



Archer Daniels Midland Company  
North American Headquarters  
PO Box 1470  
Decatur, Illinois 62525  
t (217) 424.5200  
-  
ADM.COM

May 02, 2019

**Citizen Petition Regarding Energy/Caloric Value for Nutrition Labeling of Dietary Fiber Component in Fibersol® Resistant Maltodextrin**

Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fisher Lane  
Room 1061  
Rockville, MC 20852

Dear Commissioner,

Archer Daniels Midland Company submits this Citizen Petition in accordance with 21 CFR § 10.30 and 21 CFR § 10.20 to request that the dietary fiber component of Fibersol® resistant maltodextrin be assigned an energy value of 0.7 calories per gram for use in Nutrition and Supplement Facts labels. The basis for this request is set forth below.

**A. Action Requested**

Archer Daniels Midland Company (ADM) requests the Commissioner to amend 21 CFR § 101.9, Nutrition Labeling of Food to indicate the energy value for the fiber component of Fibersol resistant maltodextrin to be 0.7 calories per gram as the basis for determining its contribution to the caloric content of foods and supplements. Information to support this request is contained in this petition and as attachments that demonstrate that Fibersol resistant maltodextrin provides this energy value instead of the default energy value at 2 calories per gram for soluble non-digestible carbohydrates indicated to be applicable to soluble fibers.

**Background**

Under Section 21 CFR § 184.1444, maltodextrin is a non-sweet nutritive saccharide polymer that consists of D-glucose units linked primarily by [alpha]-1-4 bonds and has a DE of less than 20. Fibersol resistant maltodextrin products meet these specifications. Specifically, ADM



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(through its joint venture partner Matsutani) has written FDA agreement that Fibersol resistant maltodextrin meets the definition of maltodextrin in 21 CFR § 184.1444. As such, Fibersol resistant maltodextrin is a Generally Recognized as Safe (GRAS) substance with no limitations on use other than good manufacturing practice. From a chemical/physical perspective, Fibersol resistant maltodextrin is primarily composed of soluble glucose polymers having a degree of polymerization (DP) of 3 or greater; however, small amounts of water and carbohydrates with DP of less than 3 are part of the commercial ingredient “As Is.”

## **B. Statement of Grounds**

Fibersol resistant maltodextrin was the subject of a Citizen Petition submitted to the FDA requesting consideration for labeling as a dietary fiber based on clinical data demonstrating physiological effects that are beneficial to human health.<sup>1</sup> FDA subsequently granted ADM's Citizen Petition request and has stated resistant maltodextrin/dextrin to be subject to enforcement discretion regarding its labeling of dietary fiber pending completion of a rulemaking regarding revising our regulations as part of a June 2018 guidance document.<sup>2,3</sup> As such, Fibersol resistant maltodextrin can be labeled as dietary fiber including soluble fiber when this latter label element is used on a voluntary basis.

### ***Rationale for Resistant Maltodextrin Having an Energy Value of 0.7 Calories per Gram***

The detailed rationale for recognition of the dietary fiber portion in Fibersol resistant maltodextrin as having an energy value of 0.7 calories per gram is provided in Attachment A, "Scientific Evidence to Support the Dietary Fiber Component of Fibersol Resistant Maltodextrin as Having an Energy Value of 0.7 Calories per Gram for Labeling Purposes." This document includes rationale for the use of net energy as a suitable endpoint in establishing a caloric value, and both abbreviated and expanded tabular summaries of the clinical scientific evidence relevant to the determination of the energy value for the fiber component of Fibersol resistant

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<sup>1</sup> Docket Number FDA-2016-P-2377 available at [www.regulations.gov](http://www.regulations.gov).

<sup>2</sup> June 13, 2018 acknowledgement letter from Douglas Balentine, Director, Office of Nutrition and Food Labeling, Docket ID: FDA-2016-P-2377-0011 available at [www.regulations.gov](http://www.regulations.gov).

<sup>3</sup> “Guidance for Industry: The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-declaration-certain-isolated-or-synthetic-non-digestible-carbohydrates-dietary>.



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maltodextrin. The abbreviated tabular summary identifies published studies which meet acceptable criteria for assessing energy value. The totality of scientific evidence demonstrates that the dietary fiber component of Fibersol resistant maltodextrin has an energy value of 0.7 calories per gram. In light of this evidence compiled in Attachment A, ADM presents the position that the dietary fiber component of Fibersol resistant maltodextrin should have an energy value of 0.7 calories per gram as compared to the default energy value for soluble fiber of 2 calories per gram under FDA's proposed definition of dietary fiber. For FDA's review, Appendix A contains each publication referenced in Attachment A.

#### **C. Environmental Impact**

The actions requested in this Petition are not within any of the categories for which an environmental assessment is required pursuant to 21 CFR Section 25.22. Additionally, the actions requested in this Petition are exempt from the requirement of an environmental assessment pursuant to 21 CFR Section 25.30(k). Furthermore, the undersigned do not believe that the actions requested in this Petition would have any environmental impact.

#### **D. Economic Impact**

An economic impact report is required only when requested by the Administration and such report has not been requested. 21 C.F.R. § 10.30(b).

#### **E. Certification**

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

A handwritten signature in black ink, appearing to read "Brent D. Flickinger", written in a cursive style.

Brent D. Flickinger, Ph.D.  
Vice President, Product Quality, Regulatory and Scientific Affairs