CONTAINS NON-BINDING RECOMMENDATIONS

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Guidance for Industry

Use of Material from Deer and Elk in Animal Feed

Comments and suggestions regarding the document should be submitted to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. All comments should be identified with the Docket No. 03D-0186.

For questions regarding this guidance, contact Burt Pritchett, Center for Veterinary Medicine (HFV- 222), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-453-6860, E-mail: burt.pritchett@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
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Guidance for Industry[1]

Use of Material from Deer and Elk in Animal Feed

This guidance represents the Food and Drug Administration's current thinking on the use of material from deer and elk in animal feed. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of applicable statutes or regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

FDA's guidance documents, including this guidance, 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.

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.

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,

[1] This guidance has been prepared by the Division of Animal Feeds in the Center for Veterinary Medicine (CVM) at the Food and Drug Administration.

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.

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.