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

Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On August 31, 2001, AAI International submitted a citizen petition (Docket No. 01P–0383/CP1) under 21 CFR 10.30 to FDA requesting that the agency determine whether azathioprine 25-mg tablet was withdrawn from sale for reasons of safety or effectiveness. Azathioprine 25-mg tablet is the subject of NDA 016–324. FDA approved NDA 016–324, currently held by Prometheus Laboratories, Inc. (Prometheus), on March 21, 1980. FDA has determined that azathioprine 25-mg tablet was withdrawn from sale.

FDA has reviewed its records and, under § 314.161, has determined that azathioprine 25-mg tablet was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list azathioprine 25-mg tablet in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to azathioprine 25-mg tablet may be approved by the agency.

Dated: February 11, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–4030 Filed 2–19–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0035]

Mylan Pharmaceuticals et al.; Withdrawal of Approval of 34 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 34 abbreviated new drug applications (ANDAs). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective March 22, 2002.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

ANDA No.	Drug	Applicant
61–530	Penicillin V Potassium Tablets USP, 250 milligrams (mg) and 500 mg.	Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310 Morgantown, WV 26504–4310.
61–829	Ampicillin for Oral Suspension USP, 125 mg/5 milliliters (mL) and 250mg/5 mL.	Do.
62–067	Amoxicillin Capsules USP, 250 mg and 500 mg	Do.
62–104	Neomycyin Sulfate with Hydrocortisone Ointment USP, 0.35% and 1%.	Clay-Park Laboratories, Inc., 1700 Bathgate Ave., Bronx, NY 10457.
62–280	Nystatin and Triamcinolone Acetonide Ointment USP	Do.
62–372	Mezlin (sterile mezlocillin sodium)	Bayer Corp. Pharmaceutical Division, 400 Morgan Lane, West Haven, CT 06516.
62–697	Mezlin (sterile mezlocillin sodium)	Do.
71–099	Bromatapp ER (brompheniramine maleate/phenylpropanolamine hydrochloride (HCl)) Extended-Release Tablets, 12 mg/75 mg.	Copley Pharmaceuticals, Inc., 25 John Rd. Canton, MA 02021.
71–551	Flurazepam HCl Capsules USP, 30 mg	Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.
71–927	Flurazepam HCl Capsules USP, 15 mg	Do.
72–027	Fentanyl Citrate and Droperidol Injection	AstraZeneca LP, 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803–8355.
72–070	Nalbuphine HCl Injection USP, 10 mg/mL	Do.
72–073	Nalbuphine HCl Injection USP, 20 mg/mL	Do.
72–921	Prazosin HCl Capsules USP, 2 mg	Purepac Pharmaceutical Co.
72–991	Prazosin HCl Capsules USP, 1 mg	Do.
72–992	Prazosin HCl Capsules USP, 5 mg	Do.
73–690	Calcitonin-Salmon Injection, 200 international units/mL	AstraZeneca LP.