Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

09 AUG 2019

FDA CIRCULAR
No. 2019-004

TO : **ALL CONCERNED STAKEHOLDERS AND PARTIES**

SUBJECT : **Ban of Bisphenol A (BPA) from Infant Feeding Bottles and Sippy Cups as Child Care Article Products**

I. RATIONALE

Consistent with the 1987 Philippine Constitution as a declared policy of the State to protect and promote the right to health of the Filipino people and instill health consciousness among them, Republic Act (RA) No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009", and its Implementing Rules and Regulations, the FDA hereby imposes a ban on Bisphenol A (BPA) in infant feeding bottles and sippy cups as child care article products.

II. SCOPE

This Circular shall cover infant feeding bottles and sippy cups as child care article products containing BPA and the establishments that are engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, and where applicable, the use, testing, promotion, advertising, or sponsorship of any child care articles containing BPA.

III. GENERAL INFORMATION

Bisphenol A (BPA) is an industrial chemical that is widely used as a monomer in the manufacture of polycarbonate (PC); a clear, hard plastic used in many consumer products including feeding bottles and sippy cups. Relevant epidemiological studies have shown that BPA affect the development of the nervous, immune and reproductive system and considered as endocrine disruptors which can alter the hormonal system of the human body. Extensive use of BPA in manufacturing products that come in contact with food increases the risk of exposure to this compound, mainly through the digestive tract.

Over the years, concerns have been raised about BPA's effect on human health, especially when it is used in food contact materials (FCM) and articles such as feeding bottles and sippy cups. In 2008, Canada first proposed the prohibition of polycarbonate baby bottles that contains BPA which came into force in 2010. And in 2011, the European Union (EU) along with China are among the countries which banned the manufacture including the importation of PC baby bottles with BPA.

In the Joint Food and Agriculture Organization and World Health Organization (FAO/WHO) Expert Meeting held on November 2010, the toxicological and health aspects of BPA was reviewed. The expert panels concluded that dietary exposure estimates are generally higher for infants (0-6 months) fed using PC baby bottles with the mean of 2.4 µg/kg body weight per day. This is due to migration of BPA from PC baby bottles when filling the bottle with boiling water, adding milk formula and leaving the bottle to cool down.

Thus, this Circular is issued by the FDA to better protect the health of the children and better reduce exposure to these substances.

IV. POLICIES AND GUIDELINES

1. The manufacture, importation and distribution of infant feeding bottle and sippy cups containing Bisphenol A (BPA) shall not be allowed.
2. All concerned establishments shall be given six (6) months phase-out period to recall from the market all infant feeding bottles and sippy cups containing BPA.
3. It shall be the responsibility of the manufacturer, trader, importer, distributor or wholesaler to conduct recall of their products to ensure that infant feeding bottles and sippy cups containing BPA, are removed from the market and shall no longer be made available to the market after the phase-out period.
4. The manufacturer, importer and/or distributor of the banned products shall conduct inventory and submit a report to the FDA one (1) month after the given phase-out period.
5. The manufacturer, importer and/or distributor of the banned products shall prepare a disposal plan in accordance with Department of Environment and Natural Resources- Environmental Management Bureau (DENR-EMB) rules and regulation subject to FDA approval.

V. PENALTY CLAUSE

Any establishment found to be in violation of the provisions of this issuance shall be subjected to sanctions and penalties as prescribed under RA 9711 and its IRR.

VI. EFFECTIVITY

This Circular shall take effect thirty (30) days after publication in two (2) newspapers of general circulation and submission of a copy hereof to the Office of the National Registry of the University of the Philippines Law Center.

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