

**#158**

## **Guidance for Industry**

# **Use of Material from Deer and Elk in Animal Feed**

*This version of the guidance replaces the version made available September 15, 2003.  
This document has been revised to update the docket number, contact information, and  
standard disclosures.*

Submit comments on this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket No. FDA-2003-D-0432 (formerly 03D-0186).

For further information regarding this guidance, contact [Burt Pritchett](#), Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-402-6276, E-mail: [burt.pritchett@fda.hhs.gov](mailto:burt.pritchett@fda.hhs.gov).

Additional copies of this guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either <http://www.fda.gov/AnimalVeterinary/default.htm> or <http://www.regulations.gov>.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Veterinary Medicine  
March 2016**

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### **Use of Material from Deer and Elk in Animal Feed**

*This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.*

#### **I. Introduction**

Under FDA's BSE feed regulation (21 CFR 589.2000) most material from deer and elk is prohibited for use in feed for ruminant animals. This guidance document describes FDA's recommendations regarding the use in all animal feed of all material from deer and elk that are positive for Chronic Wasting Disease (CWD) or are considered at high risk for CWD. The potential risks from CWD to humans or non-cervid animals such as poultry and swine are not well understood. However, because of recent recognition that CWD is spreading rapidly in white-tailed deer, and because CWD's route of transmission is poorly understood, FDA is making recommendations regarding the use in animal feed of rendered materials from deer and elk that are CWD-positive or that are at high risk for CWD.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

#### **II. Background**

CWD is a neurological (brain) disease of farmed and wild deer and elk that belong in the animal family cervidae (cervids). Only deer and elk are known to be susceptible to CWD by natural transmission. The disease has been found in farmed and wild mule deer, white-tailed deer, North American elk, and in farmed black-tailed deer. CWD belongs to a family of animal and human diseases called transmissible spongiform encephalopathies (TSEs). These include bovine spongiform encephalopathy (BSE or "mad cow" disease) in cattle; scrapie in sheep and goats; and classical and variant Creutzfeldt-Jakob diseases (CJD and vCJD) in humans. There is no known treatment for these diseases, and there is no vaccine to prevent them. In addition, although validated postmortem diagnostic tests are available, there are no validated diagnostic tests for CWD that can be used to test for the disease in live animals.

## *Contains Nonbinding Recommendations*

### **III. Use in animal feed of material from CWD-positive deer and elk**

Material from CWD-positive animals may not be used in any animal feed or feed ingredients. Pursuant to Sec. 402(a)(5) of the Federal Food, Drug, and Cosmetic Act, animal feed and feed ingredients containing material from a CWD-positive animal would be considered adulterated. FDA recommends that any such adulterated feed or feed ingredients be recalled or otherwise removed from the marketplace.

### **IV. Use in animal feed of material from deer and elk considered at high risk for CWD**

Deer and elk considered at high risk for CWD include: (1) animals from areas declared by State officials to be endemic for CWD and/or to be CWD eradication zones; and (2) deer and elk that at some time during the 60-month period immediately before the time of slaughter were in a captive herd that contained a CWD-positive animal.

FDA recommends that materials from deer and elk considered at high risk for CWD no longer be entered into the animal feed system. 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.

### **V. Use in animal feed of material from deer and elk NOT considered at high risk for CWD**

FDA continues to consider materials from deer and elk NOT considered at high risk for CWD to be acceptable for use in NON-RUMINANT animal feeds in accordance with current agency regulations, 21 CFR 589.2000. Deer and elk not considered at high risk include: (1) deer and elk from areas not declared by State officials to be endemic for CWD and/or to be CWD eradication zones; and (2) deer and elk that were not at some time during the 60-month period immediately before the time of slaughter in a captive herd that contained a CWD-positive animal.