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April 9, 2003

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 02F-0160

Dear Sir or Madam:

On February 27, 2003, a final rule was published in the above matter amending the food additive regulations to provide for the safe use of Vitamin D₃ as a nutrient supplement in calcium-fortified fruit juices and juice drinks (excluding fruit juices and juice drinks specially formulated or processed for infants). We request a technical amendment to the regulation as it is reproduced in the notice. The amendment would conform the regulation to reflect the actual approval.

Specifically, we note that new Section 172.380(c) authorizes the use of Vitamin D₃ in juices "that are fortified with greater than 33% of the recommended daily intake (RDI) of calcium the reference amount customarily consumed RACC (RACC)." The use proposed in the Company's petition and found safe as noted in the preamble to the regulation pertained to products fortified with calcium in amounts "equal to" as well as greater than 33% of the RDI. The "equal to" language appears to have been inadvertently omitted. We request that the paragraph be revised to read "... that are fortified with equal to or greater than 33 percent"

With respect to Section 172.380(d) and the authorization of the use of Vitamin D₃ in juice drinks, we request a comparable correction. Specifically, we ask that

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the last clause of the paragraph be revised to read "... that are fortified with equal to or greater than 10 percent"

Sincerely,

A handwritten signature in black ink that reads "Fred H. Degnan". The signature is written in a cursive style with a long horizontal stroke at the end.

Fred H. Degnan

cc: Judith Kidwell
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition