanent, there is nothing to suggest that BPA’s removal from infant formula packaging is a temporary condition. Rather, the industry, in response to consumer preference, has made an affirmative decision to permanently discontinue the use of BPA in these products. FDA’s food additive regulations, particularly 21 C.F.R. § 175.300, 177.1580, and 177.1585 and other applicable regulations should thus be amended to withdraw approval of BPA in packaging for infant formula.

Baby and Toddler Food

For the purposes of FDA regulations, infant formula is considered a “food”, however, as opposed to formula made from liquid or powder, there exists an entire class of prepared food products that are solid food consisting of a soft paste or an easily chewed food intended for babies and toddlers.²⁷ These products are often packaged in plastic containers that may be composed of BPA or in glass containers, which contain BPA as a liner of the metal lid. Much like manufacturers of baby formula, manufacturers of baby

²³ See <http://abbottnutrition.com/news/pressReleaseDetail.aspx?ContentTitle=abbott-leads-by-achieving-bpa-free-status-for-its-infant-formulas&year=2011>.

²⁴ See <http://news.gerber.com/pr/gerber/bpa-insight-and-faq-s-158818.aspx>.

²⁵ The four active infant formula manufacturers registered with the FDA include: PBM, Nestlé Nutrition, Mead Johnson Nutrition and Abbott

²⁶ One company that uses BPA in the exterior coating (non-food contact surface) of the outer cap of the packaged infant formula bottle, is transitioning to a non-BPA cap, which is expected to be completed at the end of 2012.

²⁷ Connecticut Public Act No. 09-103 defines “baby food” as a prepared solid food consisting of a soft paste or an easily chewed food that is intended for consumption by children two years of age or younger and is commercially available.

food have abandoned the use of BPA in their baby and toddler food packaging. For example:

- Plum Organics states, “From the very beginning, our containers have been and remain BPA and phthalate free”²⁸
- Ella’s Kitchen, a popular organic baby and toddler food company, states that their packaging does “not contain any Bisphenol A or Phthalates” the company also states, that their “caps and ‘straws’ are made from PE plastic (BPA free).”²⁹
- Earth’s Best states that, “BPA is only used in the coating of the metal lid on their glass jars”, but that even in this case, “there is a coating over the BPA lining so that the BPA never comes into contact with the food.”³⁰

In November 2011, a survey was taken by the Petitioner of several baby and toddler food manufacturers that together represent 100 percent of the publically identifiable major baby and toddler food companies³¹ to determine the extent of the use of BPA in their packaging. All respondents (see Attachment 1 for the responses to this survey) have stated that they do not currently use BPA in their food contact packaging for baby and toddler foods in the U.S. For example:

- Beech-Nut states that the Corporation “has shifted away from packaging its baby and toddler foods in food contact articles manufactured with BPA. That transition in packaging was completed in October 2011.”
- Nestlé Nutrition (which occupies approximately 64 percent of the baby and toddler food market) stated that “Nestlé Infant Nutrition/Gerber Products Company does not use packaging made with BPA for any of our infant and toddler products.”
- Perrigo, the parent company of PBM, which manufactures many store brand products, stated that the company “does not currently use BPA in the packaging for baby foods in the United States.”

Thus, BPA has already been eliminated from the major market share of baby and toddler food packaging, and its use will only continue to diminish as more alternatives to BPA become available, especially to be used as liners of metal lids in glass jars. Similar to the removal of BPA from baby bottles, sippy cups and infant formula there is nothing to suggest that BPA’s removal from baby and toddler food packaging is a temporary

²⁸ http://www.plumorganics.com/why_plum_6.php

²⁹ <http://www.ellaskitchen.com/helpful-stuff/>

³⁰ Call to Consumer relations hotline: 1-800-434-4246, November 13, 2011.

³¹ *Market Share Reporter*: The top baby foods and baby snacks for the 52 weeks that ended on June 14, 2009, based on sales at food stores, drug stores and mass merchandisers (excluding Wal-Mart and club stores) shows various Gerber products taking up a total 64.1% of the U.S. market, Beechnut's Stage 2 products taking up 5.2%, and the remaining marketplace made up by unidentified brands.

condition and is instead a strong market shift to permanently discontinue the use of BPA in these products. FDA's food additive regulations, particularly 21 C.F.R. § 175.300, 177.1580 and 177.1585 should thus be amended to withdraw approval of BPA in packaging for baby and toddler food.

III. State Authorities Have Prohibited the Use of BPA Resins in Liners of Infant Formula and Baby Food

Legislative and regulatory authorities in various jurisdictions have recently prohibited the manufacture or sale of canned infant formula and baby food containing BPA. These actions further substantiate the abandonment of the use of BPA containing resins in infant formula and baby food. For example, Connecticut (2009), Vermont (2010), and Maryland (2011) have all banned the use of BPA in infant formula and baby food.³²

IV. Conclusion and Proposed Amendment

In light of the abandonment of the use of BPA in packaging for all infant formula and baby and toddler food, the Petitioner respectfully requests that FDA amend 21 C.F.R. § 175.300, 177.1580, and 177.1585 and other applicable regulations to prohibit the use of BPA in packaging for infant formula, baby and toddler food.

Amend 21 C.F.R. § 175.300, as follows (new language underlined):

“Resinous and polymeric coatings may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:...”

(i) Resinous and polymeric coatings may be used in accordance with this Section except in cans or packaging used for infant formula or baby or toddler food.

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 cans or packaging used for infant formula or baby or toddler food.

³² State of Connecticut Public Act No. 09-103; Vermont Senate Bill S. 247; Maryland House Bill 4, Chapter 190.

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:...”

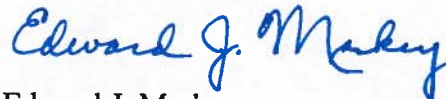
(d) Polyestercarbonate resins may be used in accordance with this Section except in cans or packaging used for infant formula or baby or toddler food.

These amendments and amendments made to other applicable regulations would have the effect of precluding the use of BPA containing food contact surfaces or articles in infant formula and baby food and appropriately reflect actions and decisions taken by major manufacturers to abandon such use.

V. 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