U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

August 11, 2022

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Center for Food Safety
518 C Street, N.E. Suite #200
Washington, D.C. 20022

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

Re: Docket Number FDA-2022-P-0182

Dear Ms. Stevenson and Mr. Hansen:

This letter is in response to your citizen petition (FDA-2022-P-0182) received on February 14, 2022, in which you requested the Food and Drug Administration (FDA) 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 Changes[13] 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).

We are advising you, in accordance with 21 CFR 10.30(e)(2), that we have not reached a decision on your petition within the first 180 days of its receipt, nor as of the date of this letter, because of other agency priorities and the limited availability of resources. When we complete our review of your petition, we will notify you of our decision. If you have any questions, please contact us.

Sincerely,

Claudine J. Kavanaugh -S

Digitally signed by Claudine J. Kavanaugh -S
Date: 2022.08.11 12:16:42 -04'00'

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Director
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