HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

Submitted via Email: MainePackagingEPR@maine.gov

May 20, 2024

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

RE: Packaging Material Exemption Request for Packaging Stewardship Program

The Healthcare Nutrition Council (HNC) is providing comments and requesting an exemption under §2146, a measure "Stewardship program for packaging", for medical foods[1] and foods for special dietary use (FSDU)[2] and infant formula.[3] HNC is an association representing manufacturers[4] of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), including those categorized as medical foods and FSDU, and parenteral nutrition (PN). Our mission is to improve patient outcomes by advancing nutrition policies and actions that raise awareness and optimize access of essential nutrition support therapies across the continuum of care.

In recognition of the population served by medical foods and FSDUs, HNC notes that the Colorado legislature made this 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. HNC urges the Maine Department of Environmental Protection to adopt similar exemptions for medical foods, FSDU, and infant formula.

HNC submits the following exemption request form, answering the questions provided in the recently published "EPR update for producers of federally-regulated packaging material."

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.

HNC requests an exemption of medical foods, FSDU, and infant formula, which are unique food products defined by federal laws/regulations.

Medical foods are defined under 21 USC 360ee(b)(3):

> The term "medical food" means a food which is 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

[1] A **medical food** as defined in section 5(b)(3) of the Orphan Drug Act. 21 USC 360ee(b)(3): "a food which is 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**."
[2] 21 CFR Part 105
[3] 21 CFR Parts 106 and 107
[4] HNC members are Abbott Nutrition, Nestle Health Science, and Nutricia North America.

requirements, based on recognized scientific principles, are established by medical evaluation.

FSDU are defined under 21 CFR Part 105:
Part 107.3.

(a) (1) The term *special dietary uses,* as applied to food for man, means particular (as distinguished from general) uses of food, as follows:

(i) Uses for supplying particular 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;
(ii) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;
(iii) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

Infant formula is defined under 21 CFR Part 107.3:

The following definitions shall apply, in addition to the definitions contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act):

Exempt formula. 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.
Manufacturer. A person who prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of an infant formula or packages or labels the product in a container for distribution. The term “manufacturer” does not include a person who prepares, reconstitutes, or mixes infant formula exclusively for an infant under his/her direct care or the direct care of the institution employing such person.
References. References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

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.

Medical Foods, FSDU, and infant formula can be required to meet specific nutrient levels and are often used under the direction of a medical professional. The Food & Drug Administration published an industry guidance document clarifying that medical foods are intended to meet distinctive nutritional requirements of a disease or condition and are used under direction or supervision of a medical professional. They are specifically formulated and processed in order to meet the nutritional requirements of the particular disease or condition that they are intended to treat. Alternative packaging could jeopardize the nutrient integrity of these products and risk reducing the quality of the nutrient delivery. The nutrient levels of each product are tailored to meet the specific needs of the consumer and must be maintained during the entirety of its shelf

life. The nutrients must also withstand rigorous manufacturing processes, such as high temperature and high pressure, which necessitate a multi-layer container that can limit recyclability.

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?

The aforementioned laws and regulations refer to Medical Foods, FSDU, and infant formula.

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 packaging material associated with Medical Foods, FSDU, and infant formula is relevant to ensuring the quality and integrity of the food. These requirements apply to all packaging that can have an impact on the safety and nutrient quality of these Federally regulated medical nutrition products.

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

If you have any questions, please contact Peter Sahagian, Healthcare Nutrition Council, at psahagian@healthcarenutrition.org or 202-207-1120.

Sincerely,

Carla A. Saunders

Carla Saunders
Executive Director