



March 25, 1998

Mr. Macit Gurol
President
Tamer International, Ltd.
17230 12th Avenue N.E.
P.O. Box 65260
Seattle, WA 98155

Dear Mr. Gurol:

This is in response to your letter of March 11, 1998, concerning your "TAMER" products, which are used to temper the acidic content of foods and beverages. You listed several active and inactive ingredients that you believe are generally recognized as safe (GRAS). You asked for FDA approval of these products.

Under the Federal Food, Drug, and Cosmetic Act, FDA does not approve food products. It is the responsibility of the manufacturer or distributor to make certain that the product being marketed is safe within the meaning of the Act and regulations promulgated thereunder. Ingredients that are used as components of food must be either generally recognized as safe (GRAS) or approved as food additives. Direct food additives that have been approved by FDA are codified in 21 CFR Part 172. GRAS substances, on the other hand, are listed in 21 CFR Parts 182 and 184.

The following ingredients that you listed are covered by the FDA regulations indicated below:

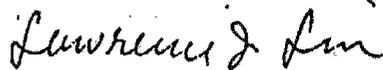
Calcium carbonate	----- 21 CFR 184.1191
Magnesium hydroxide	----- 21 CFR 184.1428
Potassium hydroxide	----- 21 CFR 184.1631
Potassium chloride	----- 21 CFR 184.1622
Sodium carboxymethylcellulose	----- 21 CFR 182.1745
Polyethylene glycol (mean molecular weight 200-9500)	----- 21 CFR 172.820

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In addition, microcrystalline cellulose is considered to be GRAS, although it is not listed in FDA regulations. Sea salt can be GRAS if it is prepared under conditions of good manufacturing practice. Instant coffee and distilled water are of course acceptable drinks.

If you have further questions, please feel free to contact us.

Sincerely yours,



Lawrence J. Lin, Ph.D.
Division of Petition Control, HFS-215
Center for Food Safety
and Applied Nutrition