NOVARTIS

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Hearing Clerk
USDA/AMS/Dairy Programs
STOP-9200, Room 1031
1400 Independence Avenue, SW
Washington, DC 20250-9200

August 15, 2005

Dear Sir or Madam:

On behalf of Novartis Nutrition Corporation (NNC), I am writing to express our views on proposals presented at the June 21-25, 2005 USDA Federal Milk Order Hearings in Pittsburgh, PA to amend the current fluid milk product definition in all Federal Milk Marketing Orders. NNC strongly opposes the adoption of any proposal eliminating the 6.5% nonfat milk solids standard; including replacing the existing standard with a 2.25% total protein level. We maintain that the current standard(s), applied within existing frameworks of exclusion based on "form and use" doctrine as well as the language in Sec. 1000.15 (b) 1, offers sufficient market clarity and economic equity to producers and manufacturers. A change in the standards that is too broad or without sufficient safeguards for products intended for special dietary use and/or nutritional beverages, may lead to health care providers and consumers, who are recommended to use our products, bearing increased costs and fewer health care options. While understanding that some in the dairy industry have concerns over new products with an unfair competitive advantage to fluid milk because of classification differences (low-carb milk and drinkable yogurt were specifically discussed at the hearings), NNC products are not marketed as an alternative to fluid milk. For the above reasons we urge you to not change the existing standard. Failing that, the USDA should ensure in the proposed and final rules that nutritional products are NOT classified as Class I fluid milk and that their status under the federal fluid milk order will not be impacted by any change in the standard. This could be accomplished by reiterating and clarifying the exemption language in Paragraph 1000.15 (b) 1.

Economic Implications

Novartis Nutrition is dedicated to researching, producing, and marketing nutritional products. These products are designed to meet nutritional needs of consumers, often patients, coping with a wide variety of medical conditions, either in a home care setting or while residing in hospitals or nursing

homes. Although some of the products that would be impacted by a change in the fluid milk standard do come in gable-top containers, these are fortified nutritional beverages and are not available in any half or full gallon containers. RESOURCE® Health Shake™, used in the treatment of malnutrition; RESOURCE® Shake Thickened™ used by malnourished patients with dysphagia; and RESOURCE® No Sugar Added Health Shake™ used in the treatment of malnourished diabetic patients are all examples of products that may be impacted by a change in standard. Currently, the preceding are not classified as Class I Fluid Milk; they are not sold in the dairy case of a retail outlet; and, they are not mass consumed by the public. Rather, they are recognized as distinct from Class I Fluid Milk due to their nutritional nature and level of nonfat milk solids; in addition, they are exclusively available via foodservice or health care channels.

None of the above products (or other, similar NNC products) are intended to compete with, or have any market advantage over, traditional Class I Fluid Milk. A change in standards resulting in the above products being re-classified as Class I product is not economically justified in that there would be zero positive net impact on fluid milk consumption – the main reason that the Dairy Farmers of America (DFA) originally sought a change in the standard. In addition, these types of products and others that perhaps would be brought into the Class I category under a new standard may result in higher costs for patients with special dietary and nutrition needs. Often times, these individuals are least able to absorb increased costs and because Medicare does not cover oral supplements, and state Medicaid coverage is limited, many patients may not be able to properly manage their illness through adequate nutrition intake. Ultimately, individuals otherwise able to manage a medical condition may develop more severe and acute symptoms that require more intense and costly treatments.

Proposals and testimony advocating a change to a 2.25% total protein minimum standard stated that no current products would be re-classified as Class I because of the change; opponents argued that a shift could result in re-classifications. Because of the differences of opinion surrounding the impact of a 2.25% standard, NNC is concerned that other existing nutritional products might be re-classified as Class I. None of the products that may be impacted are intended to compete for the same consumers or market share as traditional fluid milk. No NNC product is researched, produced, or marketed to compete with retail fluid milk.

Another market-centered concern expressed at the hearing – and one that makes the rationale of a change in the standard unwarranted as a benefit to dairy farmers and the fluid milk industry – surrounded products utilizing alternative sources of protein rather than exceeding a proposed 2.25% total dairy protein "minimum." With the uncertainty surrounding what could be included to determine protein levels (whey for example, is included in some proposals); manufacturers could move away from dairy-based protein sources to avoid being pulled into Class I. Such actions, while they may or may not be applicable to NNC products, could have a detrimental impact on the dairy industry as acceptable alternative protein sources could be used to replace milk sources. In addition, perhaps applicable to nutritional products, increased research, development and production costs could result in higher health care costs for consumers and providers.

Based on the above, we believe an outright elimination of the 6.5% standard or a replacement with a 2.25% total protein standard is unwarranted. Testimony at the hearing indicated such a shift in standard potentially would:

- Offer little economic benefit to Class I Fluid Milk Producers, and may place some at risk if manufacturers switch to non-dairy protein sources;

- Increase costs to health care programs and participants if medical nutrition products are re-classified as Class I.

