



Chocolate Manufacturers Association

OF THE UNITED STATES OF AMERICA

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October 15, 1979

Hearing Clerk (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Room 4-65
Rockville, MD 20857

RE: Docket 78N-0369 Whey Products and Hydrogen Peroxide;
Affirmation of GRAS Status as Direct Human Food
Ingredients

Docket 78N-0071 GRAS Status of Potassium Bicarbonate
and Sodium Bicarbonate

Dear Madam:

We wish to comment on two recent proposals promulgated by the Food and Drug Administration including the establishment of a common or usual name and affirmation of GRAS status for whey and whey products, and the proposed GRAS status of potassium bicarbonate and sodium bicarbonate. Our interest in these matters reflects our concern that both proposals would amend established standards of identity for certain cacao products without regard for appropriate due process.

We do not wish to address the issues of safety or names for whey products. The proposal would allow the use of whey, dried (dry) reduced lactose whey, and dried (dry) whey protein concentrate up to a maximum level of 20% in soft candy as defined in 170.3(n)(38) of 21 CFR, which includes chocolates, and 10% in all other foods. Dried (dry) reduced minerals whey would be allowed to a maximum of 10% in all food categories except baked goods and baking mixes under 170.3(n). The proposal would thus permit the use of whey products in both chocolate and baking chocolate.

We would like to mention that many of the food categories established in 170.3(n) indiscriminately include under the same group standardized and non-standardized products. Both baking chocolate 170.3(n)(9) and chocolate 170.3(n)(38) are standardized cacao

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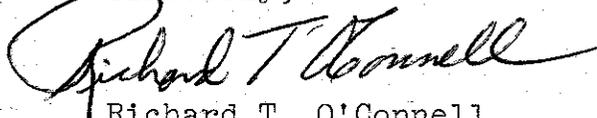
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products under Section 163.111 as alternate names for chocolate liquor. Chocolate liquor consists primarily of ground cacao nibs with a cacao fat content ranging from 50% to 58% by weight. According to the standard, chocolate liquor may be spiced, flavored, or otherwise seasoned with one or more optional ingredients specified in five categories, provided some label declaration is made. Whey products are not specified in any of the five categories and therefore, can not be used in standard baking chocolate or chocolate.

Comments were submitted earlier on behalf of Nestle Enterprises, Inc. and others concerning the GRAS petition for potassium bicarbonate and sodium bicarbonate. The effect of maintaining the limits proposed for these two ingredients in baking chocolate and chocolates would be to amend the standard of identity of these products without going through due process.

In view of the established standards and proper procedure for including food additives in standardized foods under 170.10, it is incumbent upon the FDA to amend the proposal by deleting references to standardized chocolate products or issue a proposal for the inclusion of a food additive in such definition and standard of identity. Since Section 409(b)(5) of the Food, Drug and Cosmetic Act requires the Secretary to publish notice of a petition for the establishment of a food additive regulation within 30 days after filing, it would appear a new petitioning procedure for both whey products and the bicarbonates would be required. It is our view that final orders of these proposals should be amended where appropriate for consistency with the standards of identity for chocolate products.

Sincerely,



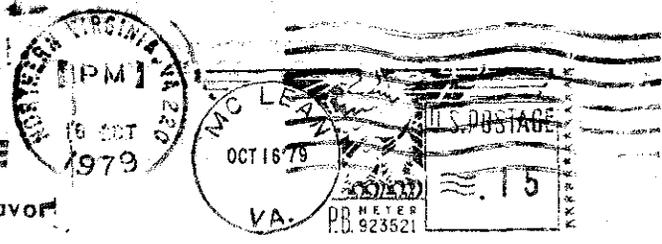
Richard T. O'Connell
President

RTO:mwk

cc: Sanford A. Miller, Bureau of Foods
Robert M. Schaffner, Bureau of Foods
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CHOCOLATE
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