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April 30, 2004

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**Re: Citizen Petition dated October 20, 2003 regarding FDA's gelatin guidance:
Docket No. 1997D-0411/CP 1
Comments and Request for Meeting**

Dear Ms Carson:

This follows up on the above-referenced citizen petition and on a related letter to FDA dated January 12, 2004, submitted on behalf of the Gelatin Manufacturers of Europe (GME) and the Gelatin Manufacturers Institute of America (GMIA). These trade associations represent producers of almost all of the gelatin made in Europe and North America.

As you know, our citizen petition requested that FDA modify its guidance document on gelatin¹ to reflect the July 17, 2003 conclusion of FDA's Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC). At that time, the TSEAC reviewed extensive studies on the extent to which the processing of gelatin provides a strong assurance that gelatin is safe with respect to bovine spongiform encephalopathy (BSE). The TSEAC concluded that these studies "demonstrate a reduction in infectivity that is sufficient to protect human health."² (Transcript of Meeting at 150, 158.)³ Our letter of January 12th requested a meeting with FDA to discuss the petition.

¹ *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 Human Use* (Docket No. 97D-0411, September 1997). In this letter, "gelatin" refers to gelatin manufactured from bovine raw materials.

² The vote was 7 in favor, 1 abstain, and 1 against.

³ See also, <http://www.fda.gov/ohrms/dockets/ac/03/minutes/3969M.htm>.

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KLEINFELD, KAPLAN AND BECKER, LLP

Karen L. Carson
April 30, 2004
Page 2

Since our petition was submitted, the U.S. Department of Agriculture (USDA) has adopted new policies in response to a case of BSE in a cow located in the United States. In particular, the USDA promulgated an interim final rule designating certain “specified risk materials” (SRMs)⁴ from USDA-inspected facilities that may not be used in human food and requiring that all non-ambulatory disabled (“downer”) cattle in the U.S. be condemned. 69 Fed. Reg. 1861 (January 12, 2004).

On January 26, 2004, FDA announced that it would promulgate an interim final rule to ensure that the same safeguards imposed by USDA also apply to food products that FDA regulates. According to that announcement, FDA’s rule would ban the following materials from FDA-regulated human food (including dietary supplements) and cosmetics:

- Any material from “downer” cattle;
- Any material from “dead” cattle (i.e., cattle that die on the farm before reaching the slaughter plant);
- A list of SRMs; and
- The product known as mechanically separated beef, which may contain SRMs.

(HHS Press Release, January 26, 2004.)

We respectfully request that FDA consider the following comments in the preparation of its interim final rule:

1. The rule should be general and not refer to any specific food (including gelatin).
2. The rule should be broad enough to cover all FDA-regulated products for oral consumption and cosmetic use by humans (which would cover gelatin for use in food as well as gelatin capsules for use in dietary supplements and pharmaceuticals).
3. The rule should be broad enough to cover both U.S.-produced and imported products.
4. The rule should define SRMs in a manner identical to USDA regulations.

⁴ SRMs include the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle.

KLEINFELD, KAPLAN AND BECKER, LLP

Karen L. Carson
April 30, 2004
Page 3

5. The effective date of the rule should be the same as the effective date of the USDA's rule; that is, it should apply to bovine materials from animals slaughtered on or after January 12, 2004.
6. The rule should implement the safeguards announced by FDA by using text such as the following:

“A product for oral consumption or cosmetic use by humans shall be adulterated if it contains or is derived from the following bovine materials:

“(1) non-ambulatory disabled (‘downer’) cattle slaughtered on or after January 12, 2004;

“(2) cattle that have died otherwise than by slaughter on or after January 12, 2004;

“(3) the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle, if such cattle were slaughtered on or after January 12, 2004; and

“(4) mechanically separated beef from cattle slaughtered on or after January 12, 2004;

“provided, however, that such bovine materials shall only cause a product to be adulterated if (a) the materials are produced in the United States and may not be used for human food pursuant to 9 CFR 301 et seq. or (b) the materials are produced outside of the United States and are subject to restrictions on importation due to bovine spongiform encephalopathy pursuant to 9 CFR Part 94.”

In addition, if FDA discontinues the use of its guidance document on gelatin (for products for oral consumption or cosmetic use by humans) concurrently with its adoption of the interim final rule, we request that FDA explain this action in the preamble to the interim final rule. Specifically, we request that FDA expressly state that the guidance is no longer applicable to gelatin for oral consumption or cosmetic use by humans, and that such guidance has been discontinued because it is considered to be no longer necessary to assure gelatin safety in light of current good manufacturing practice (CGMP). For this purpose, CGMP is defined as:

- Assurance that raw materials come from countries where (a) the feeding of cattle with feed that contains proteins derived from mammalian tissues is prohibited (except as permitted under 21 CFR 589.2000), and (b) BSE monitoring procedures in accordance with OIE standards are in place; and

KLEINFELD, KAPLAN AND BECKER, LLP

Karen L. Carson
April 30, 2004
Page 4

- Assurance that the manufacturing process for gelatin made from bone obtained from cattle is the same as, or equivalent to, processes that have been the subject of studies by qualified experts that demonstrate a reduction in infectivity accepted by the TSEAC as being sufficient to protect human health.

Alternatively, if FDA does not discontinue the use of its guidance document on gelatin (for products for oral consumption or cosmetic use by humans) concurrently with its adoption of the interim final rule, we request that FDA revise the guidance in a manner consistent with our citizen petition.

GME and GMIA appreciate the opportunity to provide this information to the agency as it considers the issues involved in drafting an interim final rule. In our letter of January 12th we requested an opportunity to meet with FDA, and we would like to renew that request at this time. Our preferred date for a meeting is May 26, 2004, or alternatively May 24th. We will follow up by telephone to schedule a time for the meeting.

Thank you for your kind consideration of this information.

Sincerely,



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