



FDA ADVISORY

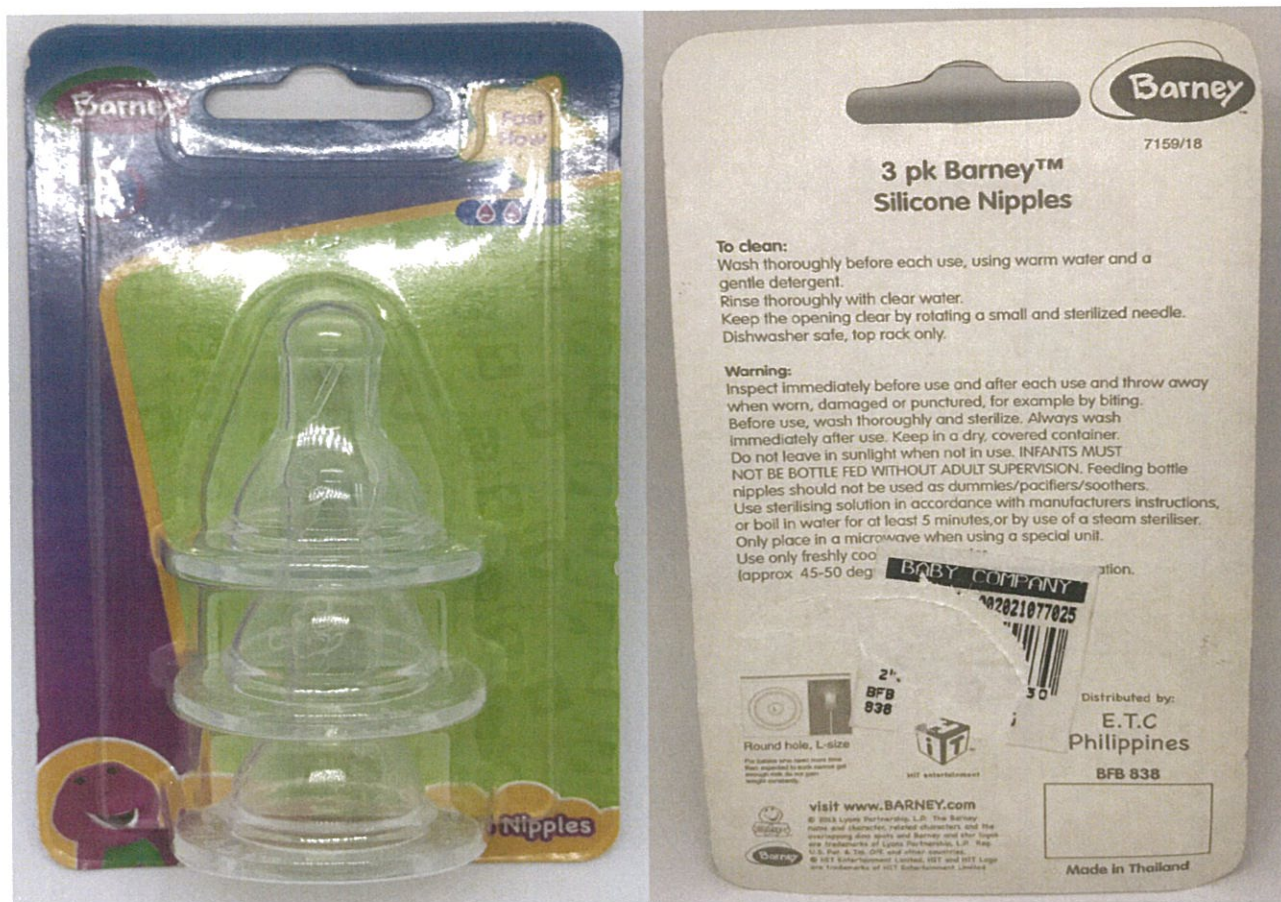
No. 2020-304

05 MAR 2020

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of Unnotified Toys and Childcare Articles (TCCA) BARNEY 3 PK BARNEY SILICONE NIPPLES (BFB 838)

The Food and Drug Administration (FDA) warns the public from purchasing and using the unnotified Toys and Childcare Articles (TCCA) product, **BARNEY 3 PK BARNEY SILICONE NIPPLES (BFB 838)** (Refer to the image below).



The abovementioned product was verified by FDA through postmarketing surveillance and shows no record of valid Certificate of Product Notification (CPN) as a form of authorization. Pursuant to Book II, Article I, Section 1 (a) of the Rules and Regulations Implementing Republic Act No. 9711, otherwise known as the “Food and Drug Administration Act of 2009”, the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising,

or sponsorship of any health product without the proper authorization from the FDA is prohibited.

Since the abovementioned unnotified toys and childcare articles product has not gone through the notification process of the FDA, the agency cannot assure their quality and safety. The use of such violative products may pose health risks to consumers.

Potential hazards may come from ingredients that are not allowed to be part of a toy and childcare article product. The use of substandard and possibly adulterated toy and childcare article product may result to health risks including, but not limited to, endocrine disruption and reproductive or development effects; or may result to injury, choking or suffocation due to its small or broken parts.

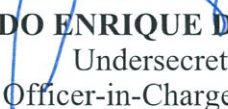
In light of the foregoing, the public is advised not to purchase the aforementioned violative product. Moreover, the public is advised to always check if a toys and childcare articles product is notified with the FDA. The FDA website (www.fda.gov.ph) has a *Search* feature which may be used by typing in the name of the product before purchasing.

All concerned establishments are warned not to distribute violative toys and childcare articles products until they have been issued the appropriate authorization, a License to Operate (LTO) for the establishment, and a Certificate of Product Notification (CPN) for the toys and childcare articles product.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that violative products are not sold or made available in the market or areas of jurisdiction.

To report any sale or distribution of unnotified toys and childcare articles products, the online reporting facility, **eReport** can be accessed at www.fda.gov.ph/ereport, or call us at the Center for Cosmetics Regulation and Research (CCRR) hotline **(02) 8857-1900 loc. 8113 or 8107**.

Dissemination of this advisory to all concerned is hereby requested.


ROLANDO ENRIQUE D. DOMINGO, MD, DPBO
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DTN: 20200227105107