ESTIMATED ANNUAL REPORTING BURDEN

Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3038	33	70	2,310	.10	231

There are no capital costs or operating and maintenance costs associated with this collection.

This estimate is based on the number of certificates received in 1996.

Dated: July 31, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–20868 Filed 8–6–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0143]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Citizen Petition'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 28, 1997 (62 FR 22959), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). OMB has now approved the information collection and has assigned OMB control number 0910–0183. The approval expires on June 30, 2000. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Dated: July 31, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–20869 Filed 8–6–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0323]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by September 8, 1997.

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.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Notice of Participation—(21 CFR 12.45) (OMB Control Number 0910–0191—Reinstatement)

Under part 12 (21 CFR part 12) regulations issued under sections 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393), any interested person may participate in a formal evidentiary hearing, either personally or through a representative by filing a notice of participation under § 12.45. Section 12.45 requires that any person filing a notice of participation state the person's specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present documentary evidence on testimony at the hearing and will comply with specific requirements in § 12.85 or, in the case of a hearing before a Public Board of Inquiry, in 21 CFR 13.25, concerning disclosure of data and information by participants. A participant's appearance can be struck by the presiding officer in accordance with § 12.45(e).

The information obtained is used by the presiding officer and other participants in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the prehearing conference and commits participation.

The affected respondents are individuals or households, State or local governments, not-for-profit institutions and businesses or other for-profit groups and institutions.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.45	92	1	92	3	276

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

The agency bases this estimate on fiscal year 1995 data in which each notice of participation filed took an estimated 3 hours to complete.

Dated: July 31, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–20870 Filed 8–6–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0325]

Duramed Pharmaceuticals, Inc., and Barr Laboratories, Inc.; Conjugated Estrogens Tablets; Proposal to Refuse to Approve Two Abbreviated New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Drug Evaluation and Research (CDER) is proposing to refuse to approve two abbreviated new drug applications (ANDA's) for synthetic conjugated estrogens tablets. Conjugated estrogens tablets are intended for estrogen replacement to treat symptoms of menopause or to prevent osteoporosis. ANDA 40–115 (Cenestin, conjugated estrogens tablets, 0.3 milligrams (mg), 0.625 mg, 0.9 mg, 1.25 mg, and 2.5 mg) has been submitted by Duramed Pharmaceuticals, Inc., 5040 Lester Rd., Cincinnati, OH 45213 (Duramed). ANDA 40–154 (conjugated estrogens tablets, 0.625 mg and 1.25 mg) has been submitted by Barr Laboratories, Inc., 2 Quaker Rd., Pomona, NY, 10970 (Barr). Food and Drug Administration (FDA) is offering Duramed and Barr an opportunity for a hearing on the proposal. The primary basis for CDER's proposed refusal to approve the ANDA's is the agency's conclusion that there is insufficient information to show that the active ingredients of synthetic conjugated estrogens tablets are the same as the active ingredients of the reference listed drug.

DATES: A hearing request is due on or before September 8, 1997; data and information in support of the hearing request are due on or before October 6, 1997.

ADDRESSES: A request for hearing, supporting data, and other comments are to be identified with Docket No. 97N–0325 and submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

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:

I. Background

Both Duramed and Barr have submitted ANDA's for synthetic conjugated estrogens tablets intended for estrogen replacement to treat symptoms of menopause or to prevent osteoporosis. The reference listed drug for this product is Premarin, manufactured by Wyeth-Ayerst, and derived from a natural source material, the urine of pregnant mares.

On September 26, 1994, Duramed submitted ANDA 40–115 for Cenestin (conjugated estrogens tablets) under section 505 (j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)). Duramed filed amendments to this ANDA on March 7 and 25, 1996; April 2 and 3, 1996; May 9 and 14, 1996; June 28, 1996; July 12, 1996; August 14, 15, 19, and 29, 1996; October 8 and 9, 1996; December 17, 1996; January 23 and 31, 1997; and February 14, 1997. On May 5, 1997, in accordance with § 314.120 (21 CFR 314.120), CDER notified Duramed by letter that Duramed's ANDA was not approvable under section 505 (j)(2)(A)(ii)(II) and (j)(3)(C)(ii) because the ANDA was insufficient to show that the active ingredients of the proposed generic drug product were the same as the active ingredients of the reference listed drug.

On July 20, 1995, Barr submitted ANDA 40–154 for conjugated estrogens tablets under section 505(j) of the act. Barr filed amendments to this ANDA on May 13, 1996, and November 14 and 18, 1996. On May 5, 1997, in accordance with § 314.120, CDER notified Barr by letter that Barr's ANDA was not approvable under section 505 (j)(2)(A)(ii)(II) and (j)(3)(C)(ii) of the act because the ANDA was insufficient to show that the active ingredients of the proposed generic drug product were the same as the active ingredients of the reference listed drug.

CDER attached a detailed memorandum to the not approvable letters issued to both Duramed and Barr. This memo, from the CDER Director to the Director of the Office of Generic Drugs, outlined the legal and scientific rationale for CDER's position that a synthetic generic version of Premarin should not be approved until the active ingredients of Premarin have been sufficiently well defined to permit an ANDA applicant to show that a synthetic generic form of Premarin has the same active ingredients. In the not approvable letters of May 5, 1997, CDER notified Duramed and Barr that they each had the option to amend or withdraw their respective ANDA's under § 314.120, or request an opportunity for a hearing under § 314.200 (21 CFR 314.200).

In response to CDER's not approvable letter, Duramed submitted an initial response on May 15, 1997, and under § 314.120(a)(5), requested a 30-day extension of time to respond pending review by its scientific and medical personnel of the not approvable letter and other information.

In a letter dated June 13, 1997, Duramed requested the opportunity for a hearing under § 314.120(a)(3) on the question of whether there are grounds for denying approval of ANDA 40–115.

On June 26, 1997, CDER issued a response to Duramed's May 15, 1997, letter documenting CDER's decision to honor Duramed's request for an extension contingent upon Duramed's agreement, under § 314.120(a)(3), that CDER would have until August 8, 1997, to give written notice of an opportunity for a hearing to Duramed, under § 314.200, on the question of whether there are grounds for refusing to approve the ANDA.

On May 15, 1997, Barr submitted a letter to FDA requesting a 60-day extension to respond to the not approvable letter dated May 5, 1997. On July 3, 1997, CDER issued a letter granting Barr's May 15, 1997, request for an extension contingent on Barr's agreement that FDA would have 50 days from the date of Barr's request for the opportunity for a hearing to provide written notice of an opportunity for a hearing. Barr submitted a letter to FDA on July 7, 1997, requesting an opportunity for a hearing on the not approvable letter and agreeing to the condition that FDA would have 50 days from July 7, 1997, to respond.

This notice includes CDER's proposed order to refuse to approve the Barr and Duramed ANDA's for synthetic conjugated estrogens drug products and responds to both Duramed's and Barr's requests for an opportunity for a hearing on the question of whether there are grounds for refusing to approve those ANDA's.