

***Comments and Written Exceptions
Submitted by The Tipton Group, Inc.***

On behalf of:

***Bravo! Foods International Corporation
PepsiCo
Starbucks Corporation
Unilever United States, Inc.***

**Relative to the Proposed Rule; Recommended Decision issued by
USDA's Agricultural Marketing Service on
Wednesday May 17, 2006
(FR Vol. 71, No. 95 beginning on page 28590)**

Docket No. AO-14-A73, et al.; DA-03-10

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Findings to Which Exceptions are Being Taken

There are several findings that we believe are unsupported by the preponderance of the facts, evidence and expert opinions presented by witnesses during the hearing. Among them are:

1. The addition of a 2.25 percent true milk protein threshold;
2. The elevation of the subjective "form and intended use" criteria to override the more measurable compositional criteria; and,
3. The added new qualifying words that appear to limit the exclusion from the fluid milk product definition of formulas for infant feeding or dietary use (meal replacement) – "that are sold to the health care industry."

Elevating the Recommended Decision to full conformity with the plain majority of evidentiary support would require only minor modification of the proposed rule.

Suggested Modifications to the Recommended Decision

The following are suggested modifications to the Recommended Decision necessary to bring the order language into conformance with the exceptions we have set forth in this document:

Sec. 1000.15 Fluid milk product.

(a) Fluid milk products shall include any milk products in fluid or frozen form intended to be used as beverages. Such products include, but are not limited to: Milk, fat-free milk, lowfat milk, light milk, reduced fat milk, milk drinks, eggnog and cultured buttermilk, including any such beverage products that are flavored; cultured; modified with added or reduced nonfat solids, milk proteins, or lactose; sterilized; concentrated; or, reconstituted. As used in this part, the term concentrated milk means milk that contains not less than 25.5 percent, and not more than 50 percent, total milk solids:

(b) Fluid milk products shall not include:

(1) Plain or sweetened evaporated milk/skim milk, sweetened condensed milk/skim milk, yogurt containing beverages containing 20 percent or more yogurt by weight, Kefir, formulas especially prepared for infant feeding or dietary use (meal replacement) *that are intended for use in that are sold to the health care industry, or products similar in form and intended use sold to retail consumers*, and whey;

(2) Milk products containing more than 9 percent butterfat;

(3) Milk products containing ~~less than 2.25 percent true milk protein and less than 6.5 percent nonfat milk solids, by weight, unless their form and intended use is comparable to the products contained in paragraph (a)(1) of this section; and~~

Sec. 1000.40 [Amended]

3. Section 1000.40 is amended by revising paragraphs (b)(2)(iii) and (b)(2)(vi) to read as follows:

(b) ***

(2) ***

(iii) Aerated cream, frozen cream, sour cream, sour half-and-half, sour cream mixtures containing nonmilk items, yogurt, including yogurt containing beverages with more than 20 percent yogurt by weight, Kefir, and any other semi-solid product resembling a Class II product;

(vi) Formulas especially prepared for infant feeding or dietary use (meal replacement) *that are intended for use in that are sold to the health care industry, or products similar in form and intended use sold to retail consumers;*

Dated: May 12, 2006.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

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Kefir & Yogurt-Containing Beverages

The companies on whose behalf these comments are submitted applaud the decision of the Department relative to yogurt-based drinks and kefir. The exclusion of drinkable products containing at least 20 percent yogurt and the exclusion of kefir are sensible steps that recognize the place of these products in the marketplace and the extent to which, though they are in liquid form, they do not compete with fluid milk.

As data presented at the hearing demonstrates, these products are one of the strong areas of growth in the dairy industry, and we believe that those who sought to classify these in Class I risked "killing the goose that laid the golden egg", and potentially reducing farmer income in an attempt to do the opposite.

The decision with regard to kefir and the threshold level established for yogurt-based drinks are appropriate and are to be commended. The same industry insight that inspired this reasonable accommodation to the realities of the marketplace and of consumer use of yogurt-based beverages should inform the balance of the final rule. Unfortunately, at present, this is not the case.

