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March 11, 2003

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, rm. 1061 Rockville, MD 20852

Re: Petition for Extension of Comment Period

To Whom It May Concern:

The undersigned, as an attorney acting on behalf of Dairy Management, Inc. ("DMI"), submits this petition to request the Commissioner of Food and Drugs to extend the comment period until May 30, 2003, for the Final Rule related to Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D, 21 C.F.R. Part 172, Docket No. 02F-0160, published in the Federal Register on February 27, 2003 (the "Vitamin D Rule" or the "Rule").

A. Action Requested

DMI respectfully requests that the comment period for the Vitamin D Rule be extended until May 30, 2003 for the reasons set forth below. Due to the current deadline for comments on the Rule, DMI further requests that the Commissioner issue a ruling on this petition by March 21, 2003.

B. Statement of Grounds

The Vitamin D Rule was published in the Federal Register on February 27, 2003. The deadline for commenting on the Rule is March 31, 2003. In order to fully assess and comment on the Rule, it is necessary to examine the petition filed by The Minute Maid Co. which precipitated the Rule, as well as the administrative record related to the Rule. The administrative record was not available until the Rule was published on February 27, 2003. DMI submitted a request for copies of the administrative record (including FDA memos, reports and other correspondence related to the petition) pursuant to the Freedom of Information Act ("FOIA") on March 4, 2003. Pursuant to the FOIA, the FDA is not required to respond to the request until April 1, 2003. In addition, because information may need to be redacted from the records requested by DMI, it is likely that DMI will not receive the requested records until well beyond April 1, 2003. Without the administrative record and the petition, DMI does not believe it can adequately assess the Rule

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and determine whether and in what form it should comment on the Rule. As a result, DMI is requesting that the comment period be extended an additional 60 days, through May 30, 2003. Such an extension will allow all interested parties to adequately examine and assess the Rule and provide comments to the Agency.

C. Environmental Impact

This request does not require the preparation of an environmental assessment or an environmental impact study because it is categorically excluded from such requirements pursuant to 21 C.F.R. 25.30.

D. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely

Amy B. Jones

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