DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 15, 2022

Meredith Stevenson
Center for Food Safety
518 C Street, N.E. Suite #200
Washington, D.C. 20002

Jaydee Hanson
International Center for Technology Assessment
303 Sacramento St, 2nd Floor
San Francisco, CA 94111

Sent via email to: mstevenson@centerforfoodsafety.org, jhanson@icta.org

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug undertake the following actions with regards to nanomaterial products in infant formula:

1. Amend regulations directed at FDA's oversight of nanomaterial products including:
    a. An amendment to 21 C.F.R. § 106.3 including the production of engineered nanoparticles as an additional express example for what constitutes a "major change" in infant formula;
    b. An amendment of 21 C.F.R. § 106.140 to include specific reference to engineered nanoparticles as a reason to notify FDA of a change in infant formula that may adulterate the product;
    c. An amendment to the table set out in 21 U.S.C. § 350a(i) and in its regulations at 21 C.F.R. § 107.100(a) to include nanomaterials with defined maximum levels;
    d. An amendment of 21 C.F.R. § 106.3 to define terms necessary to regulate engineered nanomaterial products in infant formulas in accordance with the European Commission's definitions, see note 124;
    e. A revision of FDA's 2014 Guidance on Assessing Significant Manufacturing Process Changes13 to expressly include infant formula; and
    f. An update to FDA's regulations based on the 2014 guidance.

2. Declare all currently available infant formulas containing engineered

nanoparticles as adulterated and misbranded and require a recall under 21 C.F.R. § 107.200.

3. Amend 21 C.F.R. § 106.40(a) so as to expressly prohibit the use of the GRAS for nanomaterials in infant formula in accordance with FDA's rationale in the 2014 guidance document.

4. Declare engineered nanoparticles in infant formula an imminent hazard to human health under 21 C.F.R. § 2.5(a).

Your petition was received and processed under CFR 10.30 by this office on 02/14/2022 and assigned docket number FDA-2022-P-0182. Please refer to this docket number in future correspondence on this subject with the Agency.

Also, note that the acceptance of the petition for filing is a procedural matter and in no way reflects the agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.02.15 11:38:51 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)