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**VIA HAND DELIVERY**

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**Re: Petition Seeking Amendment of Food Additive Regulation 21 C.F.R. § 177.1580 to Remove the Approval for Polycarbonate Resins in Infant Feeding Bottles and Certain Spill-Proof Cups Due to the Abandonment of these Uses.**

Dear Dr. Lin:

The undersigned submits this petition, on behalf of the American Chemistry Council (“ACC” or “Petitioner”), pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act (“FFDCA”),<sup>1</sup> 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 to remove infant feeding bottles (“baby bottles”) and spill-proof cups designed to help train babies to drink from cups (“sippy cups”) from the scope of permitted food contact applications for polycarbonate resins. This request is based solely on the grounds that these uses have been intentionally and permanently abandoned by all major product manufacturers.

Provided below is full information on the proposed amendment.

**I. Background on FDA Regulation of Polycarbonate Resins**

Polycarbonate resins are approved for use in food contact articles under 21 C.F.R. § 177.1580. Polycarbonate is a polymer made with bisphenol A (“BPA”, 4,4’-isopropylidenediphenol; CAS Reg. No. 80-05-7). Section 177.1580 broadly permits polycarbonate 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

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<sup>1</sup> 21 U.S.C. § 348(b)(1).

polycarbonate resins are produced in accordance with the regulation and meet applicable specifications and extractives limitations.<sup>2</sup> Historically, hard plastic baby bottles and sippy cups have been made from polycarbonate resins.

Section 177.1580 should be amended, as requested below, to reflect new information showing that all major product manufacturers, due to consumer preferences, have intentionally and permanently abandoned the use of polycarbonate resins containing BPA in baby bottles and sippy cups.

## **II. All Major Product Manufacturers Have Abandoned the Use of Polycarbonate Resins in Baby Bottles and Sippy Cups**

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.”<sup>3</sup> Such 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.”<sup>4</sup>

Recent scientific data and assessments by regulatory agencies, including FDA, continue to conclude that the low level of exposure to BPA from the use of baby bottles and sippy cups is well below levels that could cause health effects.<sup>5</sup> But, recent information and data also show that all major manufacturers of baby bottles and sippy cups, in response to consumer preference, have “abandoned” (i.e., have affirmatively and intentionally chosen to permanently discontinue) the use of polycarbonate resins in making these products.

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<sup>2</sup> 21 C.F.R. § 177.1580.

<sup>3</sup> 21 C.F.R. § 171.130(a).

<sup>4</sup> 21 C.F.R. § 171.130(b) (emphasis added).

<sup>5</sup> For example, the German Federal Institute for Risk Assessment stated in January 2010 FAQs for consumers, that: “[The TDI] also applies to baby bottles made of polycarbonate. The amount of bisphenol A that can be released into the baby food has to be small enough for any bisphenol A ingested by the baby to remain safely below the TDI value. This is the case for bottles that are commercially available in conjunction with normal use. Official food control could not detect any bisphenol A during spot checks on the contents of baby bottles that were heated under normal domestic conditions. Hence there is no health risk for babies fed from bottles made of polycarbonate. BfR, therefore, believes that there is no need to avoid using polycarbonate bottles.” Available at [http://www.bfr.bund.de/cm/349/selected\\_questions\\_and\\_answers\\_on\\_bisphenol\\_a\\_in\\_baby\\_bottles\\_and\\_baby\\_bottle\\_teats.pdf](http://www.bfr.bund.de/cm/349/selected_questions_and_answers_on_bisphenol_a_in_baby_bottles_and_baby_bottle_teats.pdf) (last accessed September 14, 2011).

See also, European Food Safety Authority (September 2010); European Commission Risk Assessment (June 2008); Food Standards Australia and New Zealand (November 2010); Japanese National Institute of Advanced Industrial Science and Technology (July 2011); Health Canada (October 2008); and World Health Organization/Food and Agriculture Organization of the United Nations (November 2010).

In 2009, it was widely announced and reported that the six companies manufacturing the overwhelming majority of baby bottles and sippy cups in the United States – “Avent, Disney First Years, Gerber, Dr. Brown, Playtex and Evenflow” (sic) – had voluntarily ceased manufacturing baby bottles and sippy cups made from polycarbonate.<sup>6</sup> As a consequence, these and other manufacturers have been extensively promoting their BPA-free baby bottles and sippy cups. For example:

- Phillips AVENT states that “We only sell feeding solutions made with BPA-free materials in North America. This includes all of our reusable baby bottles, pacifiers and breast pumps.”<sup>7,8</sup>
- The First Years indicates that all of their Breastflow® branded baby bottles are BPA-Free.<sup>9</sup> Likewise, all sippy cups and straw cups are indicated to be BPA-Free, including Ziploc™ cups,<sup>10</sup> Take & Toss cups,<sup>11</sup> Disney cups,<sup>12</sup> and toddler cups.<sup>13</sup>
- Dr. Brown’s states “Our Dr. Brown's bottles are made of BPA-free polypropylene plastic or BPA-free borosilicate glass. All components of the Dr. Brown's bottle, including the vent insert, vent reservoir, travel disk, nipple collar, and cap are also BPA-free polypropylene. Our nipples are made of medical-grade silicone.”<sup>14</sup> Likewise, the Dr. Brown’s training cups are advertised as “Free of Bisphenol-A.”<sup>15</sup>

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<sup>6</sup> Connecticut Attorney General’s Office Press Release, “Attorney General Announces Baby Bottle Makers Agree to Stop Using BPA; Calls for Legislative Ban” (March 5, 2009), available at <http://www.ct.gov/ag/cwp/view.asp?A=3673&Q=435360> (last accessed September 14, 2011).

<sup>7</sup> The AVENT brand became a part of Phillips in September 2006.

<sup>8</sup> Phillips Avent, “FAQs – Some common questions about bottle feeding and BPA.” Available at <http://www.usa.philips.com/c/avent-baby-bottle-feeding/11717/cat/en/> (last accessed September 14, 2011).

<sup>9</sup> The First Years, Breastflow® baby bottles, available at [http://www.thefirstyears.com/thefirstyears/Breastflow/p-1?locale=en\\_US](http://www.thefirstyears.com/thefirstyears/Breastflow/p-1?locale=en_US) (last accessed September 14, 2011).

<sup>10</sup> The First Years, Ziploc™ brand cups, available at [http://www.thefirstyears.com/wps/portal/ziploc?icid=ddmenu&locale=en\\_US](http://www.thefirstyears.com/wps/portal/ziploc?icid=ddmenu&locale=en_US) (last accessed September 14, 2011).

<sup>11</sup> The First Years, Take & Toss brand cups, available at [http://www.thefirstyears.com/taketoss?icid=ddmenu&locale=en\\_US](http://www.thefirstyears.com/taketoss?icid=ddmenu&locale=en_US) (last accessed September 14, 2011).

<sup>12</sup> The First Years, Disney brand cups, available at [http://www.thefirstyears.com/disney?icid=ddmenu&locale=en\\_US](http://www.thefirstyears.com/disney?icid=ddmenu&locale=en_US) (last accessed September 14, 2011).

<sup>13</sup> The First Years, toddler cups, available at [http://www.thefirstyears.com/thefirstyears/Toddler+Feeding/p-1?icid=ddmenu&locale=en\\_US](http://www.thefirstyears.com/thefirstyears/Toddler+Feeding/p-1?icid=ddmenu&locale=en_US) (last accessed September 14, 2011).

<sup>14</sup> Dr. Brown’s, “Frequently Asked Questions: About our Materials, What are Your Bottles Made Of?,” available at <http://www.handi-craft.com/products/bottle-faqs.htm#> (last accessed September 14, 2011).

<sup>15</sup> Dr. Brown’s, “Interchangeable Training Cup System,” available at <http://www.handi-craft.com/training-cups> (last accessed September 14, 2011).

- Playtex states that “All of our products are BPA-free.”<sup>16</sup> This includes various types of baby bottles and sippy cups along with related products.
- Evenflo designates all of their baby bottles<sup>17</sup> and toddler feeding cups<sup>18</sup> as BPA-Free.
- Nuk states that “the entire current product line manufactured by NUK USA since Jan.1.2009 (including NUK® and Gerber® branded baby bottles, pacifiers, sippy cups and tableware) is not made using materials constructed with BPA.”<sup>19,20</sup>
- MAM states that “all MAM baby products are BPA-free,”<sup>21</sup> which includes baby bottles and cups.

In today’s marketplace, polycarbonate baby bottles and sippy cups are no longer being produced and there is nothing to suggest that this is a temporary condition. Rather, the industry, in response to consumer preference, has clearly made an affirmative decision to permanently discontinue the use of polycarbonate in these products. In fact, FDA has explicitly recognized that the major manufacturers of polycarbonate baby bottles and infant feeding cups “have stopped selling new BPA-containing bottles and infant feeding cups for the U.S. market,” and has expressed support for these actions.<sup>22</sup> The food additive regulations can thus be amended to withdraw approval of an abandoned use.

### **III. International Authorities Have Prohibited the Use of Polycarbonate Resins for the Manufacture of Baby Bottles and Sippy Cups in Various Jurisdictions**

In addition to actions taken by manufacturers to abandon the use of polycarbonate resins for baby bottles and sippy cups, legislative and regulatory authorities in various jurisdictions have recently prohibited the manufacture or sale of these products containing BPA. While not based on scientific evidence or safety, these actions further substantiate the abandonment of the use of polycarbonate resins for the manufacture of baby bottles and sippy cups.

