



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

July 29, 2020

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*Sent via email to:* [mark@phaionline.org](mailto:mark@phaionline.org)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to take actions to:

- Enforce 21 C.F.R. §§ 101.3, 101.7, 102.5 and 107 against misbranded “transition formula” products represented or purported to be for children 9 to more than 12 months of age;
- Amend 21 C.F.R. § 101.3 to expressly prohibit the use of the term “infant formula” or “formula” on any drink products represented or purported to be for use by children more than 12 months old; and
- Amend 21 C.F.R. § 102 to establish a common or usual name for nonstandardized beverages represented or purported to be for use by children 12 to 36 months old, and to require disclaimers to clarify age of use and proper nutrition for young children

Your submission was received by this office on 07/28/2020, and it was assigned docket number FDA-2020-P-1718. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Malvin  
Supervisory Administrative Proceedings Officer  
Dockets Management Staff

FDA/Office of Operations (OO)

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