Dated: December 10, 1998.

Clay E. Simpson, Jr.,

Deputy Assistant Secretary for Minority Health.

[FR Doc. 99–200 Filed 1–5–99; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Emergency TANF Data Report (ACF–198).

OMB No.: 0970–0164.

Description: This information is being collected to meet the statutory requirements of section 411 of the Social Security Act. It consists of disaggregated and aggregated demographic and program information that will be used in determining participation rates, performance awards, and other statutorily required indicators for the Temporary Assistance for Needy families (FANF) program. OMB previously approved this data collection through December 31, 1998. We are now requesting an extension through March 31, 2000 in order to maintain continuity of data collection.

Respondents: State, Local or Tribal Government.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–198	54	4	451	97,416

Estimated Total Annual Burden Hours: 97,416.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Officer for the Administration for Children and Families.

Dated: December 31, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99–201 Filed 1–5–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–1199]

Zeneca Biocides; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Zeneca Biocides has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 2-methyl-4,5-trimethylene-4-isothiazolin-3-one as a preservative for paper coatings intended for use in contact with aqueous food.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7B4525) has been filed by Zeneca Biocides, Foulkstone 1405, 2nd, 1800 Concord Pike, P.O. Box 15457, Wilmington, DE 19850–5457. The petition proposes to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of 2-methyl-4,5-trimethylene-4-isothiazolin-3-one as a preservative for paper coatings intended for use in contact with aqueous foods.

The agency has determined under 21 CFR 25.32(q) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: December 7, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–198 Filed 1–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 77N–0240; DESI 12836]

Dipyridamole; Drugs for Human Use; Drug Efficacy Study Implementation; Withdrawal of Approval of Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing conditional approval of abbreviated new drug applications (ANDA's) and pertinent parts of ANDA's for certain dipyridamole drug products. FDA is also declaring three unapproved dipyridamole drug products unlawful. FDA is withdrawing approval because there is a lack of substantial evidence that these drugs are effective for long-term therapy of chronic angina pectoris.

EFFECTIVE DATE: February 5, 1999.

ADDRESSES: Requests for opinion of the applicability of this notice to a specific product should be identified with Docket No. 77N–0240 and reference number DESI 12836 and directed to the Division of Prescription Drug Compliance and Surveillance (HFD–330), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

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

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 15, 1987 (52 FR 1663), FDA revoked the temporary exemption for the drug products described in this document that permitted these products to remain on the market beyond the time limits scheduled for implementation of the Drug Efficacy Study. The notice also offered an opportunity to request a hearing on a proposal to withdraw approval of the conditionally approved new drug applications for these products insofar as they provide for the indication, long-term therapy of chronic angina pectoris. The proposal was based on the conclusion that the data submitted in support of this indication did not constitute substantial evidence of effectiveness as required by section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and 21 CFR 314.126. In a notice published in the **Federal Register** of February 23, 1987 (52 FR 5501), FDA amended the January 15, 1987, notice by adding 16 conditionally approved applications.

In response to the notices, applicants of the products described in this document requested a hearing. In 1995 and 1996, FDA requested the applicants to inform the agency in writing whether they were still interested in pursuing the hearing request and advised the applicants that the agency would consider a lack of response in 30 days to constitute withdrawal of the hearing request. Some of the applicants requested withdrawal of the hearing request, withdrawal of approval of the ANDA's, or both. The remaining applicants failed to respond to the agency's request, thereby consenting to withdrawal of the hearing request. Accordingly, FDA is now withdrawing the conditional approvals of the ANDA's and pertinent parts of other ANDA's that lack substantial evidence of effectiveness for the long-term therapy of chronic angina pectoris (chronic angina pectoris indication).

The following 13 ANDA's have also been approved for the indication ''as an adjunct to coumarin anticoagulants in the prevention of postoperative thromboembolic complications of cardiac valve replacements'' (cardiac valve indication). This notice withdraws approval of only those parts of the applications that provide for the chronic angina pectoris indication.

1. ANDA 86–944; Dipyridamole Tablets containing 25 milligrams (mg) of the drug per tablet; Geneva Pharmaceuticals (formerly Cord Laboratories, Inc.), 2555 West Midway Blvd., Broomfield, CO 80020.

2. ANDA 87–160; Dipyridamole Tablets containing 50 mg of the drug per tablet; Chelsea Laboratories, Inc., P.O. Box 15686, 8606 Roading Rd., Cincinnati, OH 45215.

3. ANDA 87–184; Dipyridamole Tablets containing 25 mg of the drug per tablet; Barr Laboratories, Inc., 2 Quaker Rd., P.O. Box 2900, Pomona, NY 10970.

4. ANDA 87–561; Dipyridamole Tablets containing 75 mg of the drug per tablet; Geneva Pharmaceuticals.

5. ANDA 87–562; Dipyridamole Tablets containing 50 mg of the drug per tablet; Geneva Pharmaceuticals.

6. ANDA 87–716; Dipyridamole Tablets containing 50 mg of the drug per tablet; Barr Laboratories, Inc.

7. ANDA 87–717; Dipyridamole Tablets containing 75 mg of the drug per tablet; Barr Laboratories, Inc.

8. ANDA 88–999; Dipyridamole Tablets containing 25 mg of the drug per tablet; Lederle Laboratories, 401 North Middleton Rd., Pearl River, NY 10965.

9. ANDA 89–000; Dipyridamole Tablets containing 50 mg of the drug per tablet; Lederle Laboratories.

10. ANDA 89–001; Dipyridamole Tablets containing 75 mg of the drug per tablet; Lederle Laboratories.

11. ANDA 89–425; Dipyridamole Tablets containing 25 mg of the drug per tablet; Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.

12. ANDA 89–426; Dipyridamole Tablets containing 50 mg of the drug per tablet; Purepac Pharmaceutical Co.

13. ANDA 89–427; Dipyridamole Tablets containing 75 mg of the drug per tablet; Purepac Pharmaceutical Co.

The following 26 ANDA's have not been approved for the cardiac valve indication, and the products lack substantial evidence of effectiveness for the angina indication. Therefore, this document withdraws approval of the entire application for the products.

1. ANDA 86–908; Dipyridamole Tablets containing 25 mg of the drug per tablet; Eon Labs Manufacturing, Inc. (formerly held by Lemmon Co.), 227–15 North Conduit Ave., Laurelton, NY 11413.

2. ANDA 87–039; Dipyridamole Tablets containing 25 mg of the drug per tablet; Chelsea Laboratories, Inc.

3. ANDA 87–492; Dipyridamole Tablets containing 25 mg of the drug per tablet; Barr Laboratories, Inc.

4. ANDA 87–583; Dipyridamole Tablets containing 25 mg of the drug per tablet; Mylan Pharmaceuticals, Inc., P.O. Box 4293, Morgantown, WV 26505.

5. ANDA 87–676; Dipyridamole Tablets containing 25 mg of the drug per tablet; Mylan Pharmaceuticals, Inc.

6. ANDA 87–754; Dipyridamole Tablets containing 25 mg of the drug per tablet; Superpharm Corp., 1769 Fifth Ave., Bayshore, NY 11706.

7. ANDA 87–755; Dipyridamole Tablets containing 75 mg of the drug per tablet; Superpharm Corp.

8. ANDA 87–873; Dipyridamole Tablets containing 25 mg of the drug per tablet; Rosemont Pharmaceutical Corp. (formerly Pharmaceutical Basics, Inc.), 301 South Cherokee St., Denver, CO 80223.

9. ANDA 87–882; Dipyridamole Tablets containing 50 mg of the drug per tablet; Mylan Pharmaceuticals, Inc.

10. ANDA 87–883; Dipyridamole Tablets containing 75 mg of the drug per tablet; Mylan Pharmaceuticals, Inc.

11. ANDA 88–018; Dipyridamole Tablets containing 50 mg of the drug per tablet; Barr Laboratories, Inc.

12. ANDA 88–019; Dipyridamole Tablets containing 75 mg of the drug per tablet; Barr Laboratories, Inc.

13. ANDA 88–300; Dipyridamole Tablets containing 50 mg of the drug per tablet; Unit Dose Laboratories, P.O. Box 10319, Rockford, IL 61131.

14. ANDA 88–301; Dipyridamole Tablets containing 75 mg of the drug per tablet; Unit Dose Laboratories.

15. ANDA 88–413; Dipyridamole Tablets containing 50 mg of the drug per tablet; Superpharm.

16. ANDA 88–442; Dipyridamole Tablets containing 25 mg of the drug per tablet; Duramed Pharmaceuticals, Inc., 5040 Lester Rd., Cincinnati, OH 45213.

17. ANDA 88–443; Dipyridamole Tablets containing 50 mg of the drug per tablet; Duramed Pharmaceuticals, Inc.

18. ANDA 88–444; Dipyridamole Tablets containing 75 mg of the drug per tablet; Duramed Pharmaceuticals, Inc.

19. ANDA 88–822; Dipyridamole Tablets containing 50 mg of the drug per tablet; Rosemont Pharmaceutical Corp.

20. ANDA 88–683; Dipyridamole Tablets containing 25 mg of the drug per tablet; Sidmak Laboratories, Inc., P.O. Box 371, East Hanover, NJ 07936.

21. ANDA 88–684; Dipyridamole Tablets containing 50 mg of the drug per tablet; Sidmak Laboratories, Inc.

22. ANDA 88–685; Dipyridamole Tablets containing 75 mg of the drug per tablet; Sidmak Laboratories, Inc.

23. ANDA 88–945; Dipyridamole Tablets containing 25 mg of the drug per tablet; Danbury Pharmacal.

24. ANDA 89–378; Dipyridamole Tablets containing 25 mg of the drug per tablet; Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Philadelphia, PA 19124.

25. ANDA 89–379; Dipyridamole Tablets containing 50 mg of the drug per tablet; Mutual Pharmaceutical Co., Inc.

26. ANDA 89–380; Dipyridamole Tablets containing 75 mg of the drug per tablet; Mutual Pharmaceutical Co., Inc.

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.