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M-I-12-15

December 7, 2012

TO: All Regional Food and Drug Directors  
Attn: Regional Milk Specialists

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Guidance for Regulatory Agencies to Use when Making Determinations of Whether Milk and/or Milk Products Meet Definition Z. Milk Products, Item 6. of Section 1. Definitions of the Grade "A" Pasteurized Milk Ordinance

Proposal 232 passed at the 2009 National Conference on Interstate Milk Shipments (NCIMS) made changes to Definition X. (Definition Z in the 2011 PMO) Milk Products contained in Section 1. Definitions of the Grade "A" Pasteurized Milk Ordinance (PMO). Of significant interest is Item 6. included in Definition Z., which has generated a number of questions. Item 6. states: "Products not included in Items 1-5 are Grade "A" milk products which have a minimum of 2.0% milk protein (Total Kjeldahl Nitrogen (TKN) X 6.38) and a minimum of sixty-five percent (65%) by weight milk, milk product or a combination of milk products." Many of the questions generated ask how the 2.0% milk protein and the 65% by weight milk, milk product or a combination of milk products criteria are being calculated and determined by FDA; and also request clarification on the part of Definition Z that refers to the "safe and suitable (as defined in 21 CFR 130.3(d)) non-Grade "A" dairy ingredient" exceptions.

The intent of this M-I is to provide information and guidance to the Regulatory Agencies and industry; so that Regulatory Agencies can more ably determine whether a product meets the Grade "A" Milk Product definition or not. Also, the purpose of this M-I is to provide some tools that will enable the Regulatory Agencies to become the predominate decision maker when it comes to making such Grade "A" Milk Product determinations.

Following are some guidance criteria utilized by FDA, calculation examples and general comments to assist Regulatory Agencies and industry when they are making such Grade "A" Milk Product determinations:

The four (4) primary criteria that should be utilized for all Grade "A" Milk Product determinations are:

1. The product is evaluated in its final consumable form, e.g., "as it is presented to the consumer". When chemical analysis of the consumer product is utilized by the Regulatory Agency, the testing results become the final determinate as to whether the product meets the criteria in Item 6 and falls within Definition Z.
2. Information provided on the principal display panel (PDP) or the information panel (IP) of the container is reviewed to determine if the product and/or ingredients listed are those shown in Definition Z. as meeting or not meeting the Grade "A" Milk Product definition.
3. The product must meet **both** the minimum 2.0% milk protein and the minimum 65% by weight milk, milk product or a combination of milk products requirements to be determined as meeting the Grade "A" Milk Product definition.
4. The weight of water to reconstitute a dairy ingredient to single strength is included in making the determination of meeting or not meeting the minimum 65% by weight requirement.

### **Initial Review**

Often, the only information initially available to the Regulatory Agency for making such Grade "A" Milk Product determinations will be that provided on the container label. If any of the exceptions cited in Definition Z., i.e. milkfat substituted in part or in whole by any other animal or vegetable fat; coffee, tea or water as the primary ingredient; infant formula; etc. are noted, then the product will be determined to not be Grade "A". The assumption with this premise is that the ingredient statement included on the container label is accurate. If in doubt, then product testing should be performed.

### **Protein Content**

If the predominate ingredient(s) listed first on the ingredient statement is a dairy ingredient(s), then the majority, if not all, of the protein may be provided by the milk component(s). However, the protein content could be affected by other non-dairy "protein rich" ingredients that are present in the product; and these will need to be taken into consideration when making the protein content determination. The amount of declared protein will be shown in the nutrition facts on the IP. The number of grams of protein declared divided by the grams per serving size and multiplied by 100 will determine if there is at least 2.0% protein present in the product.

**For Example:** Seven (7) grams of protein are declared in the nutrition facts panel for a container of product that has a 240 gram serving size; therefore, 7 divided by 240, times 100, equals 2.92% protein present in the product ( $7/240 \times 100 = 2.92\%$  Protein).

At this point, this product may be Grade "A"; however, any protein that may be provided by non-dairy ingredients will need to be evaluated. Further verification can be accomplished either by requesting more information from the manufacturer, such as specific ingredients and their respective percentages, formulation, batching/processing information, etc.; or the product could be analyzed.

