TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Operating & Maintenance Costs	Total Hours
101.36(e)	85	10	850	0.25	$83,000	213

[1] There are no capital costs associated with this collection of information.

These estimates are based on agency communications with industry and FDA's knowledge of, and experience with, food labeling. FDA estimated in the September 23, 1997, final rule (62 FR 49826 at 49846) that there was a maximum of 850 suppliers of dietary supplements and that, on average, each supplier had 40 products whose labels required revision. FDA estimates that only 10 percent, or 85 of the dietary supplement suppliers, would revise the labels of their products to incorporate nutrition levels for the daily use of their products. FDA also estimates that daily use levels for nutrition information would generally be placed on at most 25 percent, or at most 10 of a firm's estimated 40 products, although this number would vary by firm based on the types of products that it produces. FDA also believes that the burden associated with the proposed disclosure of nutrition information on a daily use basis for dietary supplements would be a one-time burden for the small number of firms that would decide voluntarily to add this additional information to the labels for their products. FDA estimates that at least 90 percent of firms would coordinate the addition of daily use nutrition information with other changes in their labels, in which case the voluntary cost of transmitting the information to consumers in labeling would be subsumed almost entirely in the cost of these other voluntary or required labeling changes. The incremental cost for these 76 firms would be approximately $50 per label for 760 labels, or $38,000 total. For the remaining 9 firms that would not coordinate changes with other labeling changes, FDA estimates that the cost would be approximately $500 per label (64 FR 1765 at 1769) for 90 labels, or $45,000 total. The estimated total operating costs in table 1 of this document are, therefore, $83,000. Respondents are already required to disclose the quantitative amount and the percentage of the daily value of a dietary ingredient on a per serving basis as part of the nutrition information for dietary supplements. Respondents may also provide such information on a per unit basis. The information provided for under the proposed rule would be generated by simple extrapolation from that information.

Dated: August 7, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–20299 Filed 8–13–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0050]

Agency Information Collection Activities; Announcement of OMB Approval; Premarket Approval of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Premarket Approval of Medical Devices'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 16, 2001 (66 FR 27147), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0231. The approval expires on August 31, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: August 7, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–20301 Filed 8–13–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0078]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Assessment of Physician and Patient Attitudes Toward Direct-to-Consumer (DTC) Promotion Drugs; Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management 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 13, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Assessment of Physician and Patient Attitudes Toward Direct-to-Consumer (DTC) Promotion Drugs; Survey

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA is

responsible for assuring that the labeling and advertising of prescription drugs is truthful and not misleading. Section 502(n) of the act (21 U.S.C 352(n)) prohibits the advertising of prescription drugs that is false or misleading or that fails to provide required information about product risks. Although advertising of prescription drugs was once primarily addressed to health professionals, consumers increasingly have become a primary target audience, and ''direct-to-consumer'' (DTC) advertising has dramatically increased in the past few years. However, DTC advertising raises many questions and issues. While it may alert consumers to new information and facilitate treatment of their medical problems, it also may confuse consumers and adversely impact the relationship between patients and their health care providers. In August 1997, when the agency issued its draft guidance on consumer directed broadcast advertisements, FDA announced that it would evaluate the effects of the guidance and of DTC promotion in general within 2 years of finalizing the guidance.

The guidance was finalized on August 9, 1999 (64 FR 43197). In the **Federal Register** notice announcing availability of the final guidance, FDA reiterated its intent to evaluate the effects of the guidance, including effects on the public health, within 2 years. As part of that evaluation, the agency conducted a baseline public information collection focused on recent patients, concerning the effects of DTC advertising on patient-doctor interactions and attitudes toward DTC advertising in general (OMB Control No. 0910–0399). The purpose of the proposed information collection is to followup on the agency's 1999 patient survey and expand information collection to include physicians. FDA needs information from physicians and patients about their reactions to, and behaviors that stem from, DTC prescription drug advertising in order to develop policy on appropriate requirements for regulating drug product promotional materials.

The collection effort will consist of two separate parts: A patient survey and a physician survey. The patient survey will be conducted through national randomized telephone interviews with a national probability sample with 775 adults 18 years of age and over who have recently visited a physician. The sample will be limited to those respondents who have seen a doctor or other health care professional in the last 3 months. Patient respondents will be asked their views about any prescription drug they may have received and prescription drugs in general, and their attitudes and behavior in relation to DTC advertising. Demographic information will also be collected.

The physician survey will be conducted through telephone interviews with a national probability sample of office based physicians who engage in patient care at least half of the time. The sampling frame of physicians will consist of names drawn from the American Medical Association's physician masterfile. In an effort to maximize the response rate for physicians, prenotification letters will be mailed to all potential physician respondents. The survey itself will cover DTC-related patient interactions, perceived patient outcomes, attitudes toward appropriate DTC categories, and general opinions about DTC advertising. Demographic information will also be collected.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
11,625 (consumer screener)	1	11,625	.017	197.6
775 (consumer survey)	1	775	.333	258.1
3,333 (physician screener)	1	3,333	.017	56.7
500 (physician survey)	1	500	.250	125.0
Total				637.4

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

In the **Federal Register** of March 19, 2001 (66 FR 15494), the agency requested comments on the proposed collections of information. Comments were received from 31 organizations and individuals. The comments were grouped according to similarity.

1. Seven comments were unrelated to the proposed information collection.

2. Sixteen comments addressed general aspects of the information collection. Of these, 12 comments were supportive of the information collection as proposed. Four comments recommended a focus on behaviors rather than attitudes. This included two comments, which suggested a case study design rather than a survey. We note that the proposed physician survey does ask the physician to focus on a specific event when answering questions about their interaction with a patient who had asked about a prescription drug, as well as any specific drugs that were discussed during the interaction. In addition, both the patient and physician surveys ask questions about the effect of DTC advertising on behaviors occurring during an office visit.

3. Eight comments addressed specific aspects of the questionnaire, including wording, sample, and additional areas of inquiry. The questionnaires were extensively revised to reflect these comments.

A pilot test of the questionnaires was conducted by the contractor to confirm estimates of timing, identify problems related to questionnaire wording and order of presentation, and ensure that the questionnaire placed a minimal burden on respondents. The pretest included nine patient test respondents and nine physician test respondents. The pretest revealed that no substantive changes were necessary.

Dated: August 7, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–20363 Filed 8–13–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0196]

Phenylpropanolamine; Proposal to Withdraw Approval of New Drug Applications and Abbreviated New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.