Gelatin Manufacturers Institute of America, Inc.

Comments on Proposed Rule

Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle

Food and Drug Administration
U.S. Department of Health and Human Services
Docket No. 2004N-0257

August 12, 2004

The Gelatin Manufacturers Institute of America, Inc. (GMIA) is a trade association whose members include all of the producers of edible, pharmaceutical and photographic gelatin in the United States and Canada, and one of the largest Mexican manufacturers.[1] GMIA members sell edible gelatin directly to hundreds of food manufacturers and distributors in the United States and a variety of export markets. GMIA members also sell gelatin directly to soft gel and hard shell capsule producers, primarily for use in dietary supplements. GMIA members export gelatin to many countries around the world for use in dietary supplement capsules.

The GMIA member companies are totally committed to ensuring that all gelatin is safe for human consumption and over the years GMIA has supported FDA on an ongoing basis to assure gelatin safety. The gelatin industry cooperated in the establishment of and complied with the FDA's 1997 gelatin industry guidance.[2] In addition, GMIA supported extensive research studies conducted by highly respected, independent scientists that

[1] GMIA members include: Atlantic Gelatin/Kraft Foods, Woburn, MA; Cangel Inc., Toronto, Ontario; Eastman Gelatine Corporation, Peabody, MA; Gelita North America, Sioux City, IA; PB Leiner, Davenport, IA and Jericho, NY; Rousselot Inc., Dubuque, IA and Waukesha, WI.

[2] *Guidance for Industry: The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-Regulated Products for Hu. man Use* (Docket No. 97D-0411, September 1997)

have demonstrated that the process of manufacturing bovine gelatin provides strong additional assurance of gelatin safety. Data from these studies were presented to the FDA's Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC) at its meeting in July, 2003. During this meeting, the TSEAC voted that these data "demonstrate a reduction in infectivity that is sufficient to protect human health."[3]

The FDA is now proposing to take further steps in its ongoing effort to ensure the safety of human food and cosmetics by requiring manufacturers to establish and maintain records sufficient to demonstrate that such products do not contain "prohibited cattle materials." The members of GMIA, once again, support this effort. As explained further below, GMIA believes that its members who produce bovine bone gelatin already have established and maintain records sufficient to demonstrate that gelatin is not manufactured from, processed with or otherwise contains "prohibited cattle materials. Furthermore, GMIA members producing bovine hide gelatin believe that the records requirement in this proposed rule can be met through current industry record keeping regarding sourcing hides from healthy animals. This, too, is more fully described below.

Bovine Bone Gelatin Intended for Use in Food. Gelatin bone sourced by GMIA member companies for the manufacture of bovine bone gelatin for food use is obtained from a small number of large U.S. meat processing companies. These companies are subject to continuous oversight by the USDA and are in full compliance with the BSE requirements for cattle materials promulgated by USDA in January 2004. The cattle materials prohibited by USDA are the same materials prohibited by the FDA Interim Final Rule.[4] To the extent that U.S. bovine bone gelatin manufacturers source from only a few plants, all of which are USDA approved, it would seem both reasonable and expedient that documentation by the gelatin manufacturers that their raw materials were sourced from plants approved and under continuing oversight by USDA should assure compliance. Thus, records are already in place to document the source of the gel bone and are sufficient to comply with this proposed rule.

Bovine Hide Gelatin Intended for Use in Food. Cattle hides sourced by GMIA member companies for the manufacture of bovine hide gelatin for

[3] FDA website: http://www.fda.gov/ohrms/dockets/ac/03/transcripts/3969t1.htm

[4] 9 CFR § 310.22; see Federal Register, Vol. 69, pp. 1862 et. seq., January 12, 2004.

food use are purchased from a small number of tanneries in the United States. These tanneries are supplied exclusively by slaughterhouses under continuous oversight by the USDA. GMIA member companies are also supplied by a few offshore suppliers operating under the supervision of Veterinary Health Services in regions considered BSE-free or provisionally free of BSE.

Cattle hides are removed as the first step in processing after the slaughter of healthy animals. The hides are then immediately taken away from the production zone where the animal carcass is further processed, including the removal of SRMs. Thus, any potential for cross contamination of hides is eliminated. Bovine hide gelatin is considered safe and free from any and all potential BSE infectivity associated with cattle material. As set forth on page 30 of the Joint FDA/USDA Advance Notice of Proposed Rulemaking on Federal Measures to Mitigate BSE Risks: Considerations for Further Action which was issued on the same date as this proposed rule: "The OIE also identifies certain commodities that should not require any BSE-related restrictions, regardless of the BSE status of the exporting country or zone. For example, the Terrestrial Animal Health Code does not recommend any restrictions, regardless of the BSE status of the country, in trade of . . . gelatin and collagen coming from hides and skins because these products or tissues have not demonstrated BSE infectivity in cattle." Records already maintained by GMIA member companies are sufficient to demonstrate that their cattle hide raw materials are sourced from healthy animals slaughtered under the supervision of the USDA or the Veterinary Health Services of the country source of origin. These records are sufficient to comply with this proposed rule.

All Bovine Gelatin Intended for Use in Food. The GMIA does not believe each individual lot of raw materials or finished product needs to be accompanied by records. Such a requirement would only add additional costs without any added public health benefit or protection for consumers that is not already addressed by FDA's rules and notices. However, to the extent that FDA insists on a more detailed affirmation, GMIA proposes that it would be sufficient for a Continuing Letter of Guarantee to be issued in a blanket form that would cover all materials provided to gelatin manufacturers and could be renewed on an annual basis. In turn, customers of bovine gelatin manufacturers would need only to seek a similar Continuing Letter of Guarantee from their gelatin supplier.

Thank you in advance for your consideration of the GMIA comments.

Sincerely,

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Chairman
GMIA Regulatory Committee

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