May 20, 2024

Submitted via email: MainePackagingEPR@maine.gov

State of Maine
Department of Environmental Protection
17 State House Station
Augusta, ME 04333

RE: Packaging Material Exemption Request for Packaging Stewardship Program

To Whom It May Concern,

Nestlé is a trusted leader in nutrition, health, and wellness. Nestlé is the world's largest food and beverage company, and the U.S. is Nestlé S.A.'s largest market with a combined product sales totaling more than $28 billion. The Nestlé portfolio in the U.S. includes conventional foods and beverage products, pet foods, infant and childhood foods, and more. Nestlé Health Science, a Nestlé operating company, represents a portfolio that includes pharmaceutical products, medical foods, foods for special dietary use (FSDU), oral nutritional supplements (ONS), and dietary supplements. These products are relied upon by patients and consumers across the country, including in Maine.

Nestlé Health Science supports the Packaging Stewardship Program's objectives to reduce the volume and increase the recyclability of packaging materials and is taking significant strides to do so across our broad product portfolio.[1] The safety, security, and availability of federally-regulated healthcare products must be considered when implementing any such packaging solutions. It is therefore necessary, and as required in the statute, to consider federal regulations that may diminish a producer's ability to meet these objectives (38 M.R.S. § 2146 Section 13(D)). We appreciate the Department's acknowledgment of the complexity of federal laws and regulations in this space and the invitation to provide this exemption request.

Specifically, we are requesting an exemption for medical food products, FSDU, and infant formula, including exempt infant formulas.[2] Each of these product categories is defined by, and

[1] Our sustainable packaging strategy | Nestlé Global (nestle.com)
[2] Nestlé Health Science also draws your attention to comments previously submitted by the Consumer Healthcare Products Association on August 25, 2023, and October 31, 2023, seeking exemption for over-the-counter drug products. Similar to medical nutrition products, the FDA regulates drug product packaging and labeling (21 CFR

subject to, federal regulations. A medical food is defined in section 5(b)(3) of the Orphan Drug Act as a food formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Special dietary uses include dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight, as well by reason of age, including but not limited to infancy and childhood (21 CFR Part 105). Not to be confused with this exemption request, an exempt infant formula is an infant formula intended for commercial or charitable distribution that is represented and labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems (21 CFR Part 107.3). While both standard and exempt infant formulas are federally regulated, exempt infant formulas are designed for specific medical conditions and are a distinct regulatory category not subject to the same regulations as standard infant formulas.

Medical foods, FSDU, and exempt infant formulas are often prescribed by a healthcare provider as medically necessary, may provide sole-source nutrition for vulnerable populations, and in some cases may be paid for by government programs such as Medicare, Medicaid, or Women, Infants, and Children (WIC). Specialized packaging is often required for these products to protect their quality and integrity during manufacturing and throughout shelf life, as well as to safely deliver the product to the patient. For example, enteral nutrition products, including nasogastric and gastronomy tube feedings, may require flexible construction, specialized connection devices, and aseptic manufacturing. Clinical guidelines on safe practices further dictate functionality requirements for packaging and proper handling, including limitations on reusability.[3] Infant formula packaging and packaging changes must be reviewed by FDA and are subject to federal food additive regulations for food contact materials (21 CFR Part 106.40). Infants are at an increased risk of exposure from potential migrants from food contact substances and, thus, require extensive migration studies, exposure estimations, and toxicological review.[4] Finally, federal law designates medical foods and infant formula as critical foods for which disruptions in manufacturing and access are to be avoided through risk management plans and, in the event of a meaningful disruption, be reported to FDA.

Part 211), including tamper-evident packaging requirements (Part 132), and certain drug product packaging is regulated by the Consumer Product Safety Commission (CPSC) under the Poison Prevention Packaging Act (PPPA).

[3] American Society for Parenteral and Enteral Nutrition, ASPEN Safe Practices for Enteral Nutrition Therapy, Consensus Recommendation, JPEN 2016, www.nutritioncare.org.

[4] Guidance for Industry: Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk (fda.gov)

In summary, these products are regulated differently than other foods and beverages, are often medically prescribed for at-risk populations, and require specialized packaging to ensure quality, safety, and delivery to the patient. Including such products in this legislation could negatively impact patients and limit access to medically necessary and potentially life-sustaining products. Notably, other states have recognized the unique aspects of these medically necessary nutrition products, as well as over-the-counter drugs, and have taken steps to protect patient access. Colorado legislature made the exemption for "medical foods, and fortified nutritional supplements" in their House Bill 1355 section 25-17-703 Definitions (13)(b)(XIV). Similar exemptions were also included in Oregon SB 582 and California SB 54. We respectfully urge the Maine Department of Environmental Protection to adopt similar exemptions for medical foods, FSDU, and infant formula.

Citations in response to the specific questions posed by the Packaging Stewardship Program are in the Attachment, below. Thank you for the opportunity to submit this request.

Sincerely,

Moreno Perugini
President, Pharma, Medical, and Active Nutrition
Nestlé Health Science
moreno.perugini@us.nestle.com

Attachment

1. **Which federal laws or regulations preclude or significantly diminish a producer's ability to increase the recyclability or reduce the volume of packaging material? Please provide specific citations and language.**

Controls to prevent adulteration caused by ingredients, containers, and closures (21 CFR Part 106.40)

(a) The only substances that may be used in an infant formula are substances that are safe and suitable for use in infant formula under the applicable food safety provisions of the Federal Food, Drug, and Cosmetic Act; that is, a substance is used in accordance with the Agency's food additive regulations, is generally recognized as safe (GRAS) for such use, or is authorized by a prior sanction.

