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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

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) interim final rule banning "prohibited cattle materials" from human food and cosmetic products. 69 Fed. Reg. 42256 (July 14, 2004).

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 bovine spongiform encephalopathy (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 interim final rule.

We urge FDA to clarify that collagen casing made from the hides of cattle slaughtered at federally inspected establishments is not a "prohibited cattle material."

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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 for quality purposes. 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

All cattle slaughtered at federally inspected establishments must pass ante-mortem inspection by USDA's Food Safety and Inspection Service (FSIS). However, the hide is removed before post-mortem inspection of the carcass by FSIS personnel.

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, the Food Safety and Inspection Service (FSIS) condemns heads of cattle 30 months or older unless an establishment can ensure that stunning does not result in brain leakage. FSIS Notice 4-04 (Jan. 14, 2004). Even if an establishment cannot ensure that brain tissue does not leak onto the hide, 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, since 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, it would not contaminate the corium, the inner layer of the hide, that is used in the production of collagen casing. Finally, any brain matter likely would be present only on the faceplate, which is removed from the rest of the hide before the corium is stripped away.

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After removal and cooling, the hide is shipped to a tannery where it is washed to remove any loose material. Next, the hide is de-haired by exposing it to a high pH solution, which would reduce any BSE infectivity if it were present in the collagen.³ The hide is then fleshed to remove any remaining meat or fat. The hide is then split longitudinally to separate the outer layer for use in leather production from the interior collagen layer. The collagen layer then goes into equipment dedicated to food grade collagen where some additional preliminary processing occurs before it is shipped to NCI's plant.

At NCI's plant, the collagen is manufactured into collagen casings for use in a wide variety of food products including sausage and breakfast links, bratwurst, beef sticks, and hot d'oeuvre size hotdogs.

2. Collagen and collagen products made exclusively from the hides of cattle slaughtered at federally inspected establishments should not be considered "prohibited cattle materials."

Under the interim final rule, no human food or cosmetic may be manufactured from, processed with, or otherwise contain "prohibited cattle materials." The term "prohibited cattle materials" includes any material from cattle that have not been inspected and passed. 69 Fed. Reg. at 42273 (21 C.F.R. § 189.5(a)(1)). The term "inspected and passed" means inspected and passed for human consumption by the appropriate regulatory authority and found to be not adulterated. *Id.* (21 C.F.R. § 189.5(a)(2)).

Under one possible reading of these provisions, any cattle material that has not passed both ante-mortem and post-mortem inspection by FSIS is a prohibited cattle material. This would mean that collagen, gelatin, and any other products made from cattle hides would be prohibited in human food and cosmetics. NCI does not believe that FDA intended this result.

NCI urges FDA to amend the interim final rule to clarify that the term "prohibited cattle materials" is not intended to encompass materials made from the hides of cattle that have passed ante-mortem inspection. Specifically, we request that the definition of "inspected and passed" be

³ European Commission, *Opinion and Report on Safety with Respect to TSE Risks of Collagen Produced from Ruminant Hides*, adopted by the Scientific Steering Committee at its meeting of 10-11 May 2001, p. 2 ("The production of collagen from hides and skins involves always an alkali step – using lime, or a lime sodium sulphide solution or a diluted sodium hydroxide solution – which can be assumed to have some TSE infectivity inactivation capacity should TSE agent be present by contamination of the hides"). The same alkali step is used in collagen production in the United States.

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modified to make clear that only ante-mortem inspection is required in the case of cattle hides and materials derived from hides.

a. FDA's rationale for banning materials from cattle that have not been inspected and passed relates to ante-mortem inspection, not post-mortem inspection.

In the preamble to the interim final rule, FDA offers several reasons why materials from cattle that have not been inspected and passed may pose a risk of BSE transmission. FDA states that cattle that have not been inspected and passed may have died on the farm or en route to slaughter,⁴ may have been condemned at slaughter because of a central nervous system disorder, or may have been slaughtered at a rendering facility.⁵ All of these reasons justify banning materials from cattle that have not passed ante-mortem inspection. None justify banning materials that have not passed post-mortem inspection.

