

***SOUTH AMERICAN GELATIN MANUFACTURERS ASSOCIATION –
S A G M A***

Sao Paulo, October 12, 2004

Division of Dockets Management
Food and Drug Administration
5630, Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004N-0081

**Use of Materials derived from Cattle in Human Food and
Cosmetics:
Interim Final Rule (69 Fed. Reg. 42256; July 14, 2004)**

**Comments of the South American Gelatine Manufacturers’
Association**

To Whom it May Concern:

SAGMA, the South American Gelatine Manufacturers’ Association,
represents more than 90% of the continent’s gelatine manufacturing industry.
In the name of our members we ask You for the following consideration:

SAGMA has carefully accompanied all information and documents offered
from the FDA referring the Final Interim Rule and analysed them in the view of
our industry.

As manufacturers of predominately bovine hide gelatine we like to remember,
that it is officially clarified, that BSE risk is inexistent in such rawmaterial.
Further more it is to state, that gelatine made from bovine rawmaterials is
safe, as demonstrated in scientific studies.

The Preamble to the Interim Final Rule describes FDA’s guidance for
industry entitled “The Sourcing and Processing of Gelatine to Reduce the
Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-
Regulated Products for Human Use” (the “Gelatine Guidance”). It is SAGMA’s

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understanding that the Gelatin Guidance has been superseded by the Interim Final Rule for Foods and Cosmetics.

At the same time SAGMA had access to the final draft of the comments on the above reference elaborated jointly by the Gelatin Manufacturers Institut of America (GMIA) and the Gelatin Manufactures of Europe (GME).

SAGMA has analysed all comments of this document and found them to represent the position of our Association without restriction.

SAGMA therefore declares its consensus to these comments and ask You to accept our concerns as commented in the joint document of GMIA and GME.

Respectfully,

Reiner Quade
Secretary General
SAGMA – South American Gelatine Manufacturers' Asociation