component of IHS will be involved or will support the research. If the Native American community is involved, its tribal government must also approve that portion of the project applicable to it.

Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC)and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947–47951, and dated Friday, September 15, 1995.

Animal Subjects

If the proposed project involves research on animal subjects, the applicant must comply with the ''PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions.'' An applicant organization proposing to use vertebrate animals in PHS-supported activities must file an Animal Welfare Assurance with the Office for Protection from Research Risks at the National Institutes of Health.

Application Submission and Deadline

The original and five copies of each application PHS Form 398 must be submitted to Sharron Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, N.E., Room 300, Mailstop E–18, Atlanta, GA 30305, on or before October 1, 1998.

1. Deadline: Applications shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date; or

b. Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. Late Applications: Applications which do not meet the criteria in 1. a. or 1. b. above are considered late applications. Late applications will not be considered and will be returned to the applicant.

Where to Obtain Additional Information

To receive additional written information and to request an application kit, call 1–888-GRANTS (1–888 472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest. (Please refer to Announcement Number 99012.) You will receive a complete program description, information on application procedures and application forms. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Oppie M. Byrd, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, N.E., Room 314, Mailstop E–18, Atlanta, GA 30305, telephone (404) 842–6546, Facsimile (404) 842–6513, Internet oxb3@cdc.gov.

Programmatic technical assistance may be obtained from Bala Swaminathan, Ph.D., National Center for Infectious Diseases, Division of Bacterial and Mycotic Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, N.E., Mailstop C–07, Atlanta, GA 30333, Telephone (404) 639–3669, Facsimile (404) 639–3333, Internet bas5@cdc.gov.

Please refer to Announcement Number 99012 when requesting information regarding this program.

You may obtain this announcement from one of two Internet sites on the actual publication date: CDC's homepage at http://www.cdc.gov or at the Government Printing Office homepage (including free on-line access to the **Federal Register** at http://www.access.gpo.gov).

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) referenced in the **INTRODUCTION** through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone: (202) 512–1800.

Dated: July 8, 1998.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–18667 Filed 7–13–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Annual Statistical Report on Children in Foster Homes and Children in Families Receiving Payments in Excess of the Poverty Income Level from a State Program Funded under Part A of Title IV of the Social Security Act.

OMB No.: 0970–0040.

Description: This information is collected to meet the statutory requirements of section 1124 of Title I of the Elementary and Secondary Education Act (as amended by PL 103–382). It is collected by DHHS from State public welfare agencies and turned over to the Department of Education which uses it to arrive at the formula for allocating Title I grant funds to State and Local elementary and secondary schools for the purpose of providing educational assistance to disadvantaged children.

Respondents: State, Local or Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–4125	52	1	264	13,746

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Estimated Total Annual Burden Hours: 13,746				

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, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 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 clarify 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: July 8, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–18658 Filed 7–13–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Relocation of the Dockets Management Branch; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 16, 1998 (63 FR 32888). The document announced the relocation and partial closing of the Dockets Management Branch (DMB). The document published with an incorrect zip code. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Jennie C. Butler, Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20852, 301–827–6860.

In FR Doc. 98–15878, appearing on page 32888, in the **Federal Register** of Tuesday, June 16, 1998, the following corrections are made:

1. On page 32888, in the second column, under ''**SUPPLEMENTARY INFORMATION**,'' in line six, the zip code is corrected to read ''20852,'' and in the second paragraph, in line eleven, the zip code is corrected to read ''20852.''

Dated: July 7, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–18691 Filed 7–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0481]

Guidance for Industry on 180–Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''180–Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act.'' The purpose of the guidance is to inform the public of FDA's application of the 180-day generic drug exclusivity provisions of the Federal Food, Drug, and Cosmetic Act (the act) in light of recent court decisions on the issue.

DATES: Written comments may be submitted on the guidance document by October 13, 1998. General comments on the agency guidances are welcome at any time.

ADDRESSES: Copies of the guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm.'' Submit written requests for single copies to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the guidance to the Dockets Management Branch, (HFD–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jerry Phillips, Center for Drug Evaluation and Research (HFD–610), 7500 Standish Pl., Rockville, MD 20855, 301–827–5846.

SUPPLEMENTARY INFORMATION: A requirement of FDA's regulations implementing the 180-day generic drug exclusivity provisions of the act has recently been successfully challenged in court. Section 314.107(c)(1) (21 CFR 314.107(c)(1)) applies and interprets section 505(j)(5)(B)(iv) of the act (21 U.S.C. 355(j)(5)(B)(iv)). Section 314.107(c)(1) contains the ''successful defense'' provision, which requires an abbreviated new drug application (ANDA) applicant to be sued for patent infringement and to prevail in the litigation in order to receive the 180-day period of marketing exclusivity. Two recent circuit court decisions, *Mova Pharmaceutical Corp.* v. *Shalala*, No. 97–5082, 1998 U.S. App. Lexis 7391 (D.C. Cir. Apr. 14, 1998) and *Granutec, Inc.* v. *Shalala*, No. 97–1873 and No. 97–1874, 1998 U.S. App. LEXIS 6685, (4th Cir. Apr. 3, 1998), held that the ''successful defense'' requirement was not supported by the act. The effect of these decisions, together with a June 1, 1998, order of the district court in *Mova*, is that FDA will not enforce the ''successful defense'' provisions of § 314.107(c)(1).

FDA intends to formally remove the ''successful defense'' provisions from § 314.107(c)(1), but that process is not complete. Following withdrawal of the regulatory provision, FDA expects to begin a rulemaking to issue new