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# Healthcare Nutrition Council

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*Sent via Email*

August 25, 2017

Agricultural Marketing Service  
US Department of Agriculture  
1400 Independence Ave SW  
Washington, DC 20250

**RE: Proposed Rule Questions Under Consideration (National Bioengineered Food Disclosure Standard)**

Dear Sir or Madam:

The Healthcare Nutrition Council (HNC), representing manufacturers of enteral nutrition formulas, parenteral solutions, supplies and equipment, including medical foods, submits these comments to the US Department of Agriculture (USDA) Agricultural Marketing Service (AMS) with regard to the proposed questions under consideration for the National Bioengineered Food Disclosure Standard. HNC has comments specifically related to question #11, which is noted below:

**Question:** Could AMS consider whether a type of food is considered a bioengineered food under the determination process?

**Context:** AMS is considering if it could exclude certain food types such as medical food and dietary supplements, among others from requiring disclosure as bioengineered.

HNC believes that medical foods, as suggested within the context of question #11, should be exempt from the requirement for disclosure of bioengineered ingredients. Medical foods are subject to their own statutory and regulatory requirements, which are inapplicable to conventional foods. They are a special category of food products that are designed to address the distinctive nutritional requirements of a disease or condition. Unlike conventional foods, they are intended exclusively for use under medical supervision. Therefore, the decision whether to use these products should be driven by the nutritional adequacy of a formulation in the medical management of the specific disease or medical condition, as determined by the assessment of a healthcare professional.

The transparency rationale which requires disclosure would not be applicable to medical foods due to their purpose of managing specific diseases or health conditions. With the safety of bioengineered ingredients well established by the FDA, their presence should not be a factor in decisions regarding which healthcare products to use for the management of patient's health. Furthermore, we are concerned that disclosure of the presence of genetically modified ingredients in these products could dissuade patients from compliance, which could be detrimental to and the appropriate management of their conditions. Finally, we are not aware of any condition that would require products made without bioengineered ingredients for the specific dietary management of that condition.

In conclusion, HNC supports an exemption within the standard for medical foods. Thank you for the opportunity to comment. If you have any questions or would like additional information, please contact me at [acooke@kellencompany.com](mailto:acooke@kellencompany.com) or 202-207-1130.

Sincerely,



Allison Cooke, MPH  
Executive Director  
Healthcare Nutrition Council