

# FDA's final medical foods guidance maintains restrictions on category

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## Introduction

On May 12 2016 the Food and Drug Administration (FDA) finalised its August 2013 draft guidance entitled "Frequently Asked Questions About Medical Foods; Second Edition". Although the draft guidance was issued nearly three years ago and was the subject of numerous comments from stakeholders, the final guidance reflects few changes and ignores the legal and science-based comments from the industry. In particular, it does not address critical research in nutritional science relevant to the role of specially formulated foods for a range of medical conditions.

The 1988 Orphan Drug Amendments defined a 'medical food' as:

*"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>(1)</sup>

In 1996 the FDA published and then, after significant substantive comments were filed, withdrew an advance notice of proposed rulemaking that attempted to provide definitions and clarification on this statutory definition.<sup>(2)</sup> In place of the advance notice, the FDA issued very general guidance in 2007 in the form of questions and answers. This guidance has been revised twice, most recently on May 12 2016.

## Guidance

The most significant error in the guidance is the retention of the phrase "which cannot be achieved by the modification of the normal diet alone". This phrase is not a part of the medical food definition and not a proper part of the regulatory regime. This misplaced addition – the subject of many comments to the FDA – comes from a labelling exemption that the FDA included in the regulations issued pursuant to the Nutrition Labelling and Education Act of 1990.<sup>(3)</sup> The FDA continually relies on this prong of the act's exemption provisions to restrict the medical foods category, claiming that it is trying to "clarify the statutory definition of a medical food". Instead, the FDA is effectively adding a requirement that does not exist in the law. Numerous comments to the draft guidance noted this error in the FDA's approach, but the final guidance does nothing to correct its mistake.

Moreover, the final guidance reaffirms that the FDA views medical foods as inappropriate for diabetes because the disease can be managed by modifying a 'regular diet'. This is perhaps the starkest example of the disconnect between nutritional science and the FDA's approach. Many of the comments sent to the FDA cite scientific research showing that individuals with diabetes benefit significantly from medical foods, and that the agency's exclusion of diabetes from the types of condition that may be treated with medical foods is likely to harm public health.

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## Comment

The FDA released the final guidance two days after announcing that it will re-evaluate its definition of 'healthy' in regulations addressing nutrient content claims. This announcement makes it clear that the FDA is willing to consider evolving nutritional science in its approach to certain claims. However, the FDA's treatment of the medical food category reflects no such recognition in the context of foods assisting individuals in managing nutritional needs associated with disease.

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## Endnotes

- (1) 21 USC § 360ee(b)(3).
- (2) 61 Fed Reg 60661 (November 29 1996); 69 Fed Reg 68831 (November 26 2004).
- (3) 21 CFR § 101.9(j)(8)(ii).

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