diagnosis and monitoring set forth an estimated annual reporting burden on the industry that would result from that rulemaking (64 FR 26657). OMB has approved this collection of information until July 31, 2002, under OMB control number 0910–0409. This revised draft guidance on the development of medical imaging drugs and biological products is in part intended to explain how FDA will interpret and apply the final rule. Thus, the estimated annual reporting burden of the draft guidance is the same as that of the final rule, with one change. In addition to the diagnostic radiopharmaceuticals that are the subject of the final rule, the revised draft guidance also addresses the development of contrast drug products, which FDA evaluates and approves under part 314, but which are not affected by the final rule.

Table 1 in this document provides an estimate of the annual reporting burden for contrast drug products. FDA estimates that the potential number of respondents who would submit applications or supplements for contrast drug products would be one. Although FDA did not approve any NDA's for contrast drugs (there are no biological contrast drug products) in fiscal year 1999, for purposes of estimating the annual reporting burden, the agency assumes that it will approve one contrast drug each fiscal year. The annual frequency of responses for contrast drugs is estimated to be one response per application or supplement. The hours per response, which is the estimated number of hours that an applicant would spend preparing the information to be submitted for a contrast drug in accordance with this draft guidance, is estimated to be approximately 2,000 hours.

The revised draft guidance would not impose any additional reporting burden because safety and effectiveness information is already required by existing regulations. In fact, clarification by the guidance of FDA's standards for evaluation of medical imaging drugs and biological products is expected to reduce the overall burden of the information collection.FDA received no comments on the analysis of information collection burdens stated in the notice of availability of the draft guidance published on October 14, 1998. In the **Federal Register** of July 31, 2000 (65 FR 46674), FDA requested comments on the revised proposed collection of information. The agency received no comments.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Contrast Drugs	1	1	1	2,000	2,000
Total					2,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 31, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–3024 Filed 2–6–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastrointestinal Drugs 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: Gastrointestinal Drugs Advisory Committee.

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

Date and Time: The meeting will be held on March 19, 2002, from 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Thomas H. Perez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6758, e-mail: PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12538. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss standards in study designs of clinical trials testing the efficacy and safety of chemopreventive agents that are being developed to gain FDA approval in reducing the risk of sporadic colorectal adenomatous polyps and sporadic colorectal cancer.

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 March 11, 2002. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 11, 2002, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Thomas H. Perez at least 7 days in advance of the meeting.

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

Dated: January 31, 2002.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 02–2951 Filed 2–6–02; 8:45 am]

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