



James R. Randall Research Center

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February 20, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA Docket No. 2003N-0496
Food Labeling: Health Claims; Dietary Guidance
68 Federal Register. 66040-66048 (November 25, 2003)

Dear Sir/Madam:

The Archer Daniels Midland Company (ADM) is pleased to provide FDA with comments regarding the Advance Notice of Proposed Rulemaking (ANPR) for Food Labeling: Health Claims and Dietary Guidance. ADM is a world leader in agricultural processing and is one of the world's largest processors of soybeans, corn, wheat and cocoa. ADM is also a leader in supply of soy meal and oil, ethanol, high fructose corn syrup and flour. In addition, ADM is building a position in such value-added products as specialty food ingredients, bioproducts and nutraceuticals (such as Vitamin E, sterols, isoflavones)

ADM welcomes the opportunity to be a participant in this rulemaking process for health claims and dietary guidance and supports the Agency's efforts to develop a process that facilitates the communication of truthful and non-misleading information to consumer. We support the development of a regulatory process by which scientifically-based, qualified health claims can be communicated to the consumer. We are providing our general comments and suggestions as follows.

ADM concurs FDA adopt Option 1 (codification of the current interim procedures and evidence-based system) with some modifications for the regulation of qualified health claims. We concur with the agency that the current procedures are consistent with the spirit of NLEA in that it maintains a system in which the data supporting qualified health claims are reviewed and approved prior to product labeling. This process establishes common and uniform scientific standards and standardization of the health claim language across industry and will help avoid public confusion based on variations of labeling for a similar qualified health claim. We also support the use of enforcement discretion letters, as this provides the best, most flexible and rapid mechanism by which FDA can revise a decision based on subsequent data. Thus, this process includes a system that addresses emergent changes in scientific evidence.

1) It is important to the food ingredient and dietary supplement industry that FDA establishes and adheres to a reasonable timeframe for review.

ADM recommends that the review period be shortened from 270 days.

Additionally, we propose a two-tiered approach for the review of qualified health claims which include scientific data submitted by a petition and a priority review with a shorter approval time period for petitions that include competent and reliable scientific data and contain an independent expert review of the data or a report authored by a recognized scientific body. Both these two processes as described below will facilitate a timely review of qualified health claim petitions.

I) A review period of 90 days after receipt of submission which includes an outside qualified expert review report written by an independent expert panel or by a recognized expert group such as the Institute of Medicine, American Heart Association, American Dietetic Association or the Federation of American Societies of Experimental Biology, etc. The health claim is automatically granted at the end of the 90 day period unless FDA denies the claim, or

II) A review period of 180 days after receipt of a claim submission if the Sponsor submits data only. The health claim is granted at the end of this time period unless FDA denies the claim. To facilitate identification of approved claims, we propose a public listing of filed notifications and to show whether these claims are pending or the review period has lapsed.

2. The industry needs more FDA guidance on the variations of acceptable wording for the health claims category.

This guidance from FDA will give the manufacturer flexibility to describe the claims and benefits of the product in a truthful manner via labeling.

3. It is important not to dilute the importance of the claims categories by including a marginal health claim category such as “D” which contain “very limited and preliminary scientific research and little scientific evidence”.

ADM recommends deleting health claim category “D” as it will not be meaningful or of value to the consumer because of the vague and unsubstantiated

benefits. Deleting this category will unclutter the claim categories to avoid confusion to the consumers. Hence there will only be “A”, “B” and “C” health claims category.

- 4. It is critical to the industry that the existing approved health claims in foods and provisions for structure-function claims in dietary supplements remain unchanged to prevent disruption in commerce.**

There is no need to re-evaluate the current approved health claims and structure function claims as they have already undergone the FDA review process and/or due regulatory process.

- 5. It is important that FDA clarify whether the health claim categories will be assigned a ranking as in “A”, “B” and “C” grades in addition to the qualifying claims language.**

A simple and effective visual symbol such as an A, B or C letter grades for the accepted specific health claim category on the product package will be helpful to the consumer in making informed choices.

- 6. It is important that FDA address the number of claims allowed on a product package and the best way to present such claims on the same package label.**

There will be situations when a food product or dietary supplement may contain the following: a) an ingredient which may contain multiple health benefits and claims such as plant phytosterols, vitamin E or soy isoflavones, and b) a product

with multiple ingredients which individually may contain a different health benefit and health claim, such as breakfast cereals, health bars and functional beverages. Manufacturers need clearer guidance on how to label under these situations to avoid confusion to the consumers.

7. It is important for the manufacturer to protect the confidentiality of their scientific data based on the unique properties and specifications of their product in order to have exclusivity to the qualified health claim.

The Sponsor company needs this incentive to protect their business investment in order to recover the considerable costs and resources incurred in conducting research and development and human clinical trials to substantiate the particular health claim. ADM recommends that FDA grants to the Sponsor time limited exclusivity on a submitted qualified health claim and allows that unpublished data remain confidential and not to be released under FOI until the Sponsor publishes the information. Substantiation data already in the public domain may be used by others to substantiate claims on their proprietary products.

8. An indication of FDA's role in the evaluation and determination of the health claim will increase consumer confidence in the product. ADM requests that FDA allow the following statements corresponding to the review situations.

I) For petitions which have been submitted and for which the time limited consideration period has expired and FDA has not denied the claim, the following

statement may be used: “FDA has reviewed and has not denied this health claim”.

II)) For petitions which FDA has reviewed and completed a favorable evaluation, the following statement may be used: “FDA has determined (or concluded) that *[insert health claim text ..]*”.

9. It is very important to know how the consumer will understand and use the qualified health claims to make informed dietary choices.

It is necessary for FDA to conduct consumer research to determine consumer attitude, perception and understanding on the benefits of the proposed qualified health claims language and labeling.

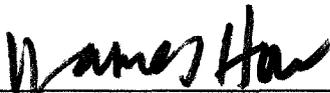
10. The public should be able to access information on the health claim submission and comment after the conclusion of the FDA review but not be involved in providing comments during the FDA review process.

This process provides the public transparency on the nature and purpose of the submission and the opportunity to comment after FDA has reviewed and published their conclusion without slowing down the review process. It will also protect the confidentiality of the submission dossier and protect the exclusivity of the qualified health claim to the Sponsor.

Conclusion

ADM appreciates the opportunity to comment on this important FDA initiative to develop a new regulatory process for qualified health claims. We encourage the development of a process that is transparent, flexible to the needs of emerging science, provides for fair marketing practices with truthful and non-misleading labeling and one which provides review of the petitions on a timely basis. ADM strives to provide safe and beneficial food and dietary supplement products for the health and well-being of the consumers.

Yours Sincerely,



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