2.25% Protein Standard

We argued against the adoption of the 2.25% protein standard at the hearing last June and in our subsequent brief. Given the considerable evidence in the record regarding the potential pitfalls associated with the implementation of a protein standard, we are perplexed as to the Department's reasoning for moving ahead with this proposal.

Numerous parties testified about the dampening affect that such a plan would have on continued growth and innovation in the use of dairy proteins in all sorts of beverage products. While it is true that the 6.5% nonfat milk solids standard allows for the formulation of products with more protein than an equivalent amount of skim milk, these products compete with fluid milk only in rare cases. It is therefore unnecessary to resort to this tactic to capture more milk into the Class I pool.

Product formulators will undoubtedly begin to use non-dairy proteins to keep products below the 2.25% threshold; but the real danger is that the introduction of such proteins will lead processors to move away from dairy ingredients entirely. The parties to these comments testified at the hearing, as did others, about

the recent advances in non-dairy proteins, such as soy, wheat, oats, etc., that make them more cheaply and easily substitutable for milk. As was stated in the testimony:

If such actions are taken by USDA [adoption of a protein standard], it is highly likely that the products that now contain some dairy-derived ingredients will be reformulated to minimize, if not eliminate, milk-derived ingredients by substituting non-milk ingredients, such as soy. The technologies are now readily available to make non-dairy ingredients fulfill functions similar to those of dairy-derived ingredients. Not only are class price issues driving food formulators to use non-dairy ingredient sources, but also the record keeping and reporting requirements and presenting records for audits by market administrators are added burdens that many food processors would prefer to avoid. This is another incentive to use non-dairy ingredients. (Tipton R 1052)

And, as was stated by the representative of Fonterra:

We see products made of soy, rice, nuts, grains and oils, all marketed with the names consumers have associated with dairy . . . The claim by the soy industry linking soy to reducing the risk of heart disease has FDA approval. Scandinavian authorities have approved a health claim for cheese where all the milk fat has been replaced by canola oil . . . The table included in my testimony shows that in nutritional applications alone, between 1999 and 2003 the use of soy protein in nutritional applications has enjoyed an average annual growth rate of 16.5 percent, while milk protein has increased by only 10.1 percent. Soy is clearly eroding the dominant market position of these products once enjoyed by milk protein. (Tucker R 456-458)

As stated above, there was considerable discussion of the potentially negative affects on farm revenue through ingredient substitution and the dampening affects on growth in certain categories that have benefited from growing interest in dairy proteins. (Box R 656-657) (Davis R 498-499) (Olsen/Ledman R 515, 517-518, 522-523) (Suever R 915-928) (Taylor R 972-976) (Tipton R 1052-1065) (Tucker R 456-458) (Waldron R 749-750, 752-753) Ignoring the reasonable but dire predictions of these experts, the Department has not given due consideration to the considerable chance that these measures will backfire and inflict harm on the very people they are intended to help – the producers – and at great expense to milk processors as well.

The Recommended Decision makes matters even worse by including virtually all sources of milk-derived proteins for the purpose of determining whether the dairy protein content exceeds or is less than 2.25 percent, but then only selects two sources of protein – nonfat milk solids and milk protein concentrates – to carry an up-charge. The Recommended Decision states: “Dry MPC, like nonfat dry milk is the end result of a manufacturing process (removal of water and lactose) to convert milk solids into a storable, easily transportable and versatile product for use in the dairy and food industry”. (*Federal Register* 71; 17 May 2006: 28601) While the statement is not inaccurate, it leads to a grossly inappropriate conclusion.

Filtered milk is a generic term describing a process whereby milk is forced through a filter. The size of the pores (the filter) and the pressure applied largely determine which components are filtered out. To our knowledge, there are not any federal or state-adopted definitions that define “filtered” products. The commercial designations usually provide three types of filtered products. Reverse osmosis is a filtering process whereby only water is removed. The resulting filtered product has the same nutrients and

components, except for water, as the original product prior to filtration. The term "ultra filtered", while undefined, is usually applied to milk from which the lactose component has been removed. Micro-filtration usually refers to the separation of various nutrients.

The Food and Drug Administration holds that reverse osmosis milk is in fact milk, since only water has been removed. The FDA allows so-called ultra filtered milk to be used in cheese because only lactose has been removed during the filtering process and it is also removed during the cheese making process because the lactose is contained in the whey and not in the cheese. The finished cheese is the same whether made from ultra filtered milk or directly from milk – neither contains lactose.

The filtration process should be viewed as a continuum. For example, and apropos to the Recommended Decision, by utilizing micro filtered processes one could go from milk to casein by using the filtration process only. Basically, the same process that removes lactose can be used to remove all other nutrients, leaving only casein. It is largely a matter of the size of the filtering pores and the pressure applied in the filtration process. None of the witnesses at the hearing possessed sufficient technical expertise to provide definitive descriptions of the processes for making milk-derived ingredients.

We do not make this point to argue that an up-charge should be applied to other forms of concentrated dairy products, but on the contrary, we raise the issue to argue that the hearing record lacks reliable facts about dairy-derived proteins and that the 2.25 percent dairy protein criteria should not be included in this decision. Rather than implement provisions that many witnesses believed would negatively impact the use of various forms of highly-concentrated proteins, we urge you to remove the 2.25 percent protein trigger from the decision. If, subsequently, it is decided the issue should be revisited, it could be the subject of another hearing where more knowledgeable witnesses could set the record straight.

Although the hearing record was replete with testimony about the probable negative consequences of imposing a 2.25 percent protein criteria, the Recommended Decision dismissed all expert testimony from the more knowledgeable and informed witnesses with the statement "no data was presented at the hearing to indicate at what price level or degree such substitution would take place." (71 FR 28600) This response to such overwhelming testimony is difficult to understand.

Many new non-dairy proteins are becoming available. They are being perfected to perform like dairy proteins, i.e. provide the same taste and functions as dairy proteins, and to enhance the attributes of the finished product. USDA reports the price of various protein sources through its various crop and price reporting services. Currently, without an up-charge and on a protein equivalency basis, dairy proteins sell at nearly double the price of virtually all competitive alternatives such as soy, wheat, beans and many other proteins derived from vegetable sources. Producers of vegetable proteins are applying process technologies of filtration and nutrient isolation not unlike that used to separate and isolate dairy nutrients to make them more functional. As noted in the explanatory section of the Recommended Decision, the Cornell University professor presented a study concluding that "if non-dairy ingredients were substituted as a result of reclassification, the study predicted that the effect on producer revenue would be lowered by 22 cents per cwt". (71 FR 28596)

With the preponderance of the evidence clearly raising grave concerns about the probable substitution of non-dairy proteins for dairy-based protein if the 2.25 % standard were adopted, we fail to grasp why USDA is so insistent on imposing this new protein standard. The hearing record is clear, that there are not now and may never be a threat to the federal milk order classification system from beverage products that

contain some dairy-derived proteins, but that do not meet the requirements for milk. Most of such products that had been introduced shortly before the hearing had been withdrawn by the time the hearing was held. USDA cannot make a finding that they have created disruptive conditions. Because of all the probable consequences of including a protein threshold, the potential gain is small, if any at all – and the negative risks are very large – it should be eliminated from this decision.

It seems even more preposterous in view of the fact that the decision narrative frequently and repeatedly has stated that the 2.25 % protein criteria is not intended to be an absolute determinant of whether a product meets the fluid milk product definition. So what purpose does the protein standard serve?

Given the proposed order language relative to “form and use” which overrides the compositional language and the frequently repeated statements in the decision narrative that “form and use” of the product is USDA’s primary criteria for classification, it is clear that USDA should not risk reduced use of milk proteins as well as reduced producer income by including the newly-proposed, highly-challenged milk protein criteria.

