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)™ 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)™ 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™ 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™ 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.

Place: Spring Room, Silver Spring Holiday Inn, 8777 Georgia Avenue, Silver Spring, Maryland 20910.

The meeting is open to the public with the exception of the period from approximately 8:30 a.m. until 9:30 a.m. on April 18, when grant applications will be reviewed.

Agenda: Updates on and discussion of Agency, Bureau and Division activities, and the legislative and budget status of programs; overview of the national nursing workforce; review of nurse practitioner workforce trends, implications and options for the future; review of nursing informatics workgroup recommendations for a national agenda.

Anyone wishing to obtain a roster of members, minutes of meeting or other relevant information should write or contact Ms. Elaine G. Cohen, Acting Executive Secretary, National Advisory Council on Nurse Education and Practice, Health Resources and Services Administration, Parklawn Building, Room 9–36, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–5786.

Agenda Items are subject to change as priorities dictate.

Dated: February 25, 1997.

J. Henry Montes,

Director, Office of Policy and Information Coordination, HRSA.

[FR Doc. 97–5071 Filed 2–28–97; 8:45 am]

BILLING CODE 4160–15–P

Office of Inspector General

Publication of the OIG Model Compliance Plan for Clinical Laboratories

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This Federal Register notice sets forth the recently issued model compliance plan for clinical laboratories developed by the Office of Inspector General in cooperation with, and input from, several provider groups and industry representatives. Many providers and provider organizations have expressed an interest in better protecting their operations from fraud through the adoption of compliance plans. We believe the development of this initial model compliance plan for clinical laboratories will serve as a positive step towards promoting a higher level of ethical and lawful conduct throughout the health care industry.

FOR FURTHER INFORMATION CONTACT: Joel J. Schaer, Office of Counsel to the Inspector General, (202) 619–0089.

SUPPLEMENTARY INFORMATION: The creation of model compliance plans has become a major initiative of the Office of Inspector General (OIG) in its effort to engage the private health care community in the fight to combat fraud and abuse. In developing these compliance plans, the OIG continues to work closely with the Health Care Financing Administration and various sectors of the health care industry.

The clinical laboratory model compliance plan represents the OIG's initial effort to develop such a plan for use by the industry. The plan considers elements of the Federal Sentencing Guidelines and policy guidance given to major independent laboratories through corporate integrity agreements. Specifically, this model plan recommends that clinical laboratories implement a number of substantive changes, such as developing better requisition forms and policies that promote the physician's right to order only medically necessary tests.

Adoption of the clinical laboratory model compliance plan set forth below, and future model compliance plans for other health care providers, will be voluntary. All future models will be similarly structured, that is, substantive policy recommendations resulting from our investigations and civil settlements combined with the elements of the Federal Sentencing Guidelines.

A reprint of the OIG model compliance plan follows.

MODEL COMPLIANCE PLAN FOR CLINICAL LABORATORIES

Introduction

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) and other Federal agencies charged with responsibility for enforcement of Federal law have emphasized the importance of voluntarily developed and implemented compliance plans. In recent years, the OIG has been asked to supply guidance as to the elements of a model compliance plan. The purpose of this issuance, therefore, is to respond to those requests by providing some guidance to health care providers that supply clinical laboratory testing services for Medicare and Medicaid beneficiaries. Like other compliance plan models that will be issued for other areas of the health care community, this guidance is based upon the OIG's experience in fraud investigations of clinical laboratories, the Health Care Financing Administration's (HCFA) regulations and guidelines, requirements imposed on clinical laboratories in corporate integrity agreements negotiated by the OIG, and input from the clinical laboratory industry.

The government, especially the OIG, has a zero tolerance policy towards fraud and abuse and will use its extensive statutory authorities to reduce fraud in Medicare and other federally funded health care programs. Compliance plans offer the health care provider an opportunity to participate in a nationwide effort to reduce fraud and abuse in our national health care programs. The OIG believes that through a partnership with the private sector, significant reductions in fraud and abuse can be accomplished. Compliance plans offer a vehicle to achieve that goal.

This information is being supplied to assist laboratory providers in crafting and refining their own compliance plans. Elements of these guidelines can be used by all laboratories, regardless of size, to establish a compliance program. We are not suggesting that all laboratories must implement all of the compliance elements discussed in this document, nor do we suggest that a laboratory that does not incorporate all of these elements will be at a disadvantage when under the scrutiny of the OIG or other governmental agency. Rather, these guidelines represent the government's suggestions on how to correct and prevent fraudulent activity, and they can be tailored to fit the individual needs and financial realities of any clinical laboratory, be it an independent national laboratory, a hospital laboratory, or a small, regional laboratory. We expect variations reflecting the specific factual context in which each individual laboratory operates.

This model compliance plan focuses on topic areas recently addressed in corporate integrity agreements with several players in the laboratory industry. Consequently, this model laboratory compliance plan is not all inclusive as to subject matter. We recognize that laboratories are accountable for complying with far more laws, regulations and guidelines than we have tried to cover in this model, and we believe that laboratories implementing compliance plans should address any and all areas where abuse may be prevalent in the industry. For example, the OIG suggests that laboratory compliance programs should include training on topics such as, the anti-kickback act, Stark self-referral issues and CLIA requirements. Depending on the nature of its business, a laboratory also may need to add specific measures covering areas such as ESRD testing and billing, which is governed by rules and regulations and which has been subject to abuse by many companies. Ultimately, each company bears the responsibility for