## **Weight Milk, Milk Product or a Combination of Milk Products**

The minimum 65% by weight milk, milk product or a combination of milk products requirement is more difficult to determine. When the predominant ingredient(s) on the ingredient statement are milk and/or milk products, then the product may be exceeding the minimum 65% by weight requirement. If specific ingredient composition, respective percentages and batching/formulation information is provided by the manufacturer, then determining where the product falls relative to the minimum 65% by weight requirement can be more easily evaluated. When water is being added to reconstitute milk ingredients to their original single strength composition, the weight of the water used to reconstitute the dairy ingredient shall be used in the calculation of the percent of that milk component present. This is based on 21 CFR 101.4(c), which states: "When water is added to reconstitute, completely or partially, an ingredient permitted by paragraph (b) of this section to be declared by a class name, the position of the ingredient class name in the ingredient statement shall be determined by the weight of the unreconstituted ingredient plus the weight of the quantity of water added to reconstitute that ingredient, up to the amount of water needed to reconstitute the ingredient to single strength. Any water added in excess of the amount of water needed to reconstitute the ingredient to single strength shall be declared as "water" in the ingredient statement." Also, 21 CFR 101.4 (b) (3), (4), (6), (7), (8) and (9) provides for concentrated, reconstituted and dry milk products, and butteroil and anhydrous butterfat, to be declared on the ingredient statement by their common or usual name. A manufacturer's use of these two (2) labeling regulations makes it important to have additional information provided when trying to determine whether the minimum 65% by weight requirement has been met. Lack of that information will require the Regulatory Agency to utilize its best judgment; or to have the product analyzed.

**For Example:** A product's nutritional statement shows that 2.92% protein is present. The ingredient statement states: milk, cream, sugar, starch, vanilla flavor, stabilizer, vitamins and color. At this point the product seems to be falling into the Grade "A" category based on the protein content and the predominant ingredients. However, the product formula information that was provided by the manufacturer indicates that all milk ingredients comprise only 62% by weight, which included the water utilized for the reconstituting of whole milk powder back to single strength. Water did not show up on the ingredient statement, since all of the water being added was being used to reconstitute the whole milk powder to single strength; and thus, "water" would not have to be declared on the ingredient statement. The final determination would be that this product is not Grade "A" based on not meeting the minimum 65% by weight requirement.

## **Safe and Suitable Non-Grade "A" Dairy Ingredients**

Definition Z of the 2011 PMO states: "Safe and suitable (as defined in 21 CFR 130.3(d)) non-Grade "A" dairy ingredients, can be utilized in the products defined in Items 1-6 when added to a level needed for a functional or technical effect, and limited by Good Manufacturing Practices (GMPs)...", and are not used to "increase weight or volume of

the product, or displace Grade "A" dairy ingredients" may be used in the manufacture of a Grade "A" milk product. In order to be able to determine whether a non-Grade "A" dairy ingredient may be used in the production of Grade "A" milk and/or milk products, data shall be provided to the Regulatory Agency and/or FDA. The data shall demonstrate objectively that the ingredient in question does in fact, deliver the needed technical and/or functional effects, which cannot be provided by a Grade "A" milk product of similar composition proximately; and that it is not being used to increase the weight or volume of the product or displace Grade "A" ingredients.

**For Example:** If the manufacturer of a Grade "A" milk product was to claim that the ingredient in question delivers increased gel strength, increased shelf-life, reduced wheying-off, better mouthfeel, better body, better texture, etc., the Regulatory Agency and/or FDA would expect to receive data which would concretely demonstrate that the ingredient actually does all of that with the finished Grade "A" milk product; and that it is so to an extent beyond that which would be provided by a currently available Grade "A" dairy ingredient with similar proximates, i.e. protein, fat, ash, lactose, moisture, etc., when used at similar concentrations in the finished Grade "A" milk product formulation.

Since many of the milk products that will be requiring an evaluation may not meet a specific standard of identity, it would be difficult to determine that a milk product category, i.e. a "dairy smoothie", will always meet or not meet Definition Z. Many, if not all of these non-standard milk products will need to be evaluated on an individual basis.

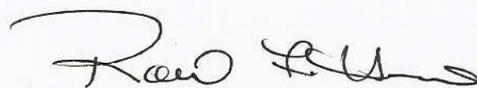
Finally, a request that FDA has of any Regulatory Agency making a determination whether a milk product does or does not meet Definition Z of the PMO is that the information, along with their justification, be forwarded to your FDA Regional Milk Specialist. They in turn will provide that information to CFSAN so that information can be distributed to all of the States.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory Agencies and State Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will also be available on the FDA Web Site at <http://www.fda.gov> at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to [robert.hennes@fda.hhs.gov](mailto:robert.hennes@fda.hhs.gov).



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