and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by September 11, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Agreement for Shipment of Devices for Sterilization—21 CFR 801.150(e) (OMB Control Number 0910–0131)—Extension

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment; a practice that facilitates the processing of devices and is economically necessary for some firms. Under § 801.150(e), manufacturers and sterilizers may sign an agreement containing the following provisions: (1) Instructions for maintaining accountability of the number of units in each shipment; (2) acknowledgment that the devices that are nonsterile are being shipped for further processing; and (3) specifications for sterilization processing.

This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices. The respondents to this collection of information are device manufacturers and contact sterilizers.

In the **Federal Register** of May 21, 2003 (68 FR 27819), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the reporting burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801.150(e)	90	20	1,800	4	7,200

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.150(a)(2)	90	20	1,800	.5	900

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

FDA's estimate for the reporting burden is based on actual data obtained from industry during the past 3 years where there are approximately 90 firms subject to this requirement. It is estimated that each of these firms on the average prepares 20 written agreements each year. This estimate varies greatly, from 1 to 100, because some firms provide sterilization services on a part time basis for only one customer while others are large facilities with many customers. The average time required to prepare each written agreement is estimated to be 4 hours. This estimate varies depending on whether the agreement is the initial agreement or is an annual renewal, on the format each firm elects to use, and on the length of time required to reach agreement. The estimate applies only to those portions of the written agreement that pertain to the requirements imposed by this regulation. The written agreement generally also includes contractual agreements that are a customary and usual business practice. On the average, the total annual recordkeeping burden is 7,200 hours (90 firms x 20 agreements x 4 hours).

The recordkeeping requirements for respondents consists of making copies and maintaining the actual reporting requests which were required under reporting section of this collection. To fulfill this requirement, FDA estimates it will take about 30 minutes to copy each package, for a total of 900 recordkeeping hours.

Dated: August 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–20523 Filed 8–11–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. 2003N–0344]

Consumer-Directed Promotion; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting on consumer-directed promotion of prescription drugs. The purpose of the meeting is to enable the agency and other persons and organizations to present the results of their research on consumer-directed promotion of prescription drug products through print, broadcast, and other types of media. FDA is particularly

interested in hearing about research by other persons and organizations that provides insight into the effects that consumer-directed promotion has on the public health. The agency is also interested in research on the groups most affected by consumer-directed promotion, including patients, caretakers, physicians, physician assistants, nurses, pharmacists, managed care organizations, and insurers.

Date and Time: The public meeting will be held on September 22, 2003, from 9 a.m. to 5 p.m., and on September 23, 2003, from 9 a.m. to 5 p.m. Presenters must send final electronic presentations in Microsoft PowerPoint, Microsoft Word, or Adobe Portable Document Format (PDF) to FDA by close of business on September 10, 2003.

Persons interested in presenting research should send requests and abstracts in writing to the Division of Dockets Management (HFA–305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville MD, 20852, by close of business on August 29, 2003.

Location: The public hearing will be held at the National Transportation Safety Board Boardroom and Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594. (Phone: 202–314–6421; Metro: L'Enfant Plaza station on the green, yellow, blue, and orange lines). See: *http://ntsb.gov/events/newlocation.htm*. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Registration and Requests for Presentation: No registration is required to attend the meeting. Seating will be on a first-come, first-served basis. If you wish to present research during the public meeting, please submit your request and an abstract of your presentation to the Division of Dockets Management (see *Date and Time*). Requests should be identified with the docket number listed in the heading of this document. Transcripts of the meeting will be available for review at the Division of Dockets Management.

For Information Regarding This Notice: Rose Cunningham, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5468, e-mail: *cunninghamr@cder.fda.gov*. If you need special accommodations due to a disability, please inform the contact person.

SUPPLEMENTARY INFORMATION:

I. Background

Part of FDA's Division of Drug Marketing, Advertising and Communication's (DDMAC) mission is to protect public health by helping to ensure that prescription drug promotion directed to professionals and consumers is truthful, contains balanced risk and benefit information, and is accurately communicated. Increased spending on consumer-directed (also called direct to consumer promotion or DTC promotion) promotion, particularly broadcast advertisements, has stimulated public debate about its value or harm to the public. Proponents argue that DTC promotion is of educational value, will improve the physician-patient relationship, will make consumers aware of conditions they have that could benefit from treatment, would potentially improve health care, and could lower long-term health care costs through early recognition and treatment. Opponents contend that: Consumers do not have the expertise to accurately evaluate and comprehend prescription drug advertising, DTC promotion is typically misleading because it fails to adequately communicate risk information, DTC promotion will damage the physician-patient relationship, it will increase drug prices, lead to over-medication and drug abuse, and it will lead to use of the most costly alternatives. FDA needs to consider all points of view in the public debate.

