



JAN 25 2021

Mark A. Gottlieb, JD  
Executive Director  
Public Health Advocacy Institute, Inc.  
360 Huntington Avenue, Ste. 117CU  
Boston, MA 02115

Re: Docket No. FDA-2020-P-1718

Dear Mr. Gottlieb,

This letter is in response to your petition (FDA-2020-P-1718) dated July 28, 2020, requesting that the Food and Drug Administration 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, to require disclaimers to clarify age of use and proper nutrition for young children

In accordance with Title 21 Code of Federal Regulations 10.30(e)(2), this letter is to advise you that we have not been able to reach a decision on your petition within the first 180 days of its receipt because of other agency priorities and the limited availability of resources. We will complete our review of your petition and consider any amendments to our regulations as warranted and in the context of other program priorities within the Center.

Should you have additional questions, do not hesitate to contact us.

Sincerely yours,

Claudine Kavanaugh, Ph.D., MPH, RD  
Director  
Office of Nutrition  
and Food Labeling  
Center for Food Safety  
and Applied Nutrition

cc:

HFA-305 (Dockets Management Staff)

HFS-024 (Strambler)

HFS-800

HFS-800 (Benjamin)

HFS-800 (Hansen)

HFS-800 (Kavanaugh)

HFS-820

HFS-820 (Amaguana)

HFS-820 (Szybist)

HFS-830 (Fitzpatrick)

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R/D: HFS-820: RMAmaguana: 01/14/2021

Reviewed: HFS-820: LCox: 01/14/2021

Reviewed: HFS-820: LSzybist: 1/21/2021

Reviewed: HFS-800: CKavanaugh/PHansen: 1/22/2021

F/T: HFS-820: JEAH: 1/20/2021

**ROUTING AND TRANSMITTAL SLIP**

Date

01/21/2020

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Miguel Amaguana, ONFL,CFSAN, FDA	RMA	01/21/2021
2. Linda Cox, ONFL,CFSAN, FDA	LCC	01/21/21
3. Lynn Szybist, ONFL,CFSAN, FDA	Lynn M. Szybist -S	Digitally signed by Lynn M. Szybist -S Date: 2021.01.21 15:46:42 -05'00'
4. Bertha Stanley, ONFL,CFSAN, FDA		
5. Claudine Kavanaugh, Ph.D.,ONFL, CFSAN, FDA	CAK	1/22/21
<input type="checkbox"/> Action	<input type="checkbox"/> File	<input type="checkbox"/> Note and Return
<input type="checkbox"/> Approval	<input type="checkbox"/> For Clearance	<input type="checkbox"/> Per Conversation
<input type="checkbox"/> As Requested	<input type="checkbox"/> For Correction	<input type="checkbox"/> Prepare Reply
<input type="checkbox"/> Circulate	<input type="checkbox"/> For Your Information	<input type="checkbox"/> See Me
<input type="checkbox"/> Comment	<input type="checkbox"/> Investigate	<input checked="" type="checkbox"/> Signature
<input type="checkbox"/> Coordination	<input type="checkbox"/> Justify	

**REMARKS**

**DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions**

<b>FROM:</b> (Name, org. symbol, Agency/Post) James Hall, ONFL, FDA	<b>Room No.-Bldg.</b> 4D-044-CFSAN
	<b>Phone No.</b> (240) 402-2371

5041-102

OPTIONAL FORM 41 (Rev. 7-78)  
Prescribed by GSA  
FPMR (41 CFR) 101-11.206