ANALYTE: Helicobacter pylori Antibodies (2513)

TEST SYSTEM, ASSAY, EXAMINATION:

Quidel QuickVue One-Step H. pylori Test for Whole Blood (52037)

SPECIALITY/SUBSPECIALITY: Urinalysis

ANALYTE: Urine Dipstick or Tablet Analytes, nonautomated (9641)

TEST SYSTEM, ASSAY, EXAMINATION:

Bayer CHEK-STIX U.T.I. Test Strips (07790)

Genesis Labs DIA SCREEN 10 Way Reagent Strips: Urinalysis (22182)

TCPI URI-TEST Glucose in Urine (61256)

TCPI URI-TEST Nitrite in Urine (61257)

[FR Doc. 97–9350 Filed 4–10–97; 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: Procedures for Requests To Use Child Care and Development Fund for Construction or Major Renovation of Child Care Facilities.

OMB No: New Collection.

Description; The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Public Law 104–193) allows tribal grantees to use Child Care and Development Fund (CCDF) grant awards for construction and renovation of child care facilities. A tribal grantee must first request and receive approval from the Administration for Children and Families (ACF) before using CCDF funds for construction or major renovation. This information collection contains the statutorily-mandated uniform procedures for the solicitation and consideration of requests. Respondents will be CCDF tribal grantees requesting to use the CCDF funds for construction or major renovation.

Respondents: Tribal Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Construction and renovation collection	100	1	20	2,000

Estimated Total Annual Burden Hours: 2,000.

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 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: April 7, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97–9396 Filed 4–10–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 97M–0136]

Thoratec Laboratories Corp.; Premarket Approval of Thoratec® Ventricular Assist Device System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Thoratec Laboratories Corp., Berkeley, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Thoratec® Ventricular Assist Device System. After reviewing the recommendation of the Circulatory Systems Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 20, 1995, of the approval of the application.

DATES: Petitions for administrative review by May 12, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Dina A. Justice, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8262.

SUPPLEMENTARY INFORMATION: On June 26, 1992, Thoratec Laboratories Corp., Berkeley, CA 94710, submitted to CDRH an application for premarket approval of Thoratec® Ventricular Assist Device System. The device is a ventricular assist device and is intended as a bridge to cardiac transplantation for use in patients suffering from end-stage heart failure. The patient should meet all of the following criteria: (1) Candidate for cardiac transplantation, (2) imminent risk of dying before donor heart procurement, and (3) dependence on, or incomplete response to, continued vasopressor support.

On December 5, 1994, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the