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August 13, 2004

BY ELECTRONIC MAIL

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

Re: Docket No. 2004N-0257; Recordkeeping Requirements for Human Food and
Cosmetics Manufactured From, Processed With, or Otherwise Containing,
Material From Cattle

Dear Sir/Madam:

On behalf of our client, Nitta Casings Inc. (NCI), we are hereby submitting the following comments on the Food and Drug Administration's (FDA) proposed recordkeeping requirements for human food and cosmetic products manufactured from, processed with, or otherwise containing, material from cattle. 69 Fed. Reg. 42275 (July 14, 2004). NCI believes that appropriate safeguards, based on current science, are needed to minimize the risk of human exposure to bovine spongiform encephalopathy (BSE).

NCI manufactures collagen casings at its facility in Somerville, New Jersey. NCI's collagen casings are manufactured from bovine hide collagen, all of which is obtained from hides of cattle slaughtered at federally inspected establishments.

NCI endorses FDA's rulemaking to protect the food supply from BSE and to make its regulations consistent with those of the U.S. Department of Agriculture (USDA). However, we believe that our product, collagen casings, poses some unique issues that may not have been taken into account by FDA in drafting the proposed rule and the related interim final rule banning "prohibited cattle materials" from human food and cosmetics.

OLSSON, FRANK AND WEEDA, P.C.

Letter to Division of Dockets Management
August 13, 2004
Page 2

With regard to the proposed recordkeeping requirements, we urge FDA to clarify that manufacturers of collagen casing may satisfy these requirements by maintaining a continuing guarantee from their collagen suppliers affirming that all of the collagen they supply comes from the hides of cattle slaughtered at federally inspected establishments.

1. Background Information

Collagen casings are made exclusively from collagen obtained from hides and skins.¹ No other cattle materials are involved in the manufacture or processing of collagen casings. At the present time, there are only two companies manufacturing collagen casing in the United States, of which NCI is one.

The process begins with removal of the cattle hide at a federally inspected establishment. All of the collagen used by NCI to make collagen casings comes from the hides of cattle slaughtered at federally inspected establishments. Almost immediately after slaughter, the hide is removed from the animal and separated from the rest of the carcass. The hide is immediately immersed in cold water that cools the hide to maintain leather quality. Removal of the hide occurs before removal of the head, brain, vertebral column, spinal cord, and other specified risk materials (SRMs). Therefore, the hide does not come into contact with, and cannot be contaminated by SRMs.²

The hide is then shipped to a tannery where it is washed to remove any loose material. Next, the hide undergoes hair removal and fleshing (removal of any remaining meat or fat). The hide is then split longitudinally to separate the outer layer for use in leather production from the interior

¹ While bone and certain other tissues also contain collagen, skin collagen is stronger than bone collagen and therefore a far superior starting material for casings. We are not aware of any manufacturer of collagen casings in the world today that uses bone collagen. Most collagen casings are made from bovine skin collagen, although some casings are made from porcine skin collagen.

² The only possible exposure of the hide to SRMs would result from brain splatter during stunning, which occurs prior to slaughter and hide removal. However, any brain material adhering to the hide would be minimal and would be present only on the outer layer of the hide. Such brain matter likely would be removed from the hide in the raceway water or during subsequent washing and de-hairing of the hide at the tannery. In addition, any brain matter likely would be present only on the face plate, which is removed from the rest of the hide at the tannery. Finally, any brain matter would only be present on the outer layer of the hide, and that outer layer is stripped away and used for leather production; only the corium, the inner layer of the hide, is used in the production of collagen casing.

OLSSON, FRANK AND WEEDA, P.C.

Letter to Division of Dockets Management
August 13, 2004
Page 3

collagen layer. The collagen layer then goes into equipment dedicated to food grade collagen where some additional preliminary processing occurs before being shipped to NCI's plant.

Bovine skin collagen is recognized internationally to be free of BSE infectivity, even if sourced from a clinically infected animal.³ Collagen casings are used in a wide variety of food products including sausage and breakfast links, bratwurst, beef sticks, hor d'oeuvre size hotdogs, kosher hotdogs, and some high-end hams.

2. In the case of bovine skin collagen, and products made from bovine skin collagen, the proposed recordkeeping requirements should be satisfied by records showing that all collagen is derived from cattle hides obtained from federally inspected establishments.

Under the proposed rule, NCI would be required to retain records demonstrating that its products were not manufactured from, processed with, or otherwise contain "prohibited cattle materials." Under FDA's interim final rule, the term "prohibited cattle materials" includes any material from non-ambulatory disabled cattle and any material from cattle that have not been inspected and passed. 69 Fed. Reg., 42256, 42273 (July 14, 2004)(21 C.F.R. § 189.5(a)(1)).

NCI believes it can, and should be allowed to, satisfy the proposed recordkeeping requirement by maintaining records showing that our collagen casings are made with collagen derived from hides obtained exclusively from federally inspected establishments. Such records should be sufficient to document that our collagen casings contain no prohibited cattle materials. Since USDA Food Safety and Inspection Service (FSIS) regulations prohibit the slaughter of non-ambulatory disabled cattle,⁴ such records demonstrate that our collagen casings are not made from material from non-ambulatory disabled cattle. Since all cattle slaughtered at federally inspected establishments must pass ante-mortem inspection, such records demonstrate that our collagen casings are not made from cattle that have not been inspected and passed for slaughter.

3. A continuing guarantee should satisfy the recordkeeping requirement.

NCI purchases collagen from tanneries that obtain cattle hides exclusively from federally inspected establishments. As previously noted, no non-ambulatory cattle may be slaughtered at a federally inspected establishment, and no cattle may be slaughtered at a federally inspected

³ The Office International des Epizooties (OIE) recommends no BSE-related restrictions on trade in collagen from hides and skins, regardless of the BSE status of the country of origin. 69 Fed. Reg. at 42295; OIE, *Terrestrial Animal Health Code 2003*, Article 2.3.13.8.

⁴ 69 Fed. Reg. 1862, 1873 (Jan. 12, 2004) (9 C.F.R. §§ 309.2(b), 309.3).

OLSSON, FRANK AND WEEDA, P.C.

Letter to Division of Dockets Management
August 13, 2004
Page 4

establishment unless it first passes inspection. Under these circumstances, and considering that hide material is not at risk for BSE transmission, we believe the only relevant record is an affirmation by the tannery that all of its hides come from federally inspected establishments.

NCI should be able to satisfy its recordkeeping obligations by maintaining such an affirmation from each of the tanneries that supplies it with collagen. Moreover, a continuing guarantee by the tannery that all of its hides are obtained exclusively from federally inspected establishments should be sufficient. Such a Letter of Guarantee should include contact information and should be renewed annually. NCI, in turn, would pass a copy of this Letter of Guarantee on to its customers.

A requirement that documentation be retained for each shipment of collagen would be difficult to comply with and unnecessary. A tannery typically obtains hides from several slaughter establishments, and the hides, and the collagen derived from the hides, are pooled. While proper traceability mechanisms are in place, it would be extremely burdensome for a tannery to continually identify a particular outgoing shipment of collagen with a particular incoming shipment of hides. If all of the collagen comes from hides obtained from federally inspected establishments, such lot-by-lot records are unnecessary.

Similarly, importers should be able to satisfy their recordkeeping obligations by means of a continuing guarantee. In the case of an importer of bovine skin collagen or collagen casings, the continuing guarantee should state that all collagen used was derived from the hides of cattle slaughtered at establishments that meet USDA/FSIS equivalency standards.

4. FDA should allow more than 30 days for industry to comply with a final rule.

FDA is proposing that its final recordkeeping rule would become effective 30 days after publication in the *Federal Register*. Thirty days is not enough time for industry to bring its records and recordkeeping practices into compliance. NCI requests that industry be given at least 90 days to comply with any new recordkeeping requirements.

5. FDA has seriously underestimated the economic impact of the proposed rule.

In its preliminary regulatory impact analysis, FDA appears to have omitted entire industries that would be subject to the proposed rule. FDA's analysis seems only to consider the industries that are end-users of cattle materials and to overlook industries that produce intermediate products. As a result, it includes no mention of the proposed rule's impact on manufacturers of collagen casing, gelatin, and other intermediate products. We hope that FDA will correct this oversight in the final rule.

OLSSON, FRANK AND WEEDA, P.C.

Letter to Division of Dockets Management
August 13, 2004
Page 5

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In conclusion, NCI urges FDA to revise the proposed rule to provide that a manufacturer of collagen casing may satisfy its recordkeeping responsibilities by retaining a continuing Letter of Guarantee, renewed annually, from each of its tannery suppliers affirming that its collagen comes exclusively from the hides of cattle slaughtered at federally inspected establishments.

NCI believes its suggestions would significantly reduce the compliance burden to industry while maintaining the same level of public health protection. We appreciate this opportunity to share our views with the agency.

Respectfully submitted,

Robert A. Hahn

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Olsson, Frank and Weeda, P.C.

cc: Office of Information and Regulatory Affairs
Office of Management and Budget
ATTN: Ms. Fumie Yokota, Desk Officer for FDA