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July 20, 2004

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

VIA ELECTRONIC MAIL

Docket No. 2004N-0264

Dear FDA,

We have been advised that the FDA requests comments on a new ANPRM, dated July 14, 2004, within the next 30 days. The request has attached several pages of specific questions to be addressed, some of which are highly scientific in nature. All questions are highly complex.

Therefore, we strongly request that the FDA grant an minimum extension of an additional 90 days so that all interested parties can carefully consider the FDA's request and submit sound, scientific, and reasonable comments and answers to the questions submitted.

Please note that several questions that were submitted in the ANPRM are entirely new to the discussions that have been held with industry and the FDA. The sheer volume of data requested is immense. Additionally, we feel it is unfair to ask for such information and then, according to your own time schedule, issue a ruling within 15 days of the ANPRM.

We will continue to work with the FDA cooperatively in all such matters and look forward to a careful and considered decision herein.

Respectfully,

Charles Largay, Jr.
Tallowmasters, LLC
President