Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 13, 2002.

Alvin Hall,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 02–4022 Filed 2–19–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1571]

Enrofloxacin for Poultry; Notice of Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a hearing on a proposal to withdraw approval of a new animal drug application (NADA). In the **Federal Register** of October 31, 2000 (65 FR 64954), the Director of FDA's Center for Veterinary Medicine (CVM) issued a notice of opportunity for a hearing (NOOH) proposing to withdraw approval of NADA 140–828 for enrofloxacin (Baytril 3.23% Concentrate Antimicrobial Solution). Bayer Corp., the sponsor of the new animal drug, responded by filing a request for a hearing on November 29, 2000.

This notice of hearing (NOH) provides factual and legal information concerning CVM's proposal to withdraw the NADA and identifies the factual issues that will be the subject of the evidentiary hearing.

DATES: A prehearing conference will be held on April 8, 2002, beginning at 10 a.m. Any person wishing to participate in this hearing shall submit a written notice of participation by March 22, 2002. Disclosure of data and information as required by part 12 (21 CFR part 12) must be made by April 22, 2002.

ADDRESSES: The prehearing conference will be held in conference room. F, 5600 Fishers Lane, Rockville, MD 20857. You must submit written notices of participation and disclosure of data and information to Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All submissions must reference docket number 00N–1571.

FOR FURTHER INFORMATION CONTACT: Robin Thomas Johnson, Office of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

SUPPLEMENTARY INFORMATION:

I. Background

Enrofloxacin belongs to the class of antimicrobial drugs called fluoroquinolones. Fluoroquinolones are used in humans and animals for therapeutic purposes. Bayer Corp., P.O. Box 390, Shawnee Mission, KS 66201–0390, sponsor of NADA 140–828 for enrofloxacin (also known under Bayer's product name ''Baytril'') was approved for use in poultry on October 4, 1996, and published on November 5, 1996 (61 FR 56892). The new animal drug is indicated for the control, in chickens, of mortality associated with *Escherichia coli (E. coli)* susceptible to enrofloxacin. It is indicated for the control, in turkeys, of mortality associated with *E. coli* and *Pasteurella multocida (P. multocida)* susceptible to enrofloxacin.

II. Statutory Grounds Proposed for Withdrawal of the NADA for Enrofloxacin

In the NOOH published on October 31, 2000 (as revised on January 22, 2001), CVM proposed to withdraw approval of NADA 140–828 for use in poultry under section 512(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S. C. 360b(e)(1)(B)) . Section 512(e)(1)(B) states:

> (e)(1) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to subsection (b) with respect to any new animal drug if the Secretary finds —
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> (B) that new evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved or that subparagraph (I) of paragraph (1) of subsection (d) applies to such drug.

CVM must provide a reasonable basis from which serious questions about the ultimate safety of the drug may be inferred. '''Serious questions' can be raised where the evidence is not conclusive, but merely suggestive of an adverse effect.'' (See 44 FR 54852 at 54861, September 21, l979 (Commissioner's DES Decision.) Once CVM provides a basis for questioning the safety of enrofloxacin, the sponsor will have the ultimate burden of showing the drug's safety. *See Rhone-Poulenc, Inc., Hess & Clark Div.* v. *FDA*, 636 F.2d 750 (D.C. Cir. 1980); 21 CFR 12.87(d); 44 FR 54852 at 54861, September 21, l979 (Commissioner's DES Decision); 49 FR 34965, September 4, 1984 (Notice of Hearing for Nitrofurazone); and, 56 FR 41902, August 23, 1991 (Commissioner's Nitrofurans Decision).

III. Summary of the Evidence

In accordance with FDA's procedural regulations (§ 12.85) CVM has placed on file with the Dockets Management Branch (address above) copies of all documents in the CVM Director's files containing factual information relating to the issues involved in the hearing, and a narrative statement summarizing the evidence CVM plans to introduce at the hearing. For the benefit of those who are unable to inspect those documents, the information placed on file by CVM is summarized below.

The primary factual issues at the hearing will be whether there is a reasonable basis from which serious questions about the safety of enrofloxacin use in poultry may be inferred, and, if so, whether the use of enrofloxacin under the approved conditions of use in poultry has been shown to be safe. This action is based on CVM's determination that the use of fluoroquinolones in poultry causes the development of fluoroquinolone-resistant *Campylobacter* spp., a human pathogen, in poultry; that this fluoroquinolone-resistant *Campylobacter* spp. is transferred to humans and is a significant cause of the development of fluoroquinolone-resistant *Campylobacter* infections in humans; and thatfluoroquinolone-resistant *Campylobacter* infections in humans are a human health hazard. (See 65 FR 64954.)

CVM has concluded, based on data from surveillance programs, published literature, and other sources, that the use of fluoroquinolones in poultry is a significant cause of fluoroquinolone-resistant *Campylobacter* on poultry carcasses and therefore a significant cause of fluoroquinolone-resistant *Campylobacter* infections in humans. This conclusion is supported by data establishing a temporal association between approval of fluoroquinolones for use in poultry and an increase influoroquinolone-resistant *Campylobacter* infections in humans; by a comparison of fluoroquinolone use in poultry with other possible cause of fluoroquinolone-resistant human infections; and a risk assessment that determined that in 1999, a mean estimate of 9,261 persons infected with campylobacteriosis and prescribed a

fluoroquinolone in the United States would have had a fluoroquinolone-resistant illness due to the use of fluoroquinolones in chickens.