(b) Infant formula containers and closures shall not be reactive or absorptive so as to affect the safety of the infant formula. The following substances may be used as packaging material that comes in contact with an infant formula:

(1) A food additive that is the subject of a regulation issued under section 409(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)) and is used consistent with the conditions of use of that regulation;

(2) A food contact substance that is the subject of an effective notification under section 409(h) of the Federal Food, Drug, and Cosmetic Act and is used consistent with the conditions of use in that notification;

(3) A substance that is exempt from regulation as a food additive under § 170.39 of this chapter and its use conforms to the use identified in the exemption letter;

(4) A substance that is generally recognized as safe for use in or on infant formula or for use in infant formula packaging;

(5) A substance the use of which is authorized by a prior sanction from the Food and Drug Administration or from the U.S. Department of Agriculture; and

(6) A substance that is not a food additive within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(s)) because the substance is not reasonably expected to become a component of food or otherwise affect the characteristics of food.

Terms and Conditions (21 CFR Part 107.50)

(a) Terms and conditions. Section 412(f)(1) of the act exempts from the requirements of section 412(a), (b), and (c)(1)(A) of the act infant formulas that are represented and labeled for use by an infant who has an inborn error of metabolism or low birth weight or who otherwise has an unusual medical or dietary problem, if such formulas comply with regulations prescribed by the Secretary. The regulations in this subpart establish the terms and conditions that a manufacturer must meet with respect to such infant formulas.

…

(b)(3) To retain the exempt status of an infant formula covered by this paragraph, the manufacturer shall submit to the Food and Drug Administration (FDA), at the address specified in paragraph (e)(1) of this section, on or before May 21, 1986, or on or before the 90th day before the first processing of the infant formula for commercial or charitable distribution, whichever occurs later, the label and other labeling of the infant formula, a complete quantitative formulation for the infant formula, and a detailed description of the medical conditions for which the infant formula is represented. FDA will review the information under paragraph (d) of this section.

…

(d)(1) FDA's Center for Food Safety and Applied Nutrition will review information submitted by infant formula manufacturers under paragraph (b) (3), (b) (4), or (c)(4) of this section. On the basis of such review and other information available to the agency, the Center for Food Safety and Applied Nutrition may impose additional conditions on, or modify requirements for, the quality control procedures, nutrient specifications, or labeling of an infant formula, or withdraw a product's exempt status. Such determinations will be made by the Director of the Center for Food Safety and Applied Nutrition.

Critical Food (Consolidated Appropriations Act, 2023 / H.R. 2617)

Subtitle D. Infant Formula. Sec. 3401. Protecting Infants and Improving Formula Supply.

(a)(2) CRITICAL FOOD.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following: ‘‘(ss) The term ‘critical food’ means a food that is— ‘‘(1) an infant formula; or ‘‘(2) a medical food, as defined in section 5(b)(3) of the Orphan Drug Act.’’.

...

Sec. 424. Requirements for Critical Food.

(a) NOTIFICATION OF MEANINGFUL DISRUPTION FOR CRITICAL FOOD.— ‘‘(1) IN GENERAL.—A manufacturer of a critical food (as defined in section 201(ss)) shall notify the Secretary of a permanent discontinuance in the manufacture or an interruption of the manufacture of such food that is likely to lead to a meaningful disruption in the supply of such food in the United States, and the reasons for such discontinuance or interruption, as soon as practicable, but not later than 5 business days after such discontinuance or such interruption.

2. **If content or construction standards are not directly specified in the citations referenced in response to Question 1, please explain how the cited federal laws or regulations indirectly specify content or construction standards.**

There are federal restrictions impacting medical food and infant formula products that limit options for both packaging materials and suppliers. Manufacturing and packaging sites must be registered with FDA, and packaging food contact materials must be approved for use. Any facility engaged in manufacturing, processing, packing, or holding medical foods for consumption in the United States must register with FDA. Further, food contact materials for use in product packaging must be used according to food additive regulations or be generally recognized as safe by the FDA for the intended use. A packaging change for an infant formula product is considered a “major notification” for which FDA is currently requiring at least 180 days for review prior to commercialization. Finally, medical food and infant formulas are designated as critical foods which require notification of meaningful disruptions to FDA and risk management plans to avoid such supply interruptions. Given the limited packaging materials available for these specialized products, impact of packaging changes on product quality and integrity, and long FDA review times for major packaging changes, such changes are likely to result in meaningful disruptions for critical food products.

3. **To which product or group of products do the federal laws or regulations referenced in response to Question 1 and any circumstances specified in response to Question 2 apply?**

These regulations apply to Medical Foods, FSDU, and Infant Formula, including Exempt Infant Formulas.

4. **Do the federal laws or regulations referenced in response to Question 1 and any circumstances specified in response to Question 2 apply to some or all packaging material associated with the product or group of products identified in response to Question 3? If some, identify the packaging material that is affected.**

The requirements discussed apply to all food contact packaging materials for these product categories. For enteral nutrition products, in particular, this can include the principal food contact packaging, as well as associated tubes, connection devices, etc.

5. Who should the Department contact with questions regarding this exemption request?

Please direct questions regarding this exemption request to Barry Ritz, PhD, Vice President of Regulatory, Scientific, and Medical Affairs, barry.ritz@rd.nestle.com.