412(a)(4) of the Immigration and Nationality Act, which provides that ''no grant or contract may be awarded under this section unless an appropriate proposal and application * * * are submitted to, and approved by, the appropriate administering official.''

Respondents: State Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–1	48	1	.5	24

Estimated Total Annual Burden Hours: 24.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded 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. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: March 20, 2007.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 07–1462 Filed 3–23–07; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Uniform Project Description (UPD) for Discretionary Grant Application Form.

OMB No.: 0970–0139.

Description: The Administration for Children and Families (ACF) has more than 40 discretionary grant program. This information collection form will be a uniform discretionary application form unable for all of these grant programs to collect the information from grant applicants needed to evaluate and rank applicants and protect the integrity of the grantee selection process. All ACF discretionary grant programs would be eligible but not required to use this application form. The application consists of general information and instructions; the Standard Form 424 series that requests basic information, budget information and assurances; the Program Narrative requesting the applicant to describe how these objections will be reached; and certifications. Guidance for the content of information requested in the Program Narrative is found in OMB Circulars A–102 and A–110.

Respondents: Applicants for ACF Discretionary Grant Programs.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
UPD	4,133	1	40	165,320

Estimated Total Annual Burden Hours: 165,320.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make 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, Fax: 202–395–6974, Attn: Desk Officer for the Administration for, Children and Families.

Dated: March 20, 2007.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 07–1463 Filed 3–23–07; 8:45 am]

BILLING CODE 4184–07–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0528]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Infant Formula Requirements

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 review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 25, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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

Infant Formula Requirements (OMB Control Number 0910–0256)—Extension

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (the act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. Among other things, section 412 of the act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere to quality control procedures, notify FDA when a batch of infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of distribution. FDA has issued regulations to implement the act's requirements for infant formula in 21 CFR part 106 and part 107 (21 CFR parts 106 and 107). FDA also regulates the labeling of infant formula under the authority of section 403 of the act (21 U.S.C. 343). Under the labeling regulations for infant formula in part 107, the label of an infant formula must include nutrient information and directions for use. The purpose of these labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately. In a notice of proposed rulemaking published in the **Federal Register** of July 9, 1996 (61 FR 36154) (the 1996 proposed rule), FDA proposed changes in the infant formula regulations, including some of those listed in tables 1 and 2 of this document. The 1996 proposed rule included revised burden estimates for the proposed changes and solicited public comment. In the interim, however, FDA is seeking an extension of OMB approval for the current regulations so that it can continue to collect information while the proposal is pending.

In the **Federal Register** of January 12, 2007 (72 FR 1539), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received. The notice incorrectly reported the ''Hours per Record'' and the ''Total Hours'' for 21 CFR 106.100 and 107.50(c)(3) in Table 2. Table 2 of this document contains the correct burden estimate.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Federal Food, Drug, and Cosmetic Act or 21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses[2]	Hours per Response	Total Hours
Section 412(d) of the act	5	13	65	10	650
106.120(b)	1	1	1	4	4
107.10(a) and 107.20	5	13	65	8	520
107.50(b)(3) and (b)(4)	3	2	6	4	24
107.50(e)(2)	1	1	1	4	4
Total					1,202

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Manufacturers may submit infant formula notifications in electronic format.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records[2]	Hours per Record	Total Hours
106.100	5	10	50	400	20,000
107.50 (c)(3)	3	10	30	300	9,000
Total					29,000

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

Dated: March 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–5470 Filed 3–23–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0255]

Determination That DURICEF (Cefadroxil USP) Tablets, 1 Gram, and Capsules, 500 Milligrams, Were 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) has determined that DURICEF (cefadroxil USP) Tablets, 1 gram (g), and Capsules, 500 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to continue to approve abbreviated new drug applications (ANDAs) for cefadroxil USP tablets, 1 g, and cefadroxil USP capsules, 500 mg.

FOR FURTHER INFORMATION CONTACT: Mary 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 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 typically a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (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 Cosmetics 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).

Under 21 CFR 314.161(a), the circumstances under which the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness include: (1) Before an ANDA that refers to that listed drug may be approved and (2) whenever a listed drug is voluntarily withdrawn from sale, and ANDAs that refer to the listed drug have been approved. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug. FDA may not approve an ANDA that does not refer to a listed drug.

DURICEF (cefadroxil USP) Tablets, 1 g, and Capsules, 500 mg, are the subjects of approved NDA 50–528 and NDA 50–512, respectively, held by Warner Chilcott, Inc. (Warner Chilcott). DURICEF is an antibiotic indicated to treat infections of the urinary tract, skin, throat, and tonsils, caused by specific bacteria, including streptococci, staphylococci, and *Escherichia coli*. Warner Chilcott has informed FDA that DURICEF (cefadroxil USP) Tablets 1 g, and Capsules, 500 mg, have been withdrawn from sale.

In a citizen petition dated June 13, 2006 (Docket No. 2006P–0255/CP1), submitted under 21 CFR 10.30, Orchid Healthcare (a division of Orchid Chemicals & Pharmaceuticals Ltd.) requested that the agency determine whether DURICEF (cefadroxil USP) Tablets, 1 g, were withdrawn from sale for reasons of safety or effectiveness. In addition, there are approved ANDAs that refer to DURICEF (cefadroxil USP) Tablets, 1 g, and Capsules, 500 mg.

The agency has determined that Warner Chilcott's DURICEF (cefadroxil USP) Tablets, 1 g, and Capsules, 500 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that DURICEF Tablets, 1 g, and Capsules, 500 mg, were withdrawn from sale for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that either DURICEF Tablets, 1 g, or Capsules, 500 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that, for the reasons outlined in this document, DURICEF (cefadroxil USP) Tablets, 1 g, and Capsules, 500 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DURICEF (cefadroxil USP) Tablets, 1 g, and Capsules, 500 mg, 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. Approved ANDAs that refer to DURICEF cefadroxil USP) Tablets, 1 g, and Capsules, 500 mg, are unaffected by the withdrawal of these products from sale. ANDAs that refer to cefadroxil USP (tablets, 1 g, and cefadroxil USP capsules, 500 mg, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for the approval of ANDAs.

Dated: March 15, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–5415 Filed 3–23–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0240]

Determination of Regulatory Review Period for Purposes of Patent Extension; REVLIMID

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for REVLIMID and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug