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, 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 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 collections techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 20, 2000.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 00–29993 Filed 11–22–00; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: The OCSE—157 Child Support Enforcement Annual Data Report.

OMB No.: 0970–0177.

Description: The information obtained from this form will be used to report Child Support Enforcement activities to the Congress as required by law, to complete incentive measure and performance indicators utilized in the program, and to assist the Office of Child Support Enforcement in monitoring and evaluation State Child Support Enforcement programs.

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
OCSE–157	54	1	4	216
Estimated Total Annual Burden Hours:				216

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, 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 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: November 20, 2000.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 00–29994 Filed 11–22–00; 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: TANF High Performance Bonus Report for Fiscal Year 2001.

OMB No.: 0970–0180.

Description: Public Law 104–93 (PRWORA) established the Temporary Assistance for Needy Families (TANF) Program. It also included provisions for rewarding States that attain the highest levels of success in achieving the legislative goals of that program. The purpose of this collection is to obtain data upon which to base the computation for measuring State performance in meeting those goals and allocating the bonus grant funds appropriated under the law. States will not be required to submit this information unless they elect to compete for the bonus grants. Respondents, therefore, may include any of the 50 States, the District of Columbia, and the U.S. Territories of Guam, Puerto Rico, and the Virgin Islands. We are requesting extension of this form through May 31, 2002.

Respondents: States and Territorial Government.

Annual Burden Estimates: 8,640.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–200	54	4	40	8,640

Estimated Total Annual Burden Hours: 8,640.

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, S.W., Washington, D.C. 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, N.W., Washington, D.C. 20503, Attn: Desk Officer for ACF.

Dated: November 20, 2000.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 00–29995 Filed 11–22–00; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1609]

Digoxin Products for Oral Use; Reaffirmation of New Drug Status and Conditions for Marketing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is reaffirming its determination that digoxin products for oral use (tablets and elixir) are new drugs and announcing the conditions for marketing the products. Manufacturers who wish to begin to market or to continue marketing digoxin products for oral use must submit new drug applications (NDA's) or abbreviated new drug applications (ANDA's). Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to revoke the regulations that establishes conditions for marketing digoxin products for oral use.

DATES: This notice is effective November 24, 2000.

ADDRESSES: All communications in response to this notice should be identified with Docket No. 00N–1609 and directed to the appropriate office listed as follows:

Applications under section 505(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)): Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., rm. E150, Rockville, MD 20855.

Applications under section 505(b) of the act: Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 12229 Wilkins Ave., Rockville, MD 20852.

Requests for an opinion on the applicability of this notice to a specific product: 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

Digoxin is a member of a group of drugs known as cardiac glycosides. The cardiac or digitalis glycosides are a closely related group of drugs having in common specific effects on the myocardium. These drugs are found in several plants and animals. The term digitalis is used to designate the whole group.

Since ancient times, squill (*Urginea* (Scilla) *maritima*) and foxglove (*Digitalis purpurea*) and other natural sources of cardiac glycosides have been used for their effects on the heart. Digoxin, which is extracted from the leaves of *Digitalis lanata*, was reportedly discovered and developed in 1930 at the Wellcome Chemical Works at Dartford. According to Burroughs Wellcome (now Glaxo Wellcome), the company has manufactured and marketed a digoxin product in the United States since 1934.

Digoxin has been used in the treatment of certain cardiac disorders for many years and labeled for use in heart failure, atrial fibrillation, atrial flutter, and paroxysmal atrial tachycardia. Digoxin is available for oral and intravenous administration.

Digoxin products for parenteral use and digoxin solution in capsules have previously been classified as new drugs (July 27, 1972, and July 26, 1982, respectively) and are subjects of approved applications. This notice addresses digoxin tablets and elixir.

Because of bioavailability problems found to exist with digoxin tablets, FDA has sought, over the years, to provide a systematic regulatory approach to ensure the uniformity of all marketed, oral digoxin products. Since 1968, digoxin tablets (and related drugs) have been covered by a number of compliance programs.

In April 1970, FDA began a program to systematically test marketed lots of digoxin tablets. FDA took this action after the agency became aware of an apparent potency problem with this cardiac glycoside. As a result of this testing program, from April to November 1970, there were 79 recalls of digoxin products. In October 1970, FDA instituted a voluntary certification program in which participating manufacturers agreed not to release new lots of digoxin tablets until samples of the lots were tested by FDA and found to meet the United States Pharmacopeia (USP) requirements for potency and content uniformity.

Later, studies showed evidence of clinically significant differences in bioavailability between some batches of digoxin tablets made by different manufacturers, and even between some batches made by the same manufacturer. Because of these problems and because available data showed a general correlation between bioavailability and dissolution, the USP monograph for digoxin tablets was revised to include a requirement for dissolution.

In the **Federal Register** of January 22, 1974 (39 FR 2471), FDA issued a regulation (21 CFR 130.51; now § 310.500 (21 CFR 310.500)) establishing conditions for marketing digoxin products for oral use (tablets and elixir). The regulation: (1) Declared all digoxin products for oral use (tablets and elixir) to be new drugs, (2) required