In the **Federal Register** of August 12, 1997 (62 FR 43171), FDA announced the availability of a draft guidance for industry concerning DTC broadcast advertisements. The draft guidance was intended to describe how advertisers could fulfill their obligations under the regulations to provide consumers with necessary risk information in connection with prescription-drug advertisements broadcast, through general public media such as radio, television, and telephone communications systems. The prescription drug advertising regulations under part 202.1 (21 CFR 202.1) distinguish between print and broadcast advertisements. In addition to presenting a fair balance between information relating to side effects and contraindications and information relating to the effectiveness of the drug, print advertisements must include a ''brief summary,'' that generally includes all risks cited in the product's approved package labeling. In contrast, advertisements broadcast through media such as television, radio, or telephone communications systems must disclose the product's major risks in either the audio or audio and visual parts of the presentation (this is sometimes called the ''major statement''); but need not provide the brief summary, as this would generally be impractical in broadcast or telephone media. Instead these advertisements may make ''adequate provision * * * for dissemination of the approved or permitted package labeling in connection with the broadcast presentation'' (§ 202.1(e)(1)). The draft guidance described, and explained the rationale behind, one possible multifaceted approach that would fulfill the ''adequate provision'' requirement.

After considering comments received from the public, the agency revised the draft guidance and published it as a final guidance on August 9, 1999 (64 FR 43197). FDA noted that although the comments did not address the specific issue of telephone advertisements, the lack of a specific discussion concerning such advertisements may have led to the assumption that the same multifaceted approach for television and radio advertisements was also appropriate for telephone advertisements. Therefore, in the final guidance, FDA clarified its position with regard to fulfilling the ''adequate provision'' requirement for telephone advertisements. Aside from this clarification and the revision of introductory language to reinforce the importance in broadcast advertisements of complying with the more general requirements of the advertising regulations, there were no major revisions to the draft guidance. The final guidance and a document entitled ''Consumer-Directed Broadcast Advertisements Guidance: Questions and Answers'' is available on FDA's Web site at *www.fda.gov/cder/guidance/index.htm*.

The agency said in the August 9, 1999, **Federal Register** notice announcing availability of the final guidance, that the agency intended to evaluate the effects of the guidance and DTC promotion, in general, on the public health. FDA said it would determine whether this guidance should be withdrawn, continued, or modified to reflect the agency's current thinking. The public meeting being announced in this document is one component of the approach the agency is taking to fulfill its commitment to this evaluation.

Another component is the research FDA has conducted on DTC promotion, including surveys of consumers in 1999 and 2002, as well as a survey of physicians in 2002 that explored how DTC promotion affects the patient-physician relationship. FDA intends to present the results of those findings at the public meeting.

II. Scope of the Meeting

In light of the many complex public health issues raised by DTC prescription drug promotion, the agency stated, in previous **Federal Register** notices that it needed rigorous studies to assess the actual effects of DTC promotion and to help guide future policy. The agency is soliciting feedback on the results of such research for presentation at this public meeting. The meeting will give parties who have conducted rigorous research an opportunity to present their findings to FDA and the public. The agency will consider its own research and the research of others to explore whether, and, if so, how, the agency's current regulatory approach should be modified, including whether the guidance on DTC broadcast advertisements should be withdrawn, continued, or modified to reflect the agency's current thinking.

FDA is interested in research related to the promotion and advertising of prescription drugs, both DTC advertising and the interaction of DTC and health care professional-oriented promotion. The research may be either broadly defined or specific, and narrowly focused, but it must meet accepted standards for rigorous research. Specific topics of interest include, but are not limited to, the following:

1. What is known about the effects of DTC promotion on patient and physician behavior, and what effects, if any, does DTC promotion have on public health? What measurements should be used as indicators of the influence of DTC promotion, and which are most important?

2. Drugs ads used in DTC promotion include full-product advertisements, which include risk and benefit information, and shorter ''reminder'' ads. These shorter advertisements do not provide contextual and risk information. In what ways do consumers differ in their processing of full product advertisements and drug promotions, such as reminder ads, that do not provide contextual and risk information?

