

Submitted via Email: [rulecomments.dep@maine.gov](mailto:rulecomments.dep@maine.gov)

August 26, 2024

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

RE: Request to Amend “Part 2: Conceptual draft rules for Stewardship Program for Packaging”

The undersigned organizations are providing comments on the reposted draft rule §2146, a measure “[Stewardship program for packaging](#).” We are reiterating our prior request to exempt medical foods,<sup>1</sup> foods for special dietary use (FSDU),<sup>2</sup> and infant formula from the rule. We acknowledge that the draft rule outlines a process for requesting an exemption from the post-consumer recycled material incentive fee. However, other states have included exemptions from similar extended producer responsibility programs. 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.

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

(D). Producer includes a low-volume producer 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, foods for special dietary use, or infant nutrition formula.**

Medical foods and FSDU 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. 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. Specialized packaging is often used for these products to protect their quality and safety as well as ensuring nutrient delivery through product shelf life. Including them in this program could negatively impact patients and potentially limit their access to these important and at times lifesaving products.

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<sup>1</sup> 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**.”

<sup>2</sup> 21 CFR Part 105

These products are regulated differently than other foods and beverages and are often prescribed by a healthcare provider to serve a specific purpose when nutrition needs cannot be met through other foods. Our goal is to ensure patients and families continue to have access to affordable nutrition products that are life-sustaining and provide required nutrition to promote health and wellbeing.

Thank you for considering the amendment to exempt medical foods, FSDU, and infant formula 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](mailto:psahagian@healthcarenutrition.org) or 202-207-1120.

Sincerely,

American Partnership for Eosinophilic Disorders  
HCU Network America  
Healthcare Nutrition Council