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August 12, 2004

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
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**Re: Docket No. 2004N-0257
Recordkeeping Requirements for Human Food and Cosmetics
Manufactured From, Processed With, or Otherwise Containing,
Material From Cattle: Proposed Rule (69 Fed. Reg. 42275; July
14, 2004)**

Comments of the Gelatin Manufacturers of Europe

To Whom It May Concern:

The Gelatin Manufacturers of Europe (GME) is a trade association representing the nine largest European gelatin manufacturers. GME hereby submits the following comments on the above-referenced proposed rule:

1. Proposed 21 CFR 189.5(c) and 700.27(c) would require manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle to establish and maintain records sufficient to demonstrate that the products are not manufactured from, processed with, or do not otherwise contain, prohibited cattle materials. The primary records to demonstrate compliance with this requirement should be records provided by the original processors or importers of cattle materials, and, to the extent applicable, these records should be those authorized by USDA or equivalent foreign regulatory authorities. Such records may include:

- USDA-approved labeling provided by a USDA-inspected establishment;
- Labeling approved by foreign regulatory authorities provided by foreign establishments;
- Mutual recognition of official agreements between the EU and the US
- USDA-approved permits for importation provided by US importers; and

2004N-0257

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Division of Dockets Management

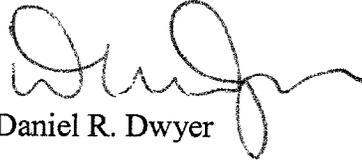
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2. Secondary records may also demonstrate compliance with the proposed requirement. These may include, for example:
- Certificates issued by foreign establishments that are responsible for downstream production of cattle materials (such as bones that originate from European de-boning facilities).
 - Guarantees provided under section 303(c)(2) of the Federal Food, Drug, and Cosmetic Act.¹

These certificates, guarantees, and other records may be general and continuing, and need not refer specifically to prohibited cattle materials so long as they certify or guarantee that the product is not adulterated or misbranded within the meaning of the Act. Such certificates, guarantees, and other records must be traceable to records such as those described in #1 above.

Respectfully submitted,



Daniel R. Dwyer

Counsel to the Gelatin Manufacturers
of Europe

¹ Section 303(c)(2) of the Act provides that no person shall be subject to penalties for interstate commerce in adulterated or misbranded foods or cosmetics if such person received a guaranty that such foods or cosmetics are not adulterated or misbranded. Under 21 CFR 7.13(a), such a guaranty may be specific to a shipment, or general and continuing.