DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Grassroots Regulatory Partnership Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) (Office of Regulatory Affairs, Nashville District Office and New Orleans District Office), in conjunction with the Health Industry Manufacturers Association (HIMA) is announcing the following workshop: Grassroots Regulatory Partnership Workshop. The topic to be discussed is FDA regulatory requirements for the medical device industry. The purpose of the workshop is to promote open dialogue between FDA and the medical device industry on quality system regulations and medical device reporting requirements.

Date and Time: The workshop will be held on Tuesday, December 16, 1997, from 8:30 a.m. to 5 p.m, and on Wednesday, December 17, 1997, from 8 a.m. to 3 p.m.

Location: The meeting will be held at the Holiday Inn Select–Vanderbilt, 2613 West End Ave., Nashville, TN 37203, 1–800–633–4427.

Contact: Rebecca K. Keenan, Food and Drug Administration (HFR–SE–350), Nashville District Office, 297 Plus Park Blvd., Nashville, TN 37217, 615–781–5380, ext. 145, FAX 615–781–5391.

Registration: Fax registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by November 20, 1997. There is no registration fee for this workshop. Space is limited, therefore interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact Rebecca K. Keenan at least 7 days in advance.

SUPPLEMENTARY INFORMATION: In 1995 President Clinton directed the heads of all Federal regulatory agencies to carry out a four step regulatory reinvention initiative. The basic idea of the President's initiative was to replace adversarial approaches with a partnership approach based on clear goals and cooperation. The President specifically directed top management from regulatory agencies to hold ''grassroots'' workshops with regulated industry, and this workshop is designed to meet that requirement.

Priority will be given to those businesses located in the Nashville and New Orleans Districts, which include the States of: Alabama, Louisiana, Mississippi, and Tennessee. Companies located outside of these States may register to attend the workshop and will be accepted if space is available.

Dated: October 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–28170 Filed 10–23–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1513]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration.

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, is publishing the following summary of proposed collections for public comment. 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.

Type of Information Collection Request: Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Medicare/Medicaid Disclosure of Ownership and Control Interest Statement and Supporting Regulations in 42 CFR 420.200–.206, 455.100–.106; *Form No.:* HCFA–1513 (OMB# 0938–0086); *Use:* The Medicare/Medicaid Disclosure of Ownership and Control Interest Statement must be used by State agencies and HCFA regional offices to determine whether providers meet the eligibility requirements for Titles 18 and 19 (Medicare and Medicaid) and for grants under Titles V and XX. Review of ownership and control is particularly necessary to prohibit ownership and control for individuals excluded under Federal fraud statutes; *Frequency:* Other (every 1 to 3 years); *Affected Public:* Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 92,000; *Total Annual Responses:* 92,000; *Total Annual Hours:* 46,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: October 17, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 97–28208 Filed 10–23–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act

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

ACTION: Notice.

SUMMARY: This notice sets forth a proposed policy statement, in the form of non-binding guidelines, to be used by the OIG in assessing whether to impose a permissive exclusion in accordance with section 1128(b)(7) of the Social Security Act. These guidelines identify specific factors with regard to whether an individual's or entity's continued participation in the Medicare and other Federal and State health care programs will pose a risk to the programs or program beneficiaries, and explain how these factors would be used by the OIG to assess a permissive exclusion decision.

COMMENT PERIOD: Parties interested in commenting on these guidelines may submit their written comments to the