



HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

Submitted via Email: rulecomments.dep@maine.gov

March 18, 2024

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

RE: Request to Amend Chapter 428: Stewardship for Program Packaging

The Healthcare Nutrition Council (HNC) is providing comments and requesting an amendment to §2146, a measure "[Stewardship program for packaging](#)", to exempt medical foods,¹ foods for special dietary use (FSDU),² and infant formula. HNC is an association representing manufacturers³ of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), including those categorized as medical foods, 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.

Medical foods, FSDU, and infant formula are often medically necessary and thus prescribed by a healthcare provider, may provide sole-source nutrition for vulnerable populations, and may be paid for by government programs such as Medicare and Medicaid, including them in this legislation could negatively impact patients and potentially limit their access to these important and at times lifesaving products. Specialized packaging is often used for these products to protect their quality and safety as well as ensuring nutrient delivery throughout product shelf life. Medical foods, FSDUs, and infant formula are often medically indicated and used with healthcare provider recommendation or supervision. Efficacy and application of delivery are paramount when designing packaging for these products and the specific and unique nature of their use necessitates specific and unique considerations regarding their inclusion in general packaging stewardship programs. Our goal is to ensure patients and families continue to have access to affordable and effective nutrition products that are life-sustaining and provide required nutrition to promote health and wellbeing.

Our proposed amendment is noted in **bold language** below:

2(W)(3). Producer includes a low-volume producer, as defined in 38 M.R.S. § 2146(1)(G), and a franchisor of a franchise located in the State but does not include the franchisee operating that franchise. Producer does not include a nonprofit organization exempt from taxation under the United States Internal Revenue Code of 1986, Section 501(c)(3). **Producer does not include manufacturers of medical foods or foods for special dietary use.**

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 HNC members are Abbott Nutrition, Nestle Health Science, and Nutricia North America.



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Thank you for considering the above amendment to exempt medical foods and FSDU manufacturers from §2146 and ensuring patients and families can have continued access to affordable specialized nutrition products. If you have any questions, please contact Peter Sahagian, Healthcare Nutrition Council, at psahagian@healthcarenutrition.org or 202-207-1120.

Sincerely,

A handwritten signature in black ink that reads "Robert Rankin". The signature is written in a cursive, flowing style.

Robert Rankin
Executive Director