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Veterinary Drugs Directorate 11 Holland Avenue, Suite 14 Address Locator: 3000A Ottawa, Ontario K1A 0K9 Canadian Food Inspection Agency 59 Camelot Drive Ottawa, Ontario K1A 0Y9

May 21, 2004

To: [See attached Distribution List]

The purpose of this letter is to address concerns that have arisen regarding the use of hormonal growth implants in milk-fed, grain-fed and grass-fed calves intended for veal production in Canada.

On April 2, 2004, the US Food and Drug Administration published a guidance document on the unapproved use of hormonal growth implants in veal calves. In the United States, the use of these implants in veal calves is prohibited by law, however, the US Department of Agriculture's Food Safety Inspection Service has found evidence that there has been unapproved use of hormonal implants in veal calves. The US has taken action to further preclude the use of these implants in veal calves. The US guidance document can be found on the FDA Web site at:

http://www.fda.gov/oc/opacom/hottopics/veal_guidance.html



Similarly in Canada, hormonal growth promotants in any form have not been approved for use in calves intended for veal production. Products approved for use in beef calves (i.e., animals destined to be slaughtered as beef) have on their label Cautions or Contraindications advising that these products are not to be used in calves intended for veal production. It is the position of Health Canada's Veterinary Drugs Directorate (VDD) that the practice of using veterinary drugs in an extra-label manner is not justified for growth promotion and should be reserved for therapeutic purposes only.

In the absence of any application for the approval of these products in calves intended for veal production, VDD has not evaluated the potential impact on human and animal health.

Based on the above, Health Canada and the Canadian Food Inspection Agency (CFIA) are taking the following steps:

- 1. We are advising potential users that these products are not to be used under any circumstances in milk-fed, grain-fed and grass-fed calves intended for veal production. We would request your help to inform your members.
- 2. VDD will be writing to the manufacturers of all hormonal growth promotants to advise them that a change will be required to the Warning part of their label, specifically, it must include a statement to the effect that the product should not be used in calves that may be slaughtered for yeal production.
- 3. CFIA will be conducting enhanced inspection and surveillance activities at plants where calves intended for veal production are slaughtered to determine whether hormonal growth promotants are being used.
- 4. When the CFIA has reason to believe that hormonal growth promotants have been used in calves intended for veal production, appropriate compliance and enforcement measures will be taken.
- 5. The CFIA is developing a technical guidance document which will address the compliance measures in greater detail and this will be forwarded to you shortly. Under the CFIA guidance, should calves have been implanted with a hormonal growth promotant, they will be allowed to be presented for slaughter 63 days after implantation provided that the implants were used in strict accordance with the label conditions established for adult cattle, and the calves are presented for slaughter no later than January 5, 2005. If the conditions set out in the



guidance document are followed, the food from these calves would not pose a risk to human health. For further information, contact Dr. Claude Boissoneault -(613) 221-7101.

While we are undertaking these important measures, we ask for your cooperation in promoting safe practices in the production of calves intended for veal production that are compliant with relevant Canadian regulatory requirements.

Yours sincerely,

Diane Kirkpatrick Director General

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Canadian Food Inspection Agency

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