3. Does DTC promotion oversimplify the safety and effectiveness of prescription drugs? If so, what effect does such oversimplification have on public health? Specifically, what effect does it have on consumer understanding of and use of prescription drugs?

4. What impact does DTC promotion have on how patients interact with their health care professionals? Does this interaction affect health care providers' prescribing decisions?

5. Can consumers understand and accurately assess claims regarding the efficacy of prescription drugs? Can consumers understand and accurately assess claims regarding the safety of prescription drugs? Do consumers understand the qualifiers in efficacy and safety claims that represent distinctions about the degree of scientific uncertainty and causality associated with a claim, such as ''may cause,'' ''risk factors include,'' ''individual results may vary,'' and other similar qualifiers? Given the fact that prescription drug use requires participation of a learned intermediary, how important is imperfect understanding?

6. What kind of additional information, if any, should be required in the presentation of comparative drug claims to help consumers understand and critically evaluate them? What kind of additional information, if any, should be required in the presentation of comparative cost claims? Should this information vary if prescription drugs are compared to other prescription drugs, over-the counter drugs, or other types of treatments?

7. Current regulations require inclusion of a ''brief summary'' of prescribing information (side effects, contraindications, and effectiveness) in print advertisements. Does this form of disclosure effectively communicate to consumers? Is it informative? Should there be alternate requirements for risk disclosure, and, if so, what should they be? Current regulations require that broadcast advertisements present a ''brief summary'' of prescribing information unless adequate provision is made for the dissemination of the approved product labeling. Also required is a statement of the major risks of the product. Are these disclosure requirements effective and informative for consumers? Are there alternate types of risk disclosures that would be more effective or informative? If so, what are the strengths and limitations of these alternative types of risk disclosures?

8. The agency issued final guidance in 1999 on how pharmaceutical companies could meet the regulatory requirements to disseminate approved labeling for a prescription product in lieu of a scrolling ''brief summary'' in broadcast advertisements. Are consumers making use of this method for obtaining brief summary information? What, if any, factors hinder effective use of this information, especially among consumer segments most needing it, such as those with limited knowledge of the brand and medical condition?

9. New technologies have spurred the growth of computer-based promotional vehicles, such as the Internet, electronic bulletin boards, and kiosks in pharmacies. These promotions are neither purely print nor broadcast. What kind and format of information is necessary to ensure that these vehicles appropriately communicate risks and benefits of the product.

10. ''Infomercials'' are program-length television or radio programs that promote prescription drugs to consumers. How well do consumers understand the sponsorship of consumer-oriented ''information'' promotions that differ in character from traditional promotion formats (15-, 30-, and 60-second ads)? How well do consumers understand the difference between benefit and risk claims based upon anecdotal evidence, such as a series of testimonials and product claims based upon scientific evidence?

11. To help ensure that advertisements contain ''fair balance,'' FDA currently requests disclosure of key risk and/or limitations of efficacy information, i.e., critical messages, in DTC prescription drug promotion. In general, are such disclosures effective and informative for this audience? What kinds of information should be disclosed?

12. Promotional materials that are disseminated directly by or on behalf of a pharmaceutical company (promotional labeling) are required to include the approved product labeling instead of a brief summary. How do consumers use product labeling, whether it is written for professionals or patients, and how does consumer use of labeling compare to consumer use of the brief summary?

13. Some manufacturer-supported DTC promotion appears to be sponsored by independent, third-party services, such as mailings from, or Web sites posted by, disease-specific foundations or disease management support services. What kind of disclosures would help consumers understand the source of the communication?

14. What additional research is needed to examine the effect of DTC advertising on public health and other DTC advertising issues? Is there research that the agency should conduct, and if so, what should be the focus of that research?

FDA is planning this public meeting to present the findings of its surveys and to hear the results of DTC research conducted by individuals, associations, organizations, academia, and companies. The objective of the meeting is for FDA to gather information to help the agency explore whether, and, if so, how, the agency's current regulatory approach to DTC prescription drug promotion should be modified. The agency believes presentations of

research results will be the best format. Therefore, the 2-day meeting will be conducted as a series of presentations. First, FDA will present the findings of its surveys, then others who have been scheduled will present their findings. A panel of FDA officials will listen to each presenter and ask questions. The audience will then have an opportunity to ask questions and provide comments on the research.

