DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on July 30, 1998, 9:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Mary J. Cornelius, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194, ext. 118, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12523. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss: (1) Reclassification of extracorporeal shock wave lithotriptors indicated for the fragmentation of kidney and ureteral calculi, (2) revised clinical and preclinical performance testing requirements, and (3) labeling.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 23, 1998. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the FDA proposed reclassification before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 23, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

FDA regrets that it was unable to publish this notice 15 days prior to the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Dated: July 10, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–P0015S]

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, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the 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: Revision of a currently approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey: National Baseline Medicare Beneficiary Knowledge Supplement; *Form No.:* HCFA–P–0015S; *Use:* This survey will establish baseline measures of Medicare beneficiary knowledge/understanding of the Medicare program, their new choices legislated under the Balanced Budget Act (BBA) which will allow HCFA to quantify current knowledge and attribute future changes in their understanding and knowledge to HCFA information and education initiatives. *Frequency:* Biennially; *Affected Public:* Business or other for-profit; *Number of Respondents:* 16,000; *Total Annual Responses:* 16,000; *Total Annual Hours:* 2,667.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, 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 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address:

HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 9, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Security and Standards Group, Health Care Financing Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–21, 21B, 21P, 21.11A, 21E]

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