

respect to such contracts, pursuant to ABN AMRO, 83 Fed. Res. Bull. (1997)(order dated Dec. 11, 1996); and in providing execution-only or clearing-only services with respect to financial and non-financial futures and options on futures contracts, pursuant to Citicorp, 81 Fed. Res. Bull. 164 (1995).

D. Federal Reserve Bank of Minneapolis (Karen L. Grandstrand, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480-2171:

1. *Community First Bankshares, Inc.*, Fargo, North Dakota; to engage *de novo* through its subsidiary, Community First Financial, Inc., Fargo, North Dakota, in permissible nonbanking activities of making and servicing loans, pursuant to § 225.25(b)(1) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, February 25, 1997.

Jennifer J. Johnson,

*Deputy Secretary of the Board.*

[FR Doc. 97-5119 Filed 2-28-97; 8:45 am]

BILLING CODE 6210-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Comment Request Proposed Projects

*Title:* Early Head Start Evaluation.  
*OMB No.:* 0970-0143.

*Description:* The Head Start Reauthorization Act of 1994 established a special initiative creating funding for services for families with infants and toddlers. In response the Administration on Children, Youth and Families (ACYF) designated the Early Head Start (EHS) program. In September 1995, ACYE awarded grants to 68 local programs to serve families with infants and toddlers. ACYF awarded grants to an additional 75 local programs in September 1996.

EHS programs are designated to produce outcomes in four domains: (1) child development, (2) family development, (3) staff development, and (4) community development. The Reauthorization required that this new initiative be evaluated. To study the effect of the initiative, ACYE awarded a contract through a competitive procurement to Mathematica Policy Research, Inc. (MPR) with a subcontract to Columbia University's Center for Young Children and Families. The

evaluation will be carried out from October 1, 1995 through September 30, 2000. Data collection activities that are the subject to this Federal Register notice are intended for the second phase of the EHS evaluation.

The sample for the child and family assessments will be approximately 3,400 families who include a pregnant women or a child under 12 months of age, in 17 EHS study sites. Each family will be randomly assigned to a treatment group or a control group. The sample for the child care assessments will include the primary child care provider for the focal child in each of the 3,400 study sample families. The surveys and assessments will be conducted through computer-assisted telephone and personal interviewing, pencil and paper self-administered questionnaires, structured observations and videotaping. All data collection instruments have been designed to minimize the burden on respondents by minimizing interviewing and assessment time. Participation in the study is voluntary and confidential.

The information will be used by government managers, Congress and others to identify the features and evaluate the effectiveness of the EHS program.

*Respondents:* Applicants to the Early Head Start program and child care providers for Early Head Start families and control group families.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
24-Month Parent Interview, Child Assessment, and Videotaping Protocol .....	1,412	1	2.5	3,530
Parent Services Follow-Up Interview:				
12-Month Follow-Up .....	1,475	1	1	1,475
18-Month Follow-Up .....	1,412	1	1	1,412
24-Month Follow-Up .....	1,365	1	1	1,365
36-Month Follow-Up .....	1,334	1	1	1,334
Child Care Provider Interview:				
Child Care Centers .....	408	1	.25	102
Center Directors .....	408	1	.17	69
Direct Provider .....	408	1	.17	69
Classroom Staff .....	119	1	.5	60
Family Child Care .....	26	1	.17	4
Providers .....	172	1	.5	86
Family Provider .....	38	1	.17	6
Assistants .....				
Relative Care Providers:				
Relative Provider .....				
Assistants .....				
Child Care Provider Observation Protocol:				
Child Care Centers .....	408	1	2	816
Family Child Care .....	119	1	2	238
Providers .....	172	1	2	344
Relative Care Providers .....				
Estimated Total Annual Burden Hours: 10,910				

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: February 25, 1997.

Bob Sargis,

*Acting Reports Clearance Officer.*

[FR Doc. 97-5147 Filed 2-28-97; 8:45 am]

BILLING CODE 4184-01-M

## Food and Drug Administration

[Docket No. 97M-0052]

### **Surgical Dynamics, Inc., a Division of United States Surgical Corp.; Premarket Approval of Ray Threaded Fusion Cage (TFC)<sup>TM</sup> With Instrumentation**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its approval of the application by Surgical Dynamics, Inc., a division of United States Surgical Corp., Norwalk, CT, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Ray Threaded Fusion Cage (TFC)<sup>TM</sup> with instrumentation. After reviewing the recommendation of the

Orthopedic and Rehabilitation Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of October 29, 1996, of the approval of the application.

**DATES:** Petitions for administrative review by April 2, 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:**

Samie M. Niver, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036.

**SUPPLEMENTARY INFORMATION:** On June 14, 1995, Surgical Dynamics, Inc., a division of United States Surgical Corp., Norwalk, CT 06856, submitted to CDRH an application for premarket approval of the Ray TFC<sup>TM</sup> with instrumentation. This device is an intervertebral body fusion device. It is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The Ray TFC<sup>TM</sup> is to be implanted via an open posterior surgical approach. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had 6 months of nonoperative therapy.

On May 23, 1996, the Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On October 29, 1996, 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 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 April 2, 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: January 16, 1997.

Joseph A. Levitt,

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

[FR Doc. 97-5076 Filed 2-28-97; 8:45 am]

BILLING CODE 4160-01-F

## Health Resources and Services Administration

### **Advisory Council; Notice of Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of December 1996:

*Name:* National Advisory Council on Nurse Education and Practice

*Date and Time:* April 17-18, 1997, 8:30 a.m.