To ensure timely handling, the outer envelope should be clearly marked with the docket number listed in the heading in this document, along with the statement ''DTC Meeting.'' Groups should submit two copies. The request to participate should contain the following information:

- Presenter's name;
- Address;
- Telephone number;
- E-mail address;
- Affiliation, if any;
- Abstract of the presentation;
- Approximate amount of time requested for the presentation.

The agency requests that persons who have collaborated on relevant research coordinate their comments and present them through a single representative. FDA will allocate the time available for the meeting among the persons who request to present research as described in this section II. Due to limited time, the agency will accept only one presenter from each company or organization. FDA reserves the right to turn down requests if the proposal is not research on an appropriate topic or is primarily qualitative. After reviewing the requests to present and the abstracts, the agency will schedule each appearance and notify each participant by e-mail or telephone of the time allotted to the person and the approximate time the person's presentation is scheduled to begin. Presenters must send final electronic presentations in Microsoft PowerPoint, Microsoft Word, or PDF to FDA by close of business on September 10, 2003. Failure to meet the deadline will result in the presenter forfeiting his or her presentation slot.

The meeting schedule will be available both on the Internet at *http://www.fda.gov/cder/ddmac/DTCmeeting2003.html* and at the meeting. After the meeting, the schedule and presentations will be placed on file in the Division of Dockets Management under the docket number listed in the heading in the this document.

III. Comments

Interested persons may submit to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written or electronic comments on or before December 1, 2003. You must submit two copies of comments, identified with the docket number found in brackets in the heading of this document. Submit electronic comments by December 1, 2003, to *http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm* or *fdadockets@oc.fda.gov*. You should annotate and organize your comments to identify the specific questions to which they refer. Comments to the docket can be reviewed in the Division of Dockets Management, Monday through Friday between 9 a.m. and 4 p.m.

IV. Transcripts

You can request a copy of the transcript of the meeting in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 30 working days after the meeting, at a cost of 10 cents per page or on a compact disk at a cost of $14.25 each. You can also examine the transcript Monday through Friday between 9 a.m. and 4 p.m. in the Division of Dockets Management.

Dated: August 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–20522 Filed 8–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Report on the Relationship Between the Costs of Administrative, Program Support, and Direct Service-Related Activities and Access of Eligible Individuals to Services and Research Opportunities

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of request for comments.

SUMMARY: The Health Resources and Services Administration (HRSA) invites comments on the proposed establishment of a limitation on administrative expenses for Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Title IV Grants for Coordinated Services and Access to Research for Women, Infants, Children, and Youth. In addition, HRSA invites comments on determining a definition of what costs are to be included in administrative expenses, and on the specific percentage limitation to be applied.

DATES: Comments must be postmarked by September 11, 2003.

ADDRESSES: Written comments should be submitted to the Division of Community Based Programs, HIV/AIDS Bureau (HAB), HRSA, Room 7A–30, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Respondents should provide a clear rationale for their suggested changes or additions. All comments will be available for public inspection and copying at the Division of Community Based Programs, HAB, Room 7A–30, Parklawn Building weekdays between 8:30 a.m. and 5 p.m. and responses to the comments will be addressed in the final notice.

FOR FURTHER INFORMATION: Wayne E. Sauseda, Director, Division of Community Based Programs, HAB, at (301) 443–0493.

SUPPLEMENTARY INFORMATION: Title IV of the Ryan White CARE Act of 1990, as amended by the Ryan White CARE Act Amendments of 2000, authorizes Grants for Coordinated Services and Access to Research for Women, Infants, Children and Youth. Title IV of the CARE Act appears in section 2671 of the Public Health Service Act, 42 U.S.C. 300ff–71. Section 2671(i)(1) requires ''the Secretary, in consultation with grantees under this part, to conduct a review of the administrative, program support, and direct service-related activities that are carried out under this part to ensure that eligible individuals have access to quality, HIV-related health and support services and research opportunities under this part, and to support the provision of such services.'' Section 2671(i)(2) further requires that ''the Secretary, in consultation with grantees under this part, shall determine the relationship between the costs of the activities referred to in paragraph (1) and the access of eligible individuals to the services and research opportunities described in such paragraph.'' The proposed limitation on administrative expenses is based on a collaborative review process conducted by HRSA. The proposed limitation on administrative expenses is based on the following:

1. An analysis of the current expenditures of Title IV grantees and their relationship to access to services and research opportunities.

- It was determined from an external and internal review that the current administrative expenditures by Title IV grantees of record are an average of 14 percent of the total budget. Currently, of