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<sup>16</sup> Playtex, “About BPA”, available at <http://www.playtexbaby.com/CupsMealtime/Tips-Tools> (last accessed September 14, 2011).

<sup>17</sup> Evenflo, Bottle Feeding, available at <http://www.evenflo.com/category.aspx?id=44> (last accessed September 14, 2011).

<sup>18</sup> Evenflo, Toddler Feeding Cups, available at <http://www.evenflo.com/category.aspx?id=4> (last accessed September 14, 2011).

<sup>19</sup> In 2009, NUK purchased Gerber’s line of accessory products. For that reason, no information from Gerber is provided in this petition.

<sup>20</sup> Nuk “Quality and Safety,” available at <http://nuk-usa.com/about/quality-and-safety.aspx> (last accessed September 14, 2011).

<sup>21</sup> MAM, “Safe with MAM – Alternatives to BPA,” available at [http://www.mambaby.com/the\\_products-bpa-free\\_products.26262.RefStoryID\\_26958.html](http://www.mambaby.com/the_products-bpa-free_products.26262.RefStoryID_26958.html) (last accessed September 14, 2011).

<sup>22</sup> FDA, “Update on Bisphenol A for Use in Food Contact Applications” (January 15, 2010), at 6, available at <http://www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM197778.pdf> (last accessed September 14, 2011).

For example, the European Union, Canada, China, and Malaysia have recently prohibited the use of polycarbonate resins for baby bottles. Similarly, ten states in the U.S.<sup>23</sup> have prohibited the use of polycarbonate resins in baby bottles and sippy cups.

**IV. Global Polycarbonate Resin Manufacturers Are Not Currently Selling Polycarbonate Resin for the Manufacture of Baby Bottles and Sippy Cups for the U.S. Market**

Specifically to support this Petition, Petitioner confidentially polled our member companies that produce polycarbonate resin to determine whether, as of September 30, 2010, any of these companies are selling polycarbonate resin to be used in the manufacture of baby bottles or sippy cups in the U.S. or for import or sale into the U.S. The inquiry was structured to allow companies to make this determination across their global manufacturing divisions.

The poll consisted of a two-part question. The first part of the question was whether the company, as of September 30, 2010, had any sales of its polycarbonate resin to customers who have indicated their intention to use, manufacture, distribute, or sell the plastic as a material of construction for baby bottles or sippy cups. The same description for these products as used in Section V below was provided. This part of the question was not limited to the U.S. market. If the answer to the first part was yes, the second part of the question was whether the company had actual knowledge that the baby bottles or sippy cups are intended for sale or import into the U.S. market. Since polycarbonate bottles and cups may be on the market elsewhere in the world, the two parts of the question together were intended to determine whether those products, regardless of where they are made, are coming to the U.S. market. The overall answer from these two parts together is “yes” or “no.”

A total of nine member companies were contacted and Petitioner also contacted two additional companies in Taiwan and two in Korea. Based on public records, the only polycarbonate resin manufacturers not contacted are small manufacturers in Russia, Iran and Brazil, none of which is likely to be supplying the U.S. market.

To Petitioner’s knowledge, as determined by this confidential data collection by Petitioner in its capacity as a third party fiduciary, and supplemented with data from public records, these 13 companies (including joint ventures that were included with their parent company) collectively represent >97% of global polycarbonate resin production capacity. The only companies known to manufacture polycarbonate resin that were not contacted together represent <3% of global production capacity.

As indicated above, each company was asked if it sells its resin for use in baby bottles or sippy cups anywhere in the world and, if so, if it has actual knowledge that those products are intended

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<sup>23</sup> The ten states are Connecticut, Delaware, Massachusetts, Maine, Maryland, Minnesota, New York, Vermont, Washington and Wisconsin.

for the U.S. market. The only response requested was “yes” or “no” as a combined response to the two part question. All answered “no.”

Based on the information collected from this inquiry, the companies contacted are not selling polycarbonate resin to be used in the manufacture of baby bottles or sippy cups in the U.S. or for import or sale into the U.S.

**V. Conclusion and Proposed Amendment**

In light of the above, Petitioner respectfully requests that FDA 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 infant feeding bottles and spill-proof cups designed to help train babies to drink from cups.

This amendment would have the effect of precluding the use of polycarbonate resins in baby bottles and sippy cups, and appropriately reflect the industry’s affirmative decision to abandon such use.

**VI. Environmental Impact**

Petitioner hereby claims a categorical exclusion from the need to prepare an environmental assessment pursuant to 21 C.F.R. § 25.32(m) for this action to prohibit or otherwise restrict or reduce the use of the subject food additive in baby bottles and sippy cups. The claim complies with the categorical exclusion criteria, and to the petitioner's knowledge, there are no extraordinary circumstances.

Respectfully submitted,



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