



National Milk Producers Federation

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Producers Inc.
Bongards' Creameries
Cooperative Milk
Producers Association
Cortland Bulk Milk
Producers Cooperative
Dairy Farmers of
America, Inc.
Ellsworth
Cooperative Creamery
FarmFirst Dairy
Cooperative
First District Assoc.
Foremost Farms USA
Land O'Lakes, Inc.
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Producers
Maryland & Virginia
Milk Producers
Cooperative Association
Michigan Milk
Producers Association
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Dairymen's Company
Mount Joy Farmers
Cooperative Association
Northwest Dairy Assoc.
Oneida-Madison Milk
Producers Cooperative
Association
Prairie Farms Dairy, Inc.
Premier Milk Inc.
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Producers' Association
Select Milk
Producers, Inc.
Southeast Milk, Inc.
St. Albans Cooperative
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Creamery Association
United Dairymen
of Arizona
Upstate Niagara
Cooperative, Inc.
Zia Milk
Producers, Inc.

March 19, 2018

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2017-N-0763

Dear Sir or Madam:

The National Milk Producers Federation (NMPF) submits these comments in response to the proposed rule published in the *Federal Register* on October 31, 2017, entitled "Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease." NMPF, established in 1916 and based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of dairy producers on Capitol Hill and with government agencies.

NMPF supports the Food and Drug Administration's (FDA) proposed rule to revoke the present regulation authorizing the use of a health claim for a relationship between soy protein and reduced risk of coronary heart disease (CHD). We commend FDA for using the most recent science to evaluate the validity of health claims that were previously authorized. FDA's proposed rule is based on a rigorous, consistent, and objective evaluation of the scientific literature, including recently-published studies.

In particular, we note that in its review of relevant science, the agency has –

- Evaluated statistics and data in individual studies, not simply the study abstracts (cf. Ref. 182);
- Appropriately used valid surrogate endpoints for CHD, including high blood pressure and two measures of serum cholesterol (cf. 82 FR 209 at 50329);

- Used meta-analyses and reviews to identify relevant studies, but evaluated those studies independently rather than relying on conclusions in the meta-analysis or review (cf. 82 FR 209 at 50328); and
- Recognized the limitations of animal and *in vitro* studies, using them only as background for potential causative mechanisms (cf. 82 FR 209 at 50328).

Nutrition and health science continually changes, and FDA's regime for health claims must recognize this basic fact. In using its clear regulatory authority to "evaluate[] new scientific information that becomes available to determine whether it necessitates a change to an SSA health claim," FDA is appropriately recognizing that regulatory judgments do not stand for all time, but can and should be periodically reviewed in light of evolving evidence. SSA, or significant scientific agreement, is among the highest evidentiary standards to meet, and it is appropriate that SSA reflect up-to-date evaluations of relevant science so that consumer purchase decisions can be based on current and accurate scientific agreement.

NMPF strongly supports FDA's rigorous review of relevant science. At the same time, we note that the proposed rule was published nearly 10 years after FDA announced its intent to reevaluate the scientific basis for the soy protein health claim (the 2007 reevaluation notice). During this decade, food manufacturers were able to continue using the authorized soy protein health claim. In future cases, where there is enough question about a health claim to justify a reevaluation, NMPF respectfully urges FDA to strive for a more expeditious outcome. An expedited, but thorough, review will provide certainty that will benefit industry and consumers alike (e.g., manufacturers can best decide how to focus efforts for product development, and consumers may opt to switch their consumption to products that do have a health claim). At the same time, we recognize that resource constraints may delay FDA's timely action on these reviews. Should FDA request additional appropriations from Congress to address this and other needs, NMPF stands ready to support such requests.

FDA states that if the soy protein health claim is revoked, the agency intends to announce enforcement discretion on a qualified health claim involving the same subject matter (i.e., CHD risk). While recognizing in principle that qualified health claims may be useful to consumers, NMPF urges FDA to evaluate the wording of such a claim or claims carefully, to be sure that consumers are not misled into believing that evidence for soy protein's benefits is stronger than it actually is.

Finally, we are troubled that the aura of health and cardiovascular protection engendered by the soy protein health claim – which now appears unjustified, according to FDA's proposed rule – has undoubtedly benefited food manufacturers who seek to market soy-based products as “milk”, “cheese”, “yogurt” or other dairy imitators. Manufacturers of these products have traded on the inferred benefits both from a health claim (which no longer has significant scientific agreement) and from the name of a standardized dairy food (without complying with federal standards of identity). It is imperative that consumers have accurate label information in addition to health claims – specifically the name of the food, which also conveys nutrition information. We are on record on multiple occasions in calling for the agency to enforce its own regulations, specifically federal standards of identity for dairy foods, and we reiterate that plea now.

NMPF appreciates FDA's work on the proposed rule and again urges that it be adopted without change.

Thank you for the opportunity to share our perspectives. Please contact us if you have additional questions.

Respectfully,



Beth Panko Briczinski, Ph.D.
Vice President, Dairy Foods & Nutrition