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Cashier A. Corbin

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000N–1571]

Enrofloxacin for Poultry; Final Decision on Withdrawal of New Animal Drug Application Following Formal Evidentiary Public Hearing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the final decision setting forth the findings of fact and conclusions of law on the issues addressed in a formal evidentiary public hearing to determine whether FDA should withdraw approval of the new animal drug application (NADA) for use of enrofloxacin in poultry. Once this final decision becomes effective on September 12, 2005, this drug may no longer be distributed or administered for this use in the United States, nor may it be exported except as allowed by law. Elsewhere in this issue of the **Federal Register**, a final rule removing the applicable regulations is published.

ADDRESSES: The transcript of the hearing, evidence submitted, and the final decision, may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to these documents.

FOR FURTHER INFORMATION CONTACT: Erik P. Mettler, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

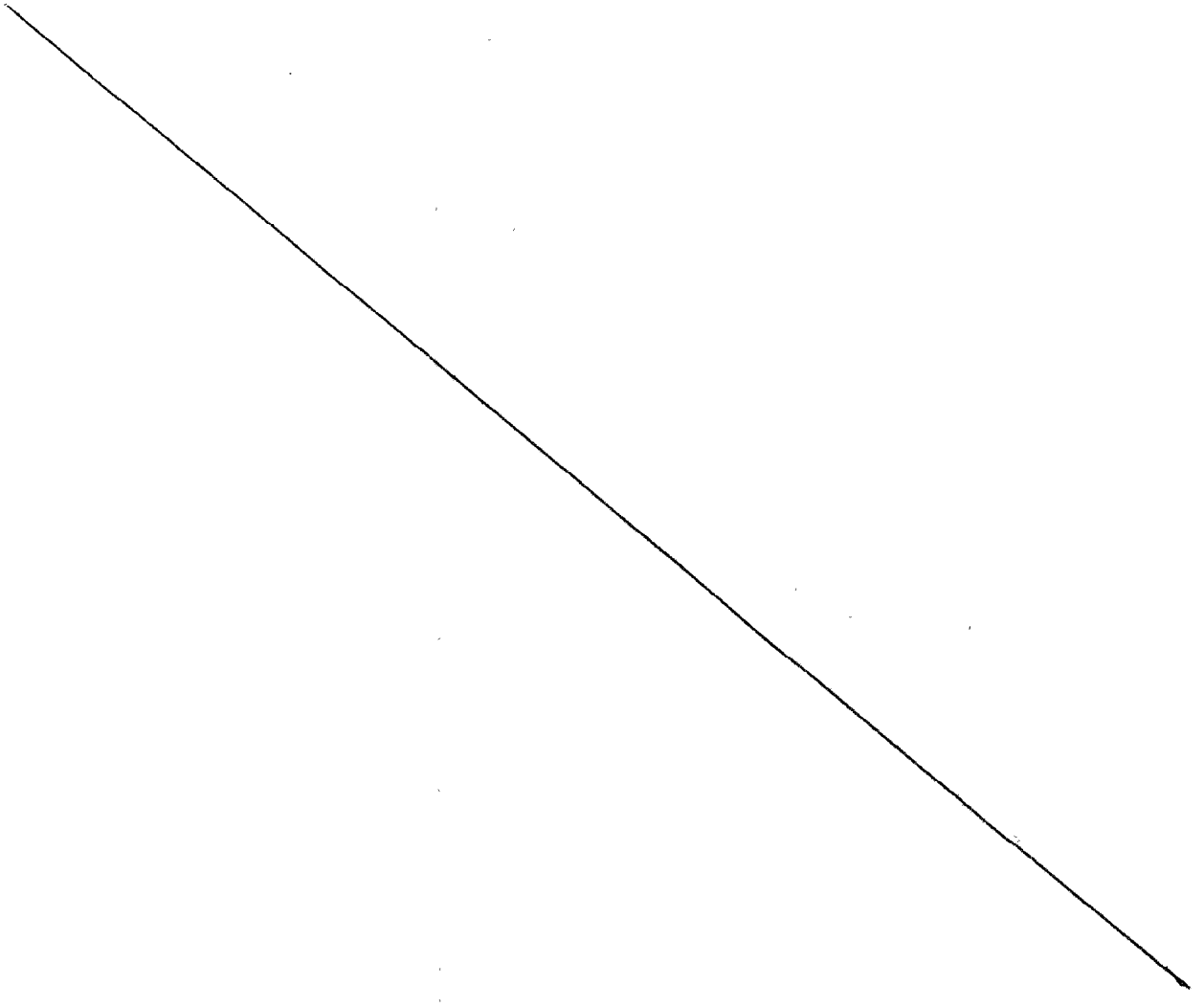
On October 31, 2000, FDA's Center for Veterinary Medicine (CVM) proposed to withdraw the approval of the NADA 140–828 for the use in chickens and turkeys of enrofloxacin, an antimicrobial drug belonging to a class of drugs known as fluoroquinolones (65 FR 64954, October 31, 2000). On November 29, 2000, Bayer Corp. (Bayer), the sponsor of enrofloxacin (sold under the trade name Baytril® 3.23% Concentrate Antimicrobial Solution), requested a hearing on the proposed withdrawal. On February 20, 2002, FDA's then Acting Principal Deputy Commissioner published a notice of hearing granting Bayer's request and identifying the factual issues that would be the subject of the evidentiary hearing (67 FR 7700, February 20, 2002). On March 21, 2002, the Animal Health Institute submitted a notice of participation under 21 CFR 12.45. Oral hearing for the purposes of cross-examination of witnesses was held at FDA from April 28 through May 7, 2003. On March 16, 2004, an FDA Administrative Law Judge (ALJ) issued an initial decision under 21 CFR 12.120. The ALJ determined that enrofloxacin had not been "shown to be safe under the conditions of use upon the basis of which the application was approved," as required under section 512(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(e)(1)(B)) and ordered that the approval of the NADA for Baytril be withdrawn. Bayer and CVM each filed exceptions to the initial decision on May 17, 2004.

After reviewing the evidence in the administrative record and the exceptions to the initial decision, I have issued a final decision withdrawing the approval of the NADA for use of enrofloxacin in poultry, for the reasons described more fully in the final decision that is the subject of this notice.

In addition, elsewhere in this issue of the **Federal Register**, a final rule removing the applicable regulations is published.

II. Electronic Access

Persons with access to the Internet may obtain the final decision at *www.fda.gov/oc/antimicrobial/baytril.pdf*. The final decision as well as documents cited in the decision are available for inspection by means of writing to, or visiting, the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All other documents related to this docket also are available for inspection, unless considered confidential.



Dated: July 27, 2005
July 27, 2005.

Lester M. Crawford,
Commissioner of Food and Drugs.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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