

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: March 12, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1373]

Agency Information Collection Activities; Announcement of OMB Approval; Mammography Facilities, Standards, and Lay Summaries for Patients

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Mammography Facilities, Standards, and Lay Summaries for Patients" 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 October 26, 2000 (65 FR 64222), 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 0910-0309. The approval expires on February 29, 2004. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: March 12, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1246]

Agency Information Collection Activities; Announcement of OMB Approval; Food