Form & Intended Use

We have grave concerns about the extent to which the Recommended Decision elevates the subjective criteria of “form and intended use” over the more objective and measurable compositional criteria that have long been used to classify products as Class I or Class II uses of milk. Of course, it is understood that the legislation authorizing the Federal Milk Marketing Order program mandated this reliance on the “form in which or the purpose for which it is used”, but historically this has been done by the establishment of criteria that would classify products accordingly. However, in this Recommended Decision, these objective compositional criteria have been subordinated to the concept of “form and intended use” in a manner that gives complete and total discretion to AMS officials to classify products according to their own preferences.

As stated in the Findings section of the Recommended Decision:

The 6.5 percent nonfat milk solids and the 2.25 percent true protein criteria are not intended to be absolute determinates of whether a product meets the fluid milk definition. In determining if a product meets the fluid milk product definition, the Department’s primary criteria will be the form and intended use of the product as required by the Agricultural Marketing Agreement Act. (FR 71 28599)

Shortly thereafter, the point is repeated:

[T]he legislation providing for milk marketing orders, as already discussed, provides for milk to be classified in accordance with the form in which or the purpose for which it is used. This requirement should be the primary basis for classifying milk. In identifying the form and intended use of milk, all Federal orders currently define a fluid milk product as a product intended to be used as a beverage. (FR 71 28599)

While the Recommended Decision goes on to discuss the role of compositional criteria, including the 9 percent butterfat standard, the 6.5 percent nonfat milk solids standard and the newly introduced 2.25 percent protein standard, it nevertheless significantly qualifies the role of these criteria when it states:

The 2.25 percent protein standard should, in most cases, be sufficient to distinguish if a product is a Class I or Class II use of milk. Nevertheless, products that may more closely resemble the listed fluid milk products in form and intended use but contain less than 2.25 percent true protein, may be determined by the Department to meet the fluid milk product definition because the products are competing with fluid milk. (FR 71 28600)

In this regard, there are barely any limits on the extent to which the Department may abrogate the compositional criteria as a standard for classification. Given the manner in which these criteria are rendered here, a beverage product containing some milk that is not specifically excluded from Class I, but is below that 6.5 percent nonfat solids standard and the 2.25 percent protein standard would previously have had comfort in knowing that this would reliably lead to its classification as a Class II product; but this elevation of "form and intended use" to the primary determinate means no product's classification can be reliably judged until USDA makes a determination. This is not a reasonable basis on which to regulate an industry.

Furthermore, this puts milk processors at risk of having products that they researched, developed and formulated with the expectation that they would be Class II classified as Class I, and perhaps undermining the products' chances to compete properly in the market. Processors formulate products to compete in specific segments and at specific price points, so the arbitrary nature of some classification decisions would make this process very difficult. This is likely to result in a situation where processors feel compelled to share information about potential new products with the Department in advance to see how they might be classified, since no one but the agency itself would know how these subjective criteria might be applied. The process of commerce and the dynamics of the marketplace cannot wait for decisions and clearances to be rendered by the Department for each and every new product.

In the past, USDA has administered classification of milk based on the form and use authority provided in the Act, however, this was accomplished by establishing criteria set forth in the order to help determine the products whose form and use should be in Class I. In the early days of the order program, this was the fluid milk products defined by federal and state regulatory agencies. Originally, these were primarily those products required to meet Grade A health and sanitation requirements. Because these were for the most part consumed as milk beverages, products meeting the federal and state definitions were defined as Class I. Thus, the requirements of the authorizing Act were fulfilled by a clear definition that included milk products that were liquid (form) and were used or consumed as a milk beverage (use). The product definitions were clear, easily known and understood.

Over the years, the definitions were changed but until now, form and use classification requirements of the Act were met by continuing to define products by composition, name, and health and sanitation requirements. In 1974, USDA inserted among the named Class I products, an undefined term -- "milk drinks". However, it simultaneously provided a clear compositional standard that specified that products containing less than 6.5 % nonfat milk solids were excluded from the fluid milk product definition.

Unfortunately, the recommendation in this decision is that a USDA employee will review new products and determine whether their "form and intended use" is sufficiently comparable to the products contained in the fluid milk product definition to warrant their inclusion irrespective of the amount of dairy components it may contain. There is no question, this open-ended and very subjective approach to classification will deter and hamper the development of products that contain dairy components but are not dairy products. The net

result of the USDA's action would be to bestow a commercial benefit on one commercial party at the expense of another.

