

From: Charlie Bergh [Charlie.Bergh@sunlandbeef.com]
Sent: Wednesday, July 21, 2004 2:14 PM
To: 'fdadocket@oc.fda.gov'
Subject: Extension request re: Docket No. 2004N-0264
FDA recipient,

Attached is a formal request for extending the comment period related to Docket No. 2004N-0264.

Thank you for your consideration regarding our request,

Charlie Bergh
General Manager
Sun Land Beef Company

04N-0264

EXT17

July 21, 2004

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

VIA ELECTRONIC MAIL

REQUEST FOR EXTENSION OF COMMENT PERIOD

Docket No. 2004N-0264

I am submitting this request that the Commissioner of Food and Drugs extend the comment period in the above matter for an additional 60 days.

A. Decision involved

The Food and Drug Administration (FDA) has announced that it will publish an advance notice of proposed rulemaking (ANPRM) on possible changes to its feed regulation (21 C.F.R. § 589.2000) and other additional measures being considered to mitigate the risk of bovine spongiform encephalopathy (BSE). 69 Fed. Reg. 42288 (July 14, 2004).

B. Action requested

I request that FDA extend the comment period on this ANPRM from 30 days to 90 days. I request that FDA give expedited consideration to this Request for Extension of Comment Period. I urge FDA not to publish a proposed rule banning SRMs from animal feed until the agency has reviewed and considered the comments on this ANPRM relevant to an SRM ban.

C. Statement of grounds

As Dr. Stephen Sundlof, Director of FDA's Center for Veterinary Medicine, acknowledged during the press and briefing on the ANPRM on July 9, the changes being considered to FDA's feed rule are highly complex. Moreover, the ANPRM represents a sharp change in direction from FDA's January 26, 2004 announcement regarding planned changes to the feed rule. Instead of taking steps to enhance the existing mammalian-to-

ruminant feed ban, FDA now is considering an entirely different approach in response to the report of the International Review Team. This new approach would involve removal of specified risk materials (SRMs) from the entire animal feed chain, as well as a ban on all mammalian and avian protein in ruminant feed. This is why FDA has taken more than five months to publish the ANPRM since receiving the International Review Team report. It seems inconsistent and unwarranted for FDA to expect the affected industries to prepare comments and collect data on these complex questions in only 30 days.

I believe that such a short comment period is exceptionally rare for an ANPRM, especially one that raises so many questions and is seeking such extensive data. I respectfully request that the FDA allow a 90-day comment period for the ANPRM.

Very truly yours,

Charlie Bergh
General Manager
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