

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0078]

DMB

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Agency Information Collection Activities; Proposed Collections; Comment Request; Assessment of Physician and Patient Attitudes Toward Direct-to-Consumer Promotion of Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on two proposed collections of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on surveys of physicians and patients to examine the impact of direct-to-consumer (DTC) promotion of prescription drugs.

DATES: Submit written or electronic comments on the collections of information by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit electronic comments on the collections of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collections of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Assessment of Physician and Patient Attitudes Toward Direct-to-Consumer Promotion of Prescription Drugs

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA is responsible for ensuring 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 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 intended to 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 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 appropriate, and other forms of information technology.

The purpose of the proposed information collection is to follow up 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.

Two data collections will be conducted: A patient survey and a physician survey. The patient survey will be conducted through randomized telephone interviews with a national probability sample consisting of 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 BURDEN¹

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 these collections of information.

Dated: 3/12/01
March 12, 2001.

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William Hubbard

William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

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Jan Windsor