Nutritional Products Should Remain Exempted

We believe Novartis Nutrition products should not be considered as Class I products even if USDA decides to move from the current 6.5% standard. It seemed that the focus of the Pittsburgh hearings centered on dairy industry concerns that new products were undercutting the market for Class I fluid milk product due to their ability to utilize new technology and remain below the 6.5% nonfat milk solid standard. The National Milk Producers Federation (NMPF) and the Dairy Farmers of America argued that in recent years products have entered the market in direct competition to Class I product in "form and use" but were able to stay below the Class I 6.5% threshold. As a result, they argued, these products achieved a cost advantage in a competitive market place.

The merit of their argument, as applied to the specific products introduced at the Hearings, is for USDA to analyze. However, NNC urges the USDA not to lose sight of nutritional products that could be impacted by removing or altering the existing standard. USDA officials asked many presenters about the form and use "doctrine's" place in defining Class I fluid milk product. NNC believes that in word and in practice, form and use should be a bright line determinant in the application of any fluid milk standards – as it is today.

Patients utilize NNC products when they are in need of nutrition as recommended by a health care professional. While some do come in carton form, they are not available in retail outlets as a refrigerated milk product. The "form" of some of these products is frozen and they are thawed before nutritional "use" consumption in a nursing or hospital facility as part of patient care. A changed standard could result in more types (not just frozen, for example) of nutritional products being at risk of reclassification. Even in their proposal to adopt a 2.25% protein standard, the NMPF sites form and use as the reason for changing existing standards to incorporate products in direct competition to fluid milk into the Class I category. They argue that certain competitive products are packaged, marketed, stored, and used exactly as Class I Fluid Milk. NNC does not have a position on the products sited by NMPF and others advocating for a change in the standard. Our potentially impacted products are not Class I in form or use. We strongly oppose any effort to weaken the form and use doctrine in theory or in word as part of the language in Section 1000.15 that exempts certain *types* of products, no matter the level of nonfat milk solids.

If the decision is to reclassify certain fluid milk products by adopting a new standard (or de facto elimination of the 6.5% standard), then we would propose clarification of paragraph 1000.15 (b) 1 language to specifically include medical nutrition products consumed for special dietary needs (which are not only distributed in a shelf stable form, but any form including frozen.) The written NMPF testimony (*NMPF Statement in support of Proposal Number 7: defining Class I on an all-dairy protein standard,* June 20, 2005, p.13) sites a 1974 decision introducing the dietary use (meal replacement) exception to certain markets as an important one. That decision stated such products "are specialty

food products prepared for limited use. Such formulas do not compete with other milk beverages consumed by the general public." [39 FR 11277, March 27, 1974; 58 FR 12659, March 5, 1993] Again, the language clearly points to use as a determinant of competition with fluid milk product. NNC products do not compete with fluid milk, that is not their intention. To eliminate any uncertainty we urge USDA, if a standard change is made, to clearly indicate that fortified nutritional beverages, products for special dietary use and medical foods will be excluded from Class I due to their form and use. To achieve this, altering the language in 100.15 b) 1) may be required. Traditionally, it has seemed the form and use doctrine (in theory and as written) coupled with the 6.5% standard had effectively assured legitimate nutritional products such as those manufactured by NNC were excluded from Class I. Our concern is that eliminating the 6.5% standard would reclassify some of our products into the Class I Fluid Milk definition. As a result, a clear and fair statement ensuring products such as ours will remain excluded from Class I due to their specialized nutritional and dietary use is needed. We strongly urge the Department to make it clear that medical nutrition products that do not compete with fluid milk will not be subject to being defined erroneously as Class I Fluid Milk.

Conclusion: Patient Care Paramount

We appreciate the USDA's efforts surrounding this important issue. NNC is committed to bringing the highest quality, most researched medical nutrition products in the marketplace to the health care professional, consumer, and patient. Many consumers rely on NNC products as an integral part of their health care plan. They utilize these products not as a replacement for fluid milk, but for special dietary and health reasons, many times at the direction of a health care professional. NNC objects to any change in the existing Class I standard that would cause higher costs for the consumer and patient population. In today's atmosphere of higher health care costs, keeping legitimate therapeutic nutritional products affordable is a benefit to all. Allowing patients to manage their conditions and avoid more severe illness are outcomes we all support. A change to the 6.5% standard without appropriate recognition and exemption of specialty nutritional products could result in higher patient costs, fewer patients effectively managing their nutritional needs, and cost increases to the health care system. Therefore, we urge the Department to take no action that would re-classify legitimate medical nutritional products as Class I Fluid Milk.

Thank you very much for the opportunity to share our views. We would welcome offering additional input at the Department's request. If you have any questions or need additional information, please feel free to contact me at (952) 848-6224.

Sincerely,

William H. Hoffman, IIII
Manager, Government Relations
Novartis Nutrition Corporation