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

application. On December 20, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before May 12, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: March 17, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–9432 Filed 4–10–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid, EPSDT, Maternal and Child Health; *Form No.:* HCFA–416; *Use:* States are required to submit annual EPSDT program reports to HCFA pursuant to Section 1902(a) (43) of the Social Security Act. These reports provide HCFA with data necessary to assess the effectiveness of State EPSDT programs, to develop trend patterns and projections nationally, and respond to inquiries. Respondents are State Medicaid agencies; *Frequency:* Annually; *Affected Public:* State, local or tribal government; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,568.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: Linda Mansfield, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 2, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97–9356 Filed 4–10–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Special Project Grants; Traumatic Brain Injury Demonstration Grants

AGENCY: Health Resources and Services Administration (HRSA).

ACTION: Notice; correction.

SUMMARY: The Health Resources and Services Administration published a document in the **Federal Register** of March 27, 1997, concerning Special Project Grants; Traumatic Brain Injury Demonstration Grants. The document contained an incorrect phone number for the Division of Maternal, Infant, Child and Adolescent Health (DMICAH).

Correction

In the **Federal Register** issue of Thursday, March 27, 1997 (62 FR 14684), in FR Doc. 97–7727, on page 14685 in the second column, correct the **FOR FURTHER INFORMATION CONTACT** caption to read:

FOR FURTHER INFORMATION CONTACT: Requests for technical or programmatic information from MCHB should be directed to the Division of Maternal, Infant, Child and Adolescent Health (DMICAH), Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–39, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. The DMICAH telephone number for TBI inquiries is 301–443–5599.

The rest of the notice remains the same.

Dated: April 7, 1997.

Claude Earl Fox,

Acting Administrator.

[FR Doc. 97–9337 Filed 4–10–97; 8:45 am]

BILLING CODE 4160–15–P