Presumably, the marketer of a product being classified by USDA would be compelled to present market data to USDA prior to introducing the product to show who purchases and uses the product, how it is used, the market channels through which it is available to consumers, etc. The uncertainty of this burdensome process will clearly impede development and experimentation thereby reducing the introductions of new drinkable products that contain small quantities of milk components. Additionally, USDA is further cautioned that the inherent vagueness of the regulation and the absence of a known procedure upon which one can reasonably rely may invite legal scrutiny.

More critical, however, is the fact that the USDA hearing notice was void of any proposals to supersede the more objective compositional criteria with the highly subjective "form and use". All of the proposals introducing new criteria did so by way of compositional criteria that, although we may have disagreed with, at least had the advantage of being easily understood and operationalized by processors. At no point during the hearing did any party suggest the adoption of radically subjective criteria that rested on "form and use." Had anyone, either from USDA or one of the representatives at the hearing, made such a suggestion, we would have vigorously objected orally and in our written brief.

Uncertainty and Potentially Arbitrary Determinations are of Grave Concern

Because of the uncertainty of how USDA might rule on the classification of certain products, we feel compelled to offer our views on how certain products should be treated under the newly proposed rules for the record.

The North American Coffee Partnership, a joint venture between Starbucks Corporation and PepsiCo, has since 1997 offered a range of ready-to-drink, convenient coffee beverages under the Starbucks® brand. This is a coffee brand and the company offers a coffee product. Milk products are used along with other ingredients like sugar, cocoa and caramel as flavor enhancements to the coffee. The current product platforms, for which there are numerous line extensions, are Bottled Frappuccino®, Starbucks DoubleShot® and Starbucks® Iced Coffee:

- The current product platforms use dairy ingredients which result in coffee beverages that have less than 2.25% true milk protein and less than 6.5% nonfat milk solids, by weight.
- The form and intended use of these three current product platforms are not "comparable" to the products contained in §1000.15(a)(1)
 - The products are not substituting or competing with fresh milk in the consumer's mind. The Partnership conducted extensive consumer research over the years to learn how, when, where and why American consumers are drinking these products. Research has confirmed the obvious: the products are coffee beverages, consumed during coffee break occasions. The Partnership routinely surveys purchasing behavior through detailed "household panel" studies in which consumers note what other beverages they are considering before selecting a Bottled Frappuccino or Starbucks Double Shot on a given occasion. Consumers regularly indicate that the competitive set for these products is comprised of coffee, iced tea, and other "invigoration beverages" such as Red Bull.

- The products are not distributed or routinely shelved with Class I fresh milk products. They are found in the beverage aisle in grocery stores. It is an ambient product line, with shelf life exceeding 25 weeks. The products are distributed and shelved just like the products with which they compete: iced tea, cold coffee, energy drinks and other non-carbonated warm shelf beverages.
- The products are not marketed as fresh milk products. The North American Coffee Partnership has invested significantly in consumer messaging over ten years through radio and television advertising, as well as packaging and shelf presence. The message has consistently been centered on the Starbucks® brand and the experience of consuming coffee. When consumers are surveyed about the occasion when they drink these products, it is a coffee break occasion.
- The products are premium-priced and single serve, and do not compete with fresh milk products on price.

It is clear that these products are examples of how the compositional criteria are sufficient to determining the products' classification under the order. They are not milk or milk drinks, and should be classified as Class II, which can be easily established by the application of compositional criteria.

Meal Replacement Exemption

We support the continued exemption for meal replacements from the fluid milk product definition. However, we do not believe the record of this proceeding justifies the narrowing of the exemption to products "that are sold to the health care industry."

