National Grain and Feed Association

June 17, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket Number 03D-0186
"Guidance for Industry: Use of Material from Deer and Elk in Animal Feed"

Dear Sirs:

The National Grain and Feed Association appreciates the opportunity to submit this statement in response to the draft guidance published on May 14 by the Food and Drug Administration concerning the use of material from deer and elk in animal feed.

Established in 1896, the NGFA is the U.S.-based non-profit trade association that consists of more than 1,000 grain, feed, processing and grain-related firms that operate more than 5,000 facilities and handle more than two-thirds of U.S. grains and oilseeds. More than 300 of the NGFA's member companies operate feed manufacturing and integrated feeding operations, ranging from the largest commercial feed manufacturer in North America to small grind-and-mix operations.

The NGFA's Mission Statement commits the organization to promoting policies that foster an efficient free-market environment that achieves an abundant, safe and high-quality food supply for domestic and world consumers. In this regard, the NGFA strongly supports FDA's use of best-available science and prudent risk-assessment in exercising its statutory responsibilities to promote food and feed safety and protect human health.

In representing the interests of commercial feed manufacturers and integrated livestock and poultry companies, the NGFA appreciates the intent of FDA's draft guidance in attempting to clarify the circumstances under which the agency would deem that feed or feed ingredients containing material from deer and elk would be considered to be adulterated within the meaning of the federal Food, Drug and Cosmetic Act because of concern over chronic wasting disease (CWD). The NGFA supports most of the core policy elements contained in the draft guidance.

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Specific Comments on Draft Guidance Document

The NGFA offers the following specific comments on the draft guidance concerning the use of all material from deer and elk in all animal feed.

As FDA implies in its draft guidance, there is no known scientific evidence that CWD is transferred to humans or non-cervid animals, such as poultry and swine. But we do not disagree with the agency's assessment that the rapid spread of CWD in white-tailed deer and what the agency describes as the "poorly understood" route of CWD transmission makes it advisable to consider restrictions on the use of deer and elk in animal feed under certain circumstances.

The NGFA does not disagree with the Section III of the draft guidance, which states that material from CWD-positive deer and elk should not be used in any animal feed or feed ingredients. We also concur with the draft guidance's statement in Section V that material from deer and elk **not** considered to be at "high risk" for CWD should be considered acceptable for use in non-ruminant animal feed in accordance with the agency's BSE-prevention rule *[29 CFR 589.2000]*. In the draft guidance, FDA classifies deer and elk as **not** being "high risk" if they: 1) come from areas not declared by state officials to be endemic for CWD and/or CWD-eradication zones; and 2) were not at some time during the 60-month period immediately before slaughter part of a captive herd that contained a CWD-positive animal. We do believe FDA should explain in any future guidance the scientific rationale used to establish the 60-month time frame.

However, because of the very nature of deer and elk hunting, dead-stock disposal and the animal slaughter and rendering process itself, the NGFA has serious concerns over the potential liability imposed on feed manufacturers and other receivers and users of feed ingredients by Section IV of the guidance, which governs the use in animal feed of material from deer and elk considered to be at "high risk" for CWD. FDA's guidance states that deer and elk would be considered to be at high risk for CWD if they: 1) come from areas declared by state officials to be endemic for CWD and/or CWD-eradication zones; and 2) were at some time during the 60-month period immediately before slaughter part of a captive herd that contained a CWD-positive animal. This section of FDA's draft guidance "recommends" that materials from deer and elk meeting these "high-risk" conditions no longer be used in animal feed.

As FDA knows, deer and elk carcasses can be delivered to renderers or slaughterhouses from a wide variety of sources, including hunters, state and county road crews that clear dead stock from highways, farmers of captive herds, and others. Frequently, these animals are transported across wide geographic areas before being delivered to the renderer or processor. **For these reasons, the NGFA believes strongly that additional language should be inserted into the guidance document to state that it is the responsibility of those renderers or slaughterhouses that process deer and elk into feed ingredients to either: 1) affirmatively ascertain that the animal does not meet the aforementioned criteria for being at "high risk" for CWD from the hunter or other person from which the animal is received, perhaps through the use**

of a signed release form; or 2) to test the animal to determine that it is negative for CWD before it is rendered or otherwise processed as a feed ingredient, in which case the animal would be permitted to be used in feed.