CVM believes that such people are likely to have had prolonged illnesses or complications. CVM concluded that development of resistance to fluorquinolones among *Campylobacter* has important consequences for human health since patients with severe enteric disease such as campylobacteriosis are usually treated empirically. CVM believes that *Campylobacter* resistance presents a dilemma for the physician. If fluoroquinolone treatment is given based on symptoms, and the patient is infected with fluoroquinolone-resistant *Campylobacter* spp., there is a risk that the treatment will not be effective, or will be less effective, and valuable time will be lost. If treatment is delayed until the causative organism and susceptibility are confirmed by a medical laboratory, again valuable time will be lost. In these situations, the disease may be prolonged or result in complications, especially in vulnerable patients with underlying health problems.

IV. Conclusion

Upon review of Bayer Corp.'s response to the NOOH, the Acting Principal Deputy Commissioner concludes that a hearing is appropriate with respect to CVM's proposal to withdraw approval of the NADA for enrofloxacin. The issue at the hearing will be as follows:

Whether new evidence shows that enrofloxacin is not now shown to be safe for use under the conditions of use upon the basis of which the application was approved. This issue includes:

A. Whether there is a reasonable basis from which serious questions about the safety of enrofloxacin use in poultry may be inferred, such as:

1. Whether enrofloxacin use in poultry acts as a selection pressure, resulting in the emergence and dissemination of fluoroquinolone-resistant *Campylobacter* spp. In poultry?

2. Whether fluoroquinolone-resistant *Campylobacter* spp. in poultry are transferred to humans and whether they contribute to fluoroquinolone-resistant *Campylobacter* infections in humans?

3. Whether fluoroquinolone-resistant *Campylobacter* infections in humans have the potential to adversely affect human health?

B. Whether the use of enrofloxacin under the approved conditions of use in poultry has been shown to be safe?

The hearing on these issues will take place in FDA conference room F. Administrative Law Judge Daniel J. Davidson will preside. Parties to the hearing will be CVM and Bayer Corp., the sponsor of the NADA for enrofloxacin. Any other interested person may participate in the hearing and be accorded the rights granted to participants by FDA regulations. Participants are required to assume the obligations of participation as set forth in FDA regulations (see part 12). Written notices of participation shall be filed with the Dockets Management Branch no later than March 22, 2002 (see § 12.45). A notice of participation shall be identified with the docket number found in brackets in the heading of this document and clearly labeled ''Enrofloxacin Hearing.''

A prehearing conference will be held on April 8, 2002. All participants are required both to attend the prehearing conference and to be prepared to comply with § 12.92, which sets forth the procedure and matters to be considered at such conference.

As discussed above, CVM has filed with the Dockets Management Branch a narrative statement setting forth its position on the hearing issues and a detailed factual description of the evidentiary background upon which it intends to rely at the hearing. CVM has also filed with the Dockets Management Branch the other documents required by § 12.85, including copies of the relevant portions of NADA, published studies, and other data, bearing on the question of whether enrofloxacin has been shown to be safe for use under the conditions of use upon the basis of which the application was approved. Interested persons may obtain a copy of the narrative statement from the Dockets Management Branch. With the exception of any data withheld from public disclosure under the provisions of 21 CFR 10.20(j), 21 U.S.C. 331(j), or 18 U.S.C. 1905, the data described above may also be examined at the Dockets Management Branch between 9 a.m. to 4 p.m., Monday through Friday. Bayer Corp. shall submit all the written data and information requiredby § 12.85 by April 22, 2002. All other participants shall submit all written data and information required by§ 12.85 by April 22, 2002. Any request to extend the period for submission of the required materials or for a postponement of the scheduled prehearing conference shall be addressed to the Administrative Law Judge.

The prehearing conference and the hearing will be open to the public. Any participants may appear in person, or by or with counsel, or with other qualified representatives, and may be heard on relevant matters.

Because this is a public hearing, it is subject to our guideline concerning the policy and procedures for electronic media coverage of public agency administrative proceedings. This guideline was published in the **Federal Register** on April 13, 1984 (49 FR 14723). These procedures are primarily intended to expedite media access to our public proceedings, including formal evidentiary hearings conducted under part 12 of the agency's regulations. Under this guideline, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record our public administrative proceedings, including the testimony of witnesses in the proceedings. Accordingly, the parties and nonparty participants to this hearing, and all other interested persons, are directed to the guideline, for a more complete explanation of the guideline's effect on this hearing.

This notice is issued under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10).

Dated: February 13, 2002.

Bernard A. Schwetz,

Acting Principal Deputy Commissioner.

[FR Doc. 02–4082 Filed 2–15–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01P–0383]

Determination That Azathioprine 25-Milligram Tablet Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that azathioprine 25-milligram (mg) tablet (Imuran) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for azathioprine 25-mg tablets.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers