Warner Lambert Co. requested a hearing for the three unapproved drug products described as follows, but later withdrew the applications.

1. ANDA 89–551; Dipyridamole Tablets containing 25 mg of the drug per tablet; Warner Lambert Co., 201 Tabor Rd., Morris Plains, NJ 07950.
2. ANDA 89–552; Dipyridamole Tablets containing 50 mg of the drug per tablet; Warner Lambert Co.
3. ANDA 89–553; Dipyridamole Tablets containing 75 mg of the drug per tablet; Warner Lambert Co.

Approval of the following four conditionally approved ANDA's is being withdrawn because the applicants failed to request a hearing for the products. Failure to file an appearance and request a hearing constitutes a waiver of the opportunity for a hearing.

1. ANDA 86–884; Dipyridamole Tablets containing 25 mg of the drug per tablet; Chelsea Laboratories, Inc.
2. ANDA 87–719; Dipyridamole Tablets containing 25 mg of the drug per tablet; Geneva Pharmaceuticals.
3. ANDA 87–830; Dipyridamole Tablets containing 75 mg of the drug per tablet; Boehringer-Ingelheim Pharmaceuticals, Inc., 90 East Ridge, Ridgefield, CT 06877.
4. ANDA 87–831; Dipyridamole Tablets containing 50 mg of the drug per tablet; Boehringer-Ingelheim Pharmaceuticals, Inc.

The effectiveness conclusions stated in the January 15, 1987, notice also applied to the 24 drug products described as follows. Although FDA withdrew approval of the products based on the written requests of the applicants who no longer market them, this notice constitutes FDA's final conclusions on the effectiveness of the products for the chronic angina pectoris indication.

1. ANDA 87–008; Dipyridamole Tablets containing 25 mg of the tablet per drug; Zenith Laboratories Inc., 140 Legrand Ave., Northvale, NJ 07647 (see 62 FR 64385, December 5, 1997).
2. ANDA 87–094; Dipyridamole Tablets containing 25 mg of the drug per tablet; Par Pharmaceutical, Inc., One Ram Ridge Rd., Spring Valley, NY 10977 (see 57 FR 7934, March 5, 1992).
3. ANDA 87–161; Dipyridamole Tablets containing 75 mg of the drug per tablet; Chelsea Laboratories, Inc. (see 59 FR 29298, June 6, l994).
4. ANDA 87–316; Dipyridamole Tablets containing 50 mg of the drug per tablet; Zenith Laboratories, Inc. (see 62 FR 64385, December 5, 1997).
5. ANDA 87–320; Dipyridamole Tablets containing 75 mg of the drug per tablet; Zenith Laboratories, Inc. (see 62 FR 64385, December 5, 1997).
6. ANDA 87–360; Dipyridamole Tablets containing 75 mg of the drug per tablet; Par Pharmaceutical, Inc. (see 57 FR 7934, March 5, 1992).
7. ANDA 87–419; Dipyridamole Tablets containing 25 mg of the drug per tablet; Danbury Pharmacal, 131 West St., Danbury, CT 06810 (see 63 FR 64266, November 19, 1998).
8. ANDA 87–432, Dipyridamole Tablets containing 75 mg of the drug per tablet; Danbury Pharmacal (see 63 FR 64266, November 19, 1998).
9. ANDA 87–650; Dipyridamole Tablets containing 50 mg of the drug per tablet; Par Pharmaceutical, Inc. (see 57 FR 7934, March 5, 1992).
10. ANDA 87–802; Dipyridamole Tablets containing 25 mg of the drug per tablet; Halsey Drug Co., Inc., 1827 Pacific St., Brooklyn, NY (see 61 FR 5562, February 13, 1996).
11. ANDA 87–803; Dipyridamole Tablets containing 75 mg of the drug per tablet; Halsey Drug Co. Inc. (see 61 FR 5562, February 13, 1996).
12. ANDA 87–843; Dipyridamole Tablets containing 25 mg of the drug per tablet; Lederle Laboratories (see 55 FR 49427, November 28, 1990).
13. ANDA 88–033; Dipyridamole Tablets containing 25 mg of the drug per tablet; Purepac Pharmaceutical Co. (see 56 FR 9956, March 8, 1991).
14. ANDA 88–315; Dipyridamole Tablets containing 25 mg of the drug per tablet; Unit Dose Laboratories (see 56 FR 9956, March 8, 1991).
15. ANDA 88–362; Dipyridamole Tablets containing 50 mg of the drug per tablet; Lederle Laboratories (see 55 FR 49427, November 28, 1990).
16. ANDA 88–363; Dipyridamole Tablets containing 75 mg of the drug per tablet; Lederle Laboratories (see 55 FR 49427, November 28, 1990).
17. ANDA 88–416; Dipyridamole Tablets containing 25 mg of the drug per tablet; Barr Laboratories, Inc. (see 61 FR 40649, August 5, 1996).
18. ANDA 88–417; Dipyridamole Tablets containing 50 mg of the drug per tablet; Barr Laboratories, Inc. (see 61 FR 40649, August 5, 1996).
19. ANDA 88–418; Dipyridamole Tablets containing 75 mg of the drug per tablet; Barr Laboratories, Inc. (see 61 FR 40649, August 5, 1996).
20. ANDA 88–466; Dipyridamole Tablets containing 50 mg of the drug per tablet; Halsey Drug Co. (see 61 FR 5562, February 13, 1996).
21. ANDA 88–800; Dipyridamole Tablets containing 50 mg of the drug per tablet; Danbury Pharmacal (see 63 FR 64266, November 19, 1998).
22. ANDA 89–348; Dipyridamole Tablets containing 25 mg of the drug per tablet; Rosemont Pharmaceutical Corp. (see 57 FR 30741, July 10, 1992).
23. ANDA 89–349; Dipyridamole Tablets containing 50 mg of the drug per tablet; Rosemont Pharmaceutical Corp. (see 52 FR 30741, July 10, 1992).
24. ANDA 89–350; Dipyridamole Tablets containing 75 mg of the drug per tablet; Rosemont Pharmaceutical Corp. (see 52 FR 30741, July 10, 1992).