We offer for FDA's consideration the following language as a suggested insert for paragraph two of Section IV *[new language boldfaced and underscored]*:

> *"IV. **Use in animal feed of material from deer and elk considered at high risk for CWD***
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> *"...FDA recommends that materials from deer and elk considered at high risk for CWD no longer be entered into the animal feed system. **FDA believes it is the responsibility of those renderers or slaughterhouses that receive and process deer and elk to either: 1) affirmatively ascertain from the person(s) delivering the animal that it does not meet the criteria for being at high risk for CWD before the animal is processed and rendered; or 2) to test the animal to determine that it is free of CWD before it is processed or rendered as a feed ingredient. FDA does not object to the use in animal feed of deer and elk that test negative for CWD.** Under present circumstances, FDA is not recommending that feed made from deer and elk from a non-endemic area be recalled if a State later declares the area endemic for CWD or a CWD eradication zone. In addition, at this time, FDA is not recommending that feed made from deer and elk believed to be from a captive herd that contained no CWD-positive animals be recalled if that herd is subsequently found to contain a CWD-positive animal."*

Of course, notwithstanding any guidance issued by FDA, renderers, slaughterhouses, feed manufacturers and others have the freedom to make a business decision not to use any deer or elk as an ingredient in animal feed. In addition, we believe FDA's guidance should recognize good-faith efforts by feed manufacturers and other receivers/users of feed ingredients to protect themselves from liability by inserting language into contracts to the effect that the supplier warrants that feed ingredients do **not** contain material from deer and elk that meet the FDA criteria for CWD high-risk animals.

We do support the provisions of Section IV that state that FDA, "under present circumstances," is not recommending that feed made from deer and elk from a non-endemic area be recalled if a state later declares the area to be endemic for CWD or a CWD eradication zone. And we support the provision under which FDA states it is not recommending that feed made from deer and elk believed to be from a captive herd that contained no CWD-positive animals be recalled if that herd subsequently is found to contain a CWD-positive animal.

Recommendation Concerning Rulemaking

The NGFA also wants to take this opportunity to reiterate its belief that FDA should initiate a rulemaking process under the Administrative Procedures Act to implement its policies concerning CWD and the use of deer and elk in animal feed.

This is consistent with our recommendations in 2002, when we expressed concerns over the process the agency used to issue a notice on Nov. 12, 2002, in which FDA initially said it would "not permit" material from deer and elk that test positive for CWD – or which originate from areas believed to be of "high risk" for CWD – to be used as an ingredient in feed for any animal species. In that notice, FDA said animals would be considered to be at high risk for CWD if they came from CWD-positive herds; from free-ranging animals from what then were the two endemic areas (Colorado and Wyoming); or the eradication zone in Wisconsin; or from any areas designated around any new foci of CWD infection that might be identified through surveillance or hunter-harvest testing. In its Nov. 12, 2002 notice, FDA also stated that animal feed or feed ingredients already on the market that contain such material should be "recalled or otherwise removed from circulation." FDA subsequently on Nov. 21, 2002 issued a second notice that deleted the "not permit" language of its original notice and replaced it with a statement that the agency "strongly advise(d)" that material from deer and elk meeting the conditions described above not be used as a feed ingredient. Both FDA notices caused significant confusion in the midst of the 2002 deer-hunting season.

The issuance of a draft guidance document, and the solicitation of public comments prior to its finalization, is certainly preferable to the issuance of notices as FDA did in 2002. But as it told FDA in 2002, the NGFA continues to believe that the prudent – and legal – course of action for FDA when attempting to restrict or ban the use of a particular class of animal protein in animal feed, is for the agency to follow a public rulemaking process that provides a transparent opportunity for interested parties to submit scientific evidence, arguments and views, and for the agency to perform a risk assessment and cost-benefit analysis. This is precisely the model that FDA followed when promulgating the highly significant final regulations in 1997 that prohibit the use of specific mammalian proteins – including deer and elk – in ruminant feed to protect against the establishment or amplification of bovine spongiform encephalopathy (BSE) in the United States. That rulemaking process also galvanized broad support from affected industries and consumers for the BSE-prevention policy course FDA took, which was important to achieving near universal compliance.

While we acknowledge that FDA does not have sufficient time to complete a rulemaking prior to this fall's deer-hunting season, we urge the agency to announce plans to initiate such a rulemaking process concurrently with the date it issues any final guidance to the industry concerning this matter.

Conclusion

The NGFA appreciates the opportunity to provide its views on this important matter, and pledges its continued efforts to achieve the mutual objective of preserving a safe and high-quality food and feed supply for U.S. consumers.

Sincerely,

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National Grain and Feed Association