GENERAL MILLS, INC. • GENERAL OFFICES • 9200 Wayzata Boulevard • Minneapolis, Minnesota

August 16, 1979

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

Dear Sir:

Subject: GRAS Affirmation Proposal - Whey, concentrated whey, dried (dry) whey. Docket No. 78-0369

The GRAS affirmation proposal for unmodified forms of whey (21 CFR 184.1979) lists specific use levels for several food categories and a 10% maximum use level for "all other food categories". We are aware of certain snack food products [170.3(n)(37)] that have been marketed for over twenty years which contain more than 10% of unmodified dry whey.

However, we would like to address the larger issue of establishing specific GMP limits on unmodified whey products. We recognize that restrictions on certain modified wheys may be necessary. However, the Commissioner has found that unmodified "whey, concentrated whey, and dried (dry) whey are eligible for GRAS status based upon their common use in food in the United States before January 1, 1958." Furthermore, since whey is a highly nutritious food for which the proposal raises no questions of safety, we feel that specific limitations within GMP's are unwarranted. Therefore, we request that 21 CFR 184.1979(d) be amended to read:

> "The ingredient is used at levels not to exceed good manufacturing practices in accordance with 184.1(b)(1)."

Additionally, whey, concentrated whey, and dried (dry) whey, as they are defined in 184.1979, differ only in water content. The differences between these forms of whey as they

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Mailing Address: P. O. Box 1113, Minneapolis, Minnesota 55440

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would appear in a final product are, therefore, insignificant and would be of little or no concern to the consumer. Therefore, we request that 21 CFR 184.1979(e) concerning labeling the source of whey, be omitted or amended to reflect the current regulation 21 CFR 101.4(b)(7) wherein "Whey, concentrated whey, reconstituted whey, and dried whey may be declared as 'whey'."

Sincerely,

Thomas D. Trautman

Thomas D. Trautman, Ph.D.
Toxicologist
Quality Control

TDT/jl

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