Any drug product that is identical, related, or similar to the drug products named above and is not the subject of an approved new drug application is covered by the applications listed above and is subject to this notice (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Prescription Drug Compliance and Surveillance (address above).

The Director of the Center for Drug Evaluation and Research, under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to her (21 CFR 5.82), finds that, on the basis of new information on the drugs and the evidence available when the applications were approved, there is a lack of substantial evidence that the products named above will have the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling for the indication of long-term therapy of chronic angina pectoris.

Therefore, based on the foregoing finding, approval of the applications listed above and all their amendments and supplements insofar as they pertain to the indication, long-term therapy of chronic angina pectoris, is withdrawn effective February 5, 1999. Shipment in interstate commerce of these products or of any identical, related, or similar product that is not the subject of a fully approved new drug application will then be unlawful.

Dated: December 14, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–156 Filed 1–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pharmacy Compounding Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pharmacy Compounding Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 4 and 5, 1999, 8:30 a.m. to 5 p.m.

Location: CDER Advisory Committee Conference Room 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Igor Cerny, or Tony Slater, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or by e-mail at CERNY@CDER.FDA.GOV, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12440. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and provide FDA with advice about the agency's development and publication of a list of bulk drug substances that may be used in pharmacy compounding that do not have a United States Pharmacopeia or National Formulary monograph and are not components of FDA-approved drugs. Specifically, the committee is likely to address the following drug substances as candidates for the bulk drugs list: 4-aminopyridine, 3,4-diaminopyridine, betahistine dihydrochloride, cyclandelate, dinitrochlorobenzene, diphenylcyclopropenone, hydrazine sulfate, mild silver protein, pentylenetetrazole, and squaric acid dibutyl ester. The committee may also review drug products to be included on a list which have been withdrawn or removed from the market for reasons of safety or efficacy which may not be used in compounding that qualifies for the applicable statutory exemptions.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 21, 1999. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 21, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 28, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–154 Filed 1–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1146]

Discussion Paper: ''A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a discussion paper entitled ''A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (discussion paper). This discussion paper is the second step in the agency's consideration of issues related to the use of antimicrobial new animal drugs in food-producing animals. FDA is making the discussion paper available to the public to initiate discussions with the scientific community and other interested parties on the agency's thinking about appropriate underlying concepts to be used to develop microbial safety policies protective of the public health.

DATES: Written comments on the discussion paper should be submitted by April 6, 1999.

ADDRESSES: Submit written requests for single copies of the discussion paper to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist the office in processing your requests.

Submit written comments on the discussion paper to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the discussion paper and the docket number found in brackets in the heading of this document.

See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the discussion paper.

FOR FURTHER INFORMATION CONTACT:

Sharon R. Thompson, Office of the Director (HFV–1), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798.

Margaret A. Miller, Office of New Animal Drug Evaluation (HFV–100), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1620.

Linda R. Tollefson, Office of Surveillance and Compliance (HFV–200), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6644.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 18, 1998 (63 FR 64094), FDA published a notice of availability of a draft guidance entitled ''Guidance for Industry: Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals.'' The release of this draft guidance was the first step in the agency's consideration of issues related to the use of antimicrobial new animal drugs in food-producing animals. The draft guidance lays out the agency's rationale for its current thinking about its authority under the Federal Food, Drug, and Cosmetic Act to consider the human health impact of the microbial effects associated with the use of antimicrobial new animal drugs in food-producing animals. Since the 1970's, and until scientific evidence indicated that a change was necessary, the agency had evaluated the human health impact of the microbial effects of only certain uses of antimicrobial new animal drugs in animal feeds. The draft guidance provides that the agency now believes that sponsors of all antimicrobial new animal drugs intended for use in food-producing animals need to provide information that will allow the agency to evaluate the human health impact of the microbial effects of the intended uses. In assessing the human health impact of such uses, the draft guidance states that two separate but related factors should be evaluated: (1) The quantity of antimicrobial drug-resistant enteric bacteria formed in the animal's