Ante-mortem inspection by FSIS is an important measure to protect the food supply from BSE contamination. At ante-mortem inspection, FSIS personnel condemn any cattle exhibiting behaviors characteristic of BSE or other neurological disorders as well as nonambulatory, disabled cattle. Condemned cattle are sent to rendering or incineration.

Post-mortem inspection, on the other hand, is not capable of detecting animals at higher risk of BSE. There are no visible symptoms of BSE that can be detected by post-mortem examination of the carcass. Post-mortem inspection only protects against BSE to the extent that it detects SRM contamination of edible tissues being inspected.⁶ While this may protect against SRM contamination of meat and other edible tissues derived from the carcass, it has no bearing on the safety of the hide that was earlier removed from that carcass. The fact that SRMs might be found in

⁴ Cattle that die on the farm or en route to slaughter are considered to be at higher risk for BSE and do not undergo ante-mortem inspection for BSE and other diseases.

⁵ Cattle that are not slaughtered at a federally inspected establishment do not undergo ante-mortem inspection for BSE and other diseases.

⁶ The *Terrestrial Animal Health Code* of the Office International des Epizooties (OIE) makes no mention of post-mortem inspection as a safeguard against BSE. It does stress the importance of ante-mortem inspection, recommending trade in meat and meat products only if derived from cattle that have passed ante-mortem inspection. OIE, *Terrestrial Animal Health Code 2004*, Articles 2.3.13.14 through 2.3.13.16.

meat or other edible tissues does not reveal anything about the safety of the hide. Nor would post-mortem inspection of hides serve any purpose. As previously noted, the possibility of SRM contamination of hides is extremely remote.

b. Cattle hides and collagen made from cattle hides are recognized internationally as safe commodities free of BSE infectivity.

Cattle hides and bovine skin collagen are internationally recognized as safe commodities. The OIE has so much confidence in the safety of bovine skin collagen that it asserts that it is safe even if made from the hide of an animal with clinical BSE. The OIE recommends no BSE-related restrictions on trade in collagen from hides and skins, regardless of the BSE status of the country of origin.⁷

The Scientific Steering Committee of the European Commission has concluded that collagen is safe for human consumption, provided only that it is sourced from hides that have passed ante-mortem inspection and the risk of SRM contamination is minimal. According to its report, cattle hides “are not considered to be part of the group of tissues that potentially represent a risk with regard to TSEs [transmissible spongiform encephalopathies].”⁸

Although the United States and Canada imposed reciprocal trade restrictions on each other’s ruminant products following the discovery of BSE-positive cattle in Canada and the United States in 2003, both countries continue to allow trade in cattle hides and derivative products.⁹

⁷ “When authorizing import or transit of the following commodities, Veterinary Administrations should not require any BSE related conditions, regardless of the BSE status of the cattle population of the exporting country or zone:.... d. gelatin and collagen prepared exclusively from hides and skins (excluding hides and skins from the head).” OIE, *Terrestrial Animal Health Code 2004*, Article 2.3.13.1. As previously stated, the collagen used by NCI is stripped from the hide after removal of the faceplate (*i.e.*, the hide from the head).

⁸ European Commission, *Opinion and Report on Safety with Respect to TSE Risks of Collagen Produced from Ruminant Hides*,. See also EC, *Updated Opinion on the Safety with Regard to TSE Risks of Gelatine Derived from Ruminant Bones or Hides from Cattle, Sheep or Goats* (reaching the same conclusion regarding gelatin made from cattle hides).

⁹ See Canadian Food Inspection Agency, Update to Import Restrictions – United States (listing hides, wool, skins and their derivatives as examples of exempt commodities); 68 Fed. Reg. 31939 (May 29, 2003) (listing ruminant hides and ruminant hide derived products from Canada as eligible for entry).

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c. Banning cattle hides because they have not passed post-mortem inspection would remove a safe source of collagen and gelatin and would serve no public health purpose.

If cattle hides were considered to be “prohibited cattle materials” because they have not passed post-mortem inspection, then collagen and gelatin made from cattle hides would be banned from use in human food and cosmetic products. This action would remove a safe source of collagen and gelatin. It would also have a drastic impact on the collagen casing industry, the gelatin industry, and other industries that use these products. It would have a devastating impact on NCI as well as the more than 100 U.S. companies that use our collagen casings in their food products. Additionally, this action would affect numerous companies overseas that use NCI products and their immediate suppliers, all of which have become accustomed to the use of collagen casings in the meat processing industry. Many of these companies only manufacture products that use collagen casing, and therefore might go out of business. Certain products, including sausages and beefsticks, that cannot be made without collagen casing would cease to exist.

Banning cattle hides and their derivative products from human food and cosmetics would serve no public health purpose. As previously discussed, it is ante-mortem inspection, not post-mortem inspection, that is important for BSE protection. Collagen made from hides is recognized internationally to be free of BSE infectivity. In fact, collagen and gelatin made from hides are safer in terms of BSE risk than collagen and gelatin made from bones.¹⁰

NCI therefore urges FDA to clarify that collagen and collagen products made from the hides of cattle slaughtered at federally inspected establishments (*i.e.*, that have passed ante-mortem inspection) are not “prohibited cattle materials.”

3. FDA has seriously underestimated the economic impact of the interim final rule.

In its regulatory impact analysis, FDA appears to have omitted entire industries that are subject to the interim final 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 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.

¹⁰ EC, *Updated Opinion on the Safety with Regard to TSE Risks of Gelatine Derived from Ruminant Bones or Hides from Cattle, Sheep or Goats*, p. 3 (“The risk of contamination with TSE infectivity is much higher with bones, as compared to hides”).

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If FDA were to require that collagen must come from hides that have passed both ante-mortem and post-mortem inspection, the economic impact would be devastating for the collagen casing industry. NCI estimates that it would lose U.S. sales amounting to approximately \$30 million a year. It estimates that the total loss of U.S. sales revenue to all producers of collagen casing would be significantly more than \$50 million per year. NCI believes that such a loss would necessitate closure of its New Jersey production facility with a loss of over 200 well-paid manufacturing jobs.

The impact on NCI's customers and the industries that use collagen casing would be even more profound. If there are any manufacturers of collagen casing that would be able to comply with such a requirement, they would have neither the hide supply nor the manufacturing capacity to fill the void in the market that would be left by the loss of collagen products made from hides that have not passed post-mortem inspection. In most cases, there is no substitute product that can take the place of collagen casings, films and doughs, nor is there any substitute technology that would enable food manufacturers to forego use of collagen casings, films, and doughs. NCI estimates that businesses that sell food products made with collagen casings and films would stand to lose retail sales of more than \$2 billion. The estimated retail value of food products that use collagen casings and films is as follows:

| <u>Product Type</u> | <u>Retail Value</u> |
|-----------------------|---------------------|
| Fresh breakfast links | \$ 672,000,000 |
| Processed sausage | \$ 230,000,000 |
| Snack sticks | \$1,006,000,000 |
| Cocktail sausage | \$ 291,000,000 |
| Total Value: | \$2,199,000,000 |

A loss in retail sales of this order would likely mean the closure of many plants and the loss of thousands of manufacturing jobs.

NCI also disagrees with FDA's conclusion regarding the impact of this rule on small businesses. FDA states that this rule would not "have a significant economic impact on a substantial number of small entities" and that the only cost to small businesses would be the cost of switching to alternative ingredients. 69 Fed. Reg. at 42271. Most of NCI's customers are small businesses as defined by the Small Business Administration. Many of these companies only manufacture or primarily manufacture products made with collagen casing. Contrary to FDA's statement, there is no alternative ingredient that can substitute for collagen casing in these products. A restriction that would effectively prohibit the use of collagen made from cattle hides in human food would probably force many of these small entities out of business.

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For all of the foregoing reasons, NCI urges FDA to amend the interim final rule to provide that, in the case of cattle hides and collagen made exclusively from cattle hides, “inspected and passed” refers only to ante-mortem inspection.

We appreciate this opportunity to share our views with the agency.

Respectfully submitted,

Robert A. Hahn
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RAH:jdm

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