

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0160]

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Certifier *R. Hawkins*

**Withdrawal of Guidance Document on Use of Unapproved Hormone Implants
in Veal Calves**

AGENCY: Food and Drug Administration, HHS.

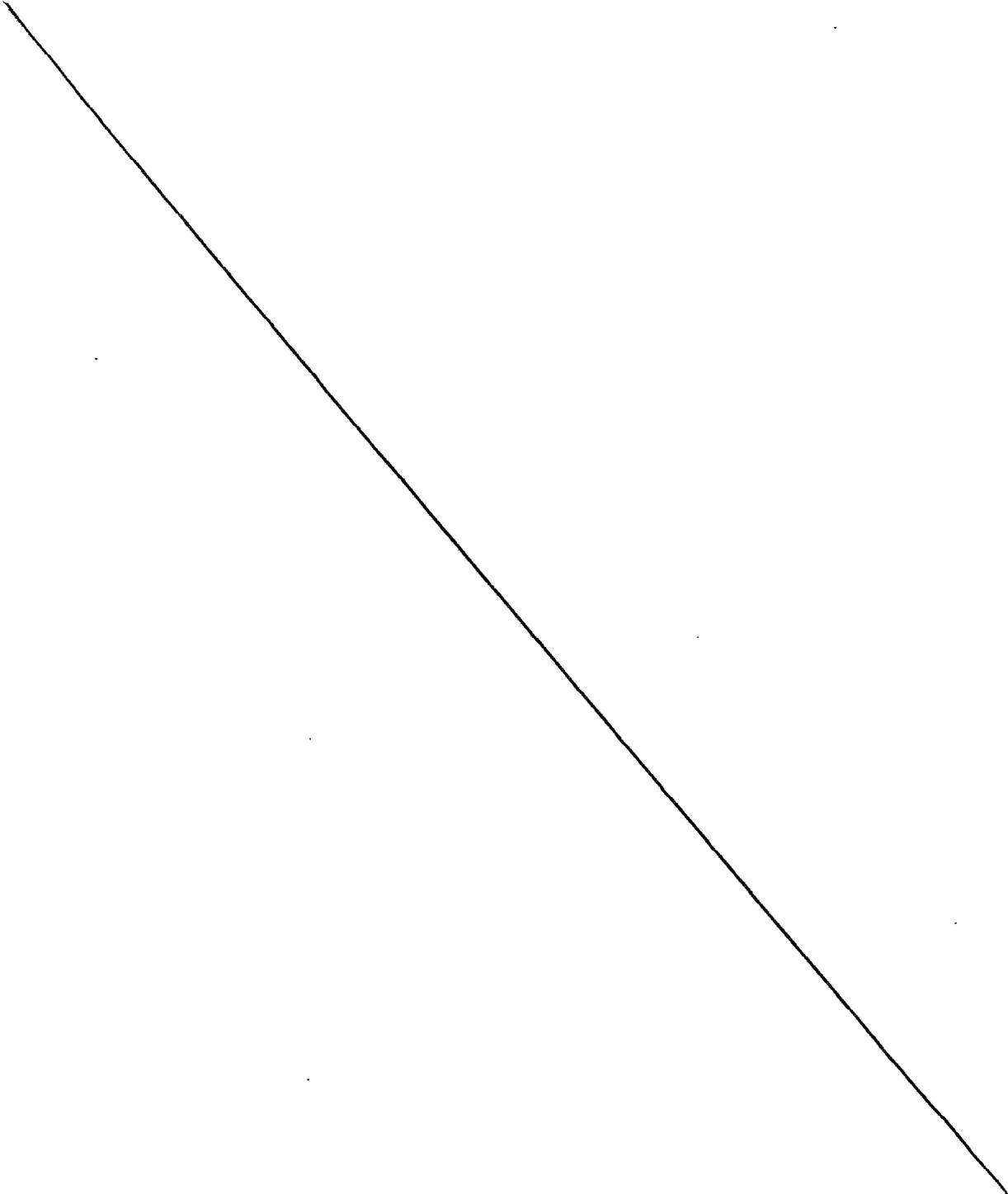
ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing a guidance for industry (#172) entitled "Use of Unapproved Hormone Implants in Veal Calves." This guidance, which was issued on April 2, 2004, is being withdrawn because the policy contained within it only applied to veal calves presented for slaughter prior to June 6, 2004.

FOR FURTHER INFORMATION CONTACT: Gloria J. Dunnavan, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1166, e-mail: *gloria.dunnavan@fda.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** dated April 8, 2004 (69 FR 18594), FDA announced the availability of a guidance for industry (#172) entitled "Use of Unapproved Hormone Implants in Veal Calves." This guidance outlined special measures to ensure the safety of veal in response to the identified illegal use of unapproved hormone implants in veal calves. The policy outlined in this guidance only applied to veal calves presented for slaughter prior to June 6, 2004. Therefore, the guidance is no longer relevant and is being withdrawn. Because there is no approved animal drug application providing for the use of these implants in veal calves, such use is illegal. Under

section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b), use of an unapproved new animal drug results in the drug being unsafe, and, therefore,



the drugs are adulterated under section 501(a)(5) of the act (21 U.S.C. 351(a)(5)). In addition, food that bears or contains these drugs is adulterated under section 402(a)(2)(C)(ii) of the act (21 U.S.C. 342(a)(2)(C)(ii)).

Dated: 7/9/04

July 9, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.
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