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Guidance for Industry

Use of unapproved hormone implants in veal calves

Comments and suggestions regarding this guidance should be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the Docket No. 2004D-0160. Comments also may be submitted electronically on the Internet at http://www.fda.gov/dockets/ecomments

If you have questions regarding the guidance document, contact Gloria J. Dunnavan, Center for Veterinary Medicine (HFV- 230), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-1168, e-mail: gloria.dunnavan@fda.gov.

Additional copies of this draft guidance document may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at http://www.fda.gov/cvm.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
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This guidance represents the Food and Drug Administration's (FDA) current recommendations regarding the use of unapproved hormone implants in non-ruminating veal calves. 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 and 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

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) veterinarians have recently found evidence of unapproved, growth-promoting animal drug implants in veal calves being presented for slaughter at several establishments. Veal calves may have been implanted with growth-promoting hormones that may include progesterone, testosterone, estradiol, zeranol, and trenbolone. FDA and FSIS have begun an investigation to determine the extent to which unapproved animal drug implants are being used in the veal calf industry. This document provides guidance on the appropriate disposition of veal calves that have been implanted with such implants.

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.

II. Use of unapproved hormone implants in veal calves

FDA has not approved any implants that contain hormones for veal calves. FDA defines veal calves to include any non-ruminating calf, regardless of breed, intended to be, or having been processed for veal. Because there is no approved animal drug application providing for the use of these implants in non-ruminating calves, such use is illegal. Under section 512 of the Federal Food, Drug, and Cosmetic Act (the Act), use of an unapproved new animal drug results in the drug being unsafe, and, therefore, the drugs are adulterated under section

501(a)(5). In addition, food that bears or contains these drugs is adulterated under section 402(a)(2)(C)(ii) of the Act.

III. Special measures to ensure safety of veal for human consumption

Veal calves that have been implanted with growth-promoting hormones may be adulterated. However, they may be made acceptable for human consumption if special precautions are taken. The special precautions are as follows:

1. The veal calf is not processed for food within 63 days of implantation.

2. The veal calf has been implanted in accordance with the labeled dose for beef, in accordance with the directions on the implant, and in the proper location (under the skin of the ear).

3. The veal calf is presented for slaughter prior to June 06, 2004.

4. The veal calf is presented for slaughter with appropriate certification as outlined in a related notice being issued by FSIS.

FDA is basing this 63-day holding period on its determination that by this time the unapproved drugs will have depleted to the level that does not pose a risk to human health. FDA considered the information known about the hormones that may have been implanted. Because trenbolone has the longest time to deplete from the animals' tissues, FDA has used information on trenbolone as the basis for determining the appropriate holding period. In connection with its approval of trenbolone in adult cattle, FDA established an acceptable daily intake (ADI) of 0.4 µg/kg body weight (21 CFR 556.739). An ADI is the measure of exposure to a drug residue that is known to be safe for humans through toxicological analysis. Based on the ADI for trenbolone, FDA estimates that the safe concentrations for trenbolone in edible tissues are as follows:

Liver: 240 µg/kg

Kidney: 480 µg/kg

Muscle: 80 µg/kg

Fat: 480 µg/kg

While residue depletion data for trenbolone in calves are not available, extrapolations from studies in calves and larger cattle indicate that the highest dose of trenbolone in an implant (200 mg) would be depleted below the safe concentration identified above by 63 days after implantation in a calf.

The agency's analysis is based on the best information available at this time and on the conditions in this policy, including that this is a one-time event and that illegal implants will not continue to occur.

FDA will work with USDA/FSIS to verify that the calves presented for slaughter meet these conditions. As part of this process, FSIS plans to conduct random sampling and analysis of veal tissue for hormone residues and samples of implants may be sent to FDA, DEN-VAS for identification. The policy contained in this guidance only applies to veal calves presented for slaughter prior to June 06, 2004.

FDA stresses that this policy does not excuse any illegal conduct that has occurred. The agency intends to use its full range of enforcement options where appropriate and intends to take enforcement actions to ensure that this activity does not continue. Moreover, the agency stresses that this policy is based on the premise that there will be no additional illegal use of these implants in veal calves.