availability of space on a first come, first serve basis. Members of the public who wish to present oral statements should contact Ms. Patricia Norris by telephone, fax machine, or mail as shown below and as soon as possible at least 4 days before the meeting. The Chair will reserve time for presentations by persons requesting to speak and asks that oral statements be limited to five minutes. The order of persons wanting to make a statement will be assigned in the order in which requests are received. Individuals unable to make oral presentations can mail or fax their written comments to the NBAC staff office at least five business days prior to the meeting for distribution to the Commission and inclusion in the public record. The Commission also accepts general comments at its website at bioethics.gov. Persons needing special assistance, such as sign language interpretation or other special accommodations, should contact NBAC staff at the address or telephone number listed below as soon as possible.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia Norris, National Bioethics Advisory Commission, 6100 Executive Boulevard, Suite 5B01, Rockville, Maryland 20892–7508, telephone 301–402–4242, fax number 301–480–6900.

Dated: March 15, 1999.

Eric M. Meslin,

Executive Director, National Bioethics Advisory Commission.

[FR Doc. 99–6901 Filed 3–19–99; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0462]

Agency Emergency Processing Request Under OMB Review; Collection; Survey of Manufacturers, Distributors, Repackagers, and Other Drug Distribution Facilities for Year 2000 Compliance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns a survey of manufacturers, distributors, repackagers, and other drug distribution facilities of Year 2000 compliance. The list of the Year 2000 compliant facilities will be made available to the public via the World Wide Web. FDA is requesting OMB approval within 9 days of receipt of this submission.

DATES: Submit written comments on the collection of information by April 12, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) permits the Secretary of Health and Human Services (the Secretary) to disseminate information regarding food, drugs, devices, and cosmetics in situations involving in the opinion of the Secretary imminent danger to health, or gross deception of the consumer. FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. FDA is requesting certain information, i.e., manufacturer, drug distribution, etc., immediately to allow health care facilities and others to assess their vulnerability to Year 2000 problems and to make corrective actions, if necessary, well in advance of January 1, 2000. The potential existence of Year 2000 problems in the drug industry, could pose potentially serious health and safety consequences. The use of normal clearance procedures would prolong the time needed to assess Year 2000 compliance by regulated industry.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Survey of Drug Manufacturers, Distributors, and Repackagers, and Other Drug Distribution Facilities for Year 2000 Compliance

Facilities will be asked to provide a status on their Year 2000 readiness. They will also be asked if they have contingency plans. The survey will also ask if they have tested, verified, and certified their systems. The request will also ask for a single point of contact at the manufacturer to discuss information.

The manufacturer will be able to provide facsimile, electronic, or paper copy of the information to FDA for inclusion in the web site data base. Government agencies, as well as health care facilities and the general public, will have access to the web site to be able to assess their vulnerability to Year 2000 problems and to take corrective actions, if necessary, in advance of January 1, 2000. The posting of information on compliant facilities is designed to provide health care facilities with a positive statement as to the status of compliant firms.

Respondents: Manufacturers, distributors, repackagers, and others in the distribution chain of drug products.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
4,000	1	4,000	18	72,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA mailing lists were used to estimate the number of firms who would be subject to this collection. FDA estimates that it will take firms an average of 18 hours to collect, prepare, and submit the requested information. These estimates include allowance for variance in the number to be reported by a manufacturer.

Dated: March 15, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–6882 Filed 3–19–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 77N–0240; DESI 1786]

Certain Single–Entity Coronary Vasodilators Containing Isosorbide Dinitrate; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is proposing to withdraw approval of 25 abbreviated new drug applications (ANDA's) for certain single-entity coronary vasodilator drug products containing isosorbide dinitrate. FDA is offering the holders of the applications an opportunity for a hearing on the proposal. The basis for the proposal is that the sponsors of these products have failed to submit acceptable data on bioavailability and bioequivalence.

DATES: Requests for a hearing are due by April 21, 1999; data and information in support of hearing requests are due by May 21, 1999.

ADDRESSES: A request for hearing, supporting data, and other comments are to be identified with Docket No. 77N–0240 and submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857.

Comments in response to this notice, identified with the reference number DESI 1786 and a request for applicability of this notice to a specific product, should be 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:

I. Background

In a notice (DESI 1786) published in the **Federal Register** of February 25, 1972 (37 FR 4001), FDA announced its evaluation of reports received from the National Academy of Sciences/National Research Council, Drug Efficacy Study Group on certain coronary vasodilator drugs. FDA classified isosorbide dinitrate drug products as: Probably effective for the treatment and prevention of anginal attacks when administered sublingually, and possibly effective for their labeled indications relating to the management, prophylaxis, or treatment of anginal attacks when administered orally.

In notices published in the **Federal Register** of December 14, 1972 (37 FR 26623), July 11, 1973 (38 FR 18477), August 26, 1977 (42 FR 43127), October 21, 1977 (42 FR 56156), and September 15, 1978 (43 FR 41282), FDA temporarily exempted certain single-entity coronary vasodilators, including isosorbide dinitrate, from the time limits established for the Drug Efficacy Study Implementation (DESI) program. The notices established conditions for marketing these products and identical, similar, or related products § 310.6 (21 CFR 310.6) whether or not they had been marketed and whether or not they were subjects of approved new drug applications (NDA's). FDA required manufacturers and distributors to have ANDA's (conditionally approved, pending the results of ongoing studies) to market a product not the subject of NDA's. If at least one drug sponsor was conducting clinical studies on a chemical entity, FDA permitted the marketing of all firms' products containing the same chemical entity in a similar dosage form, provided each product met the other conditions. Not all sponsors, therefore, were required to conduct clinical studies. Because bioavailability is specific for an individual product, however, FDA required each firm to conduct a bioavailability study on its own product.

In a notice published in the **Federal Register** of August 3, 1984 (49 FR 31151), after completing its review of the clinical studies submitted for single-entity isosorbide dinitrate, FDA announced its conclusions that these drugs are effective. The notice set forth the marketing and labeling conditions for the products. Additionally, FDA required the submission of supplements providing acceptable in vitro dissolution tests and in vivo bioavailability/bioequivalence studies. The August 3, 1984, notice stated that supplements not fully approved within 1 year would be subject to proceedings to withdraw the previous approval and to remove the products from the market. This deadline was extended to June 26, 1987, in a notice published in the **Federal Register** of December 26, 1985 (50 FR 52856).

The sponsors of the drug products listed in section II of this document are not in compliance with the notices of August 3, 1984, and December 26, 1985, in that they either have not submitted any bioavailability/bioequivalence data or have not submitted additional data on incomplete or inadequate studies. Accordingly, this notice reclassifies the products listed in section II of this document as lacking substantial evidence of effectiveness, proposes to withdraw approval of the applications, and offers an opportunity for a hearing on the proposal.

II. ANDA'S Subject to This Notice

1. ANDA 85–783; Isordil Chewable Tablets containing 10 milligrams (mg) of isosorbide dinitrate per tablet; Wyeth–Ayerst Laboratories (formerly held by Ives Laboratories, Inc.), P.O. Box 8299, Philadelphia, PA 19101.

2. ANDA 86–045; Isosorbide Dinitrate Tablets containing 5 mg of the drug per tablet; Bolar Pharmaceutical Co., Inc., 130 Lincoln St., Copiague, NY 11726.

3. ANDA 86–186; Isosorbide Dinitrate (controlled release, colored) Capsules containing 40 mg of the drug per capsule; Eon Labs Manufacturing, Inc. (formerly held by The Vitarine Co., Inc.), 227–15 North Conduit Ave., Laurelton, NY 11413.

4. ANDA 86–191; Isosorbide Dinitrate (sublingual) Tablets containing 5 mg of the drug per tablet; Bolar.

5. ANDA 86–224; Isosorbide Dinitrate (controlled release) Tablets containing 40 mg of the drug per tablet; Geneva Pharmaceuticals, Inc.(formerly held by Cord Laboratories, Inc.), 2555 West Midway Blvd., P.O. Box 446, Broomfield, CO 80038–0446.

6. ANDA 86–362; Isosorbide Dinitrate (sublingual) Tablets containing 2.5 mg of the drug per tablet; Bolar.

7. ANDA 86–388; Sorbitrate (chewable) Tablets containing 10 mg of isosorbide dinitrate per tablet; Zeneca Pharmaceuticals, 1800 Concord Pike, Wilmington, DE 19897.

8. ANDA 86–788; Isosorbide Dinitrate (controlled release, green) Tablets containing 40 mg of the drug per tablet; Forest Laboratories, Inc., 919 Third Ave., New York, NY 10022.