There are two changes at the heart of this issue. The first relates to the elimination of the requirement that products excluded under this exemption must be packaged in a hermetically-sealed container. The second is the amendment to the language defining the terms of the meal replacement exemption, which specifically narrows the scope of the exemption to products "that are sold to the health care industry." (FR 71 28604) We have no objection to removing the criterion based on packaging (i.e., removing hermetically sealed container requirement), as long as all the products covered by the current exemption continue to be explicitly exempted by the new language, and are not limited to products "that are sold to the health care industry."

As noted in the Recommended Decision, the current language calls for products prepared for "dietary use (meal replacement)", to be exempt from the fluid milk product definition. However, the new language appears to qualify that description and thereby limit it to products formulated for "dietary use (meal replacement) sold to the health care industry." (FR 71 28602) The Department's explanation for the proposed elimination of the hermetically sealed container requirement was "...that packaging is not a legitimate criterion for considering some meal replacement products as Class II products and others in Class I. This same argument applies to the need to eliminate the proposed limitation to "products sold to the health care industry." The sales channel of the product (i.e., sold to consumers at retail versus sold to the health care industry) is not a legitimate criterion for considering some meal replacement products as Class II products and others in Class I. Whether the dietary products (meal replacements) are sold to the health care industry or not, the dietary products (meal replacements) are intended to be used to replace the nutrition of normal meals and not intended to be used in the same manner as fluid milk. The dietary

products (meal replacements) sold other than to the health care industry still have the same basic form and intended use and it is therefore reasonable that they should be similarly classified. Dietary products (meal replacements) even if sold to consumers at retail should be excluded from the fluid milk product definition and should be considered Class II products.

One party to this testimony, Unilever United States, is the manufacturer and marketer of Slim-Fast, the leading meal replacement, weight-control product on the market. These products are formulated and marketed to replace two meals each day as part of a personalized weigh-loss diet plan. Some Slim-Fast products are sold directly to health care professionals, health care institutions, and weight management centers for use as a meal replacement in physician-supervised weight loss programs. Slim-Fast is utilized by weight management professionals frequently enough that Unilever has devoted significant resources to providing guidance to these practitioners. (See attachment I)

Nonetheless, although many consumers are introduced to Slim-Fast products through professionally administered programs, more than ninety percent of Slim-Fast products find their way to retailers who then sell them directly to consumers for weight management whether or not supervised by a professional. According to the logic now utilized by the Department, consumers who purchase Slim-Fast Ready-To-Drink products through retailers, whether supervised by a professional or not, are somehow consuming a Class I beverage in competition with dairy beverages while consumers purchasing Slim-Fast directly through an institution, whether supervised by a professional or not, somehow *do not* consume Class I beverages in competition with other dairy products. In fact, consumers of Slim-Fast may seek professional guidance tailored to their weight loss needs directly through the Slim-Fast website, including personalized guidance regarding meals, exercise, and special health needs. (See attachment II) These consumers, whether they purchased the product through a retail establishment or not, are using the Slim-Fast program, including its Ready-To-Drink Meal Replacement Shakes, as part of a coordinated health improvement or maintenance plan. The sales channel simply does not matter, unless the Department is attempting to subsidize the use of meal replacement beverages in health care institutions and weight loss clinics by penalizing retail consumers for seeking professional guidance elsewhere.

In his testimony last June, E. Linwood Tipton, who represented these parties at the hearing, presented the following arguments in support of maintaining the meal replacement exemption and explaining why products like Slim-Fast rightly belong in this category. He stated:

Slim-Fast observes the following criteria for the development of its products, each of which reaffirms their identity as a meal replacement, distinct from milk and other beverages:

- Formulated meal replacement products are intended for use as part of a weight control diet;
- When substituted for normal meals, they help maintain adequate nutrition while reducing overall caloric intake;
- Meal replacements are formulated to supply about one third of the daily value for essential vitamins and minerals;
- Meal replacements are formulated to supply at least 20% of the daily value for protein per serving;
- Meal replacements are formulated to supply a good source of fiber; and
- Meal replacement drinks are labeled with instructions that a drink be consumed in place of one or two meals per day. (Tipton R 1070-1071)

Other notable differences between meal replacement drinks and dairy beverages include the fact that meal replacement drinks such as Slim-Fast are not sold in the dairy or even the beverage section of retail outlets: they are sold in weight-loss sections or dedicated meal replacement sections among competing products.

Mr. Tipton went on to say:

In many areas outside of milk pricing, the law does not treat Slim-Fast as a beverage. For example, of the 11 states that have mandatory bottle deposit laws for beverage containers (which add a deposit amount, usually 5-10¢ per container, that is refundable upon return of the used container, and are intended to reduce solid waste and litter), none require such deposits for Slim-Fast or other similar meal replacement products. Finally, AC Nielsen, which tracks market data for every product sold in a grocery store, tracks Slim-Fast in the Weight Loss Category along with diet pills and other similar products specially formulated to aid in weight loss. The example of Slim-Fast clearly demonstrates the wisdom of the meal replacement exclusion that has been a part of USDA regulations for 31 years, and which should be preserved. (Tipton R 1071-1072)

It is appropriate to include products sold to the health care industry within the meal replacement exemption – because they do not compete with fluid milk – but they should not be the sole products excluded from Class I in this way. The Findings section of the Recommended Decision discusses this in a way that suggests a broader category of products may be eligible for the exemption, but the new order language does not provide the latitude indicated by the explanatory paragraphs. The Findings section states: “Dietary products (meal replacements) should be excluded from the fluid milk product definition and should be considered Class II products . . . Meal replacements are categorized as those products sold to the health care industry and may include other products that are similar in form and intended use.” (Emphasis added) (FR 71 28602) However, the amended order language relating to the products excluded from the Class I definition, which appears at the end of the Recommended Decision, reads, “(vi) Formulas especially prepared for infant feeding or dietary use (meal replacement) that are sold to the health care industry;” which does not provide any room to include consumer products sold at retail which otherwise meet the description of a meal replacement.

The effect that this oversight will have is clear. Slim-Fast, the leading meal replacement, is not only available in a Ready-To-Drink form, but is available as a powder that can be mixed with any number of consumable liquids including water, soy milk, and even fruit juices. In addition, it is available as a meal-replacement bar. These powdered mix and bar products, although functionally equivalent to Ready-To-Drink meal replacement beverages, will not be subject to the Class I categorization. Thus, the Class I categorization may inspire a shift in consumer consumption along price lines: the Ready-To-Drink versions of meal replacements will not be attractively priced compared to functionally equivalent mixes and bars.

Furthermore, Unilever will have a non-dairy alternative formulation of Slim-Fast available to consumers shortly. (See attachment III) While this formulation was developed to meet the dietary needs of lactose intolerant consumers in need of a complete meal replacement, additional milk order regulation and added Class I costs would make this formulation more attractive to even non-lactose intolerant consumers from a retail price perspective while simultaneously increasing profit margins for retailers. Similarly, other

manufacturers of liquid meal replacements are developing or have developed non-dairy formulations that may become attractively priced, higher profit alternatives to current formulations.

The parties to these comments would urge in the strongest possible terms that the Department revisit this issue and consider revising this language to include products beyond those sold just to the health care industry. It is one thing to add products sold to the health care industry because they do not compete with fluid milk, which as we have stated is reasonable, but it is another to remove all other categories of products that have previously qualified as meal replacements in the process. For the sake of simplicity, these parties would recommend adding "or products that are similar in form and intended use sold to retail consumers."

Slim-Fast Ready-To-Drink meal-replacement products fit in a diet to control or lose weight by substituting Slim-Fast for two meals per day. It is not suggested or implied that Slim-Fast be used as a beverage to accompany other food or to be used to satisfy the body's requirements for a liquid. Furthermore, the Slim-Fast diet plan only recommends Slim-Fast products as a meal replacement and specifically recommends consumption of such beverages as water, calorie free sodas, and skim-milk throughout the day while using Slim-Fast meal-replacement products. (See attachment IV) The sole intended and actual use for Slim-Fast Ready-To-Drink products is as a meal replacement. Consumer research shows 93% of the Ready-To-Drink Slim-Fast shakes are consumed alone, without other food or drink. Between 82-85% of Slim-Fast shakes are consumed to replace a meal; 5-10% are consumed to replace a missed meal; 8-10% are consumed between meals as a snack; and 2-3% are consumed as a dessert. None whatsoever are consumed to replace a beverage.

These are truly meal replacement products and the sales channels are primarily retail outlets, although certain quantities are distributed through health care industry outlets. The use of these products is not similar to that of milk. The positioning of Slim-Fast in retail stores is in the weight loss section for those stores that have sections or in the pharmacy section of some stores. It is safe to say it is never in the refrigerated dairy section of the store.

**Replacing the Language "Packaged in Hermetically-Sealed Containers"
with "Packaged in Containers that are Shelf Stable at Ambient Temperatures"**

The hearing record does not provide adequate evidence to eliminate the provisions explicitly exempting meal replacements sold in hermetically-sealed containers. The Slim-Fast witness, Mr. Tipton, presented the following testimony opposing the elimination of the hermetically-sealed provisions contained in the orders. There was no other contravening testimony.

Proposal number 3 would replace the requirement that special products that are excluded from Class I be "packaged in hermetically-sealed containers" with new language – "packaged in containers that are shelf stable at ambient temperatures". Virtually all, if not all of the special formulas currently excluded from Class I or proposed for exclusion, are subject to FDA's thermally processed low-acid foods regulations (21 CFR 113). These regulations require all such foods with a finished equilibrium pH greater than 4.6 to be aseptically processed and packaged in hermetically-sealed containers. As a result, we are not certain that the newly proposed language would, in reality, include any packaging material or process not covered by FDA's low acid food regulations. We support continued use of the current criteria that is known terminology and consistent with FDA's terminology and regulations. The only additional products that the new language might

apply to are foods (beverages) with a pH of 4.6 or lower that would have sufficient acidity to be outside the low acid food regulations. Prior to the 1974 decision on classification, all fluid milk products that were packaged in hermetically-sealed glass or can containers were excluded from Class I. In the 1974 decision, USDA changed these provisions and concluded that all fluid milk products whether sterilized or unsterilized should be included in Class I. However, at that time, USDA specifically concluded "Evaporated milk and condensed milk sold for home use are intended primarily for cooking purposes. They are not consumed normally as a beverage. Infant and dietary formulas, which are being sold in hermetically-sealed glass or all-metal containers, are specialized food products prepared for a limited use. Such formulas do not compete with other milk beverages consumed by the general public. Similarly, fluid products containing only a minimal amount of nonfat milk solids are not considered as being in the competitive sphere of the traditional milk beverages." (39 FR 8715) The Federal Order Reform rule of 1999 continued the exemption and it now reads, "formulas especially prepared for infant feeding or dietary use (meal replacement) that are packaged in hermetically-sealed containers." Notwithstanding this long history of classification of meal replacement products in Class II, one of the proposals submitted for the hearing would do away with the specific meal replacement exclusion. There is no basis for doing this. Although we believe the phrase "dietary use" includes meal replacement products such as Slim-Fast, a product of Unilever United States and a party to this testimony, we urge USDA to continue to specify meal replacements as a food exempted from Class I. Slim-Fast products are a true prototype of the "meal replacement" exclusion. (Tipton R 1068-1071)

We urge the Department to reexamine its conclusions with regard to the meal replacement exemption and amend the proposed language to bring greater clarity to the exclusion and to provide for the exemption of products like those discussed here.

Conclusion

We are grateful to the Department for the opportunity to participate in this process and present the views of the companies which are parties to these comments. We sincerely hope the final rule will reflect the findings of the records and will result in clear, understandable, transparent regulations that will benefit all interested parties.

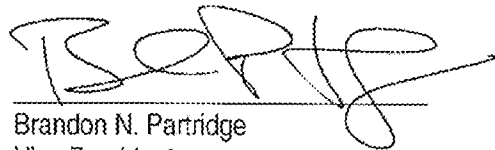
Respectfully submitted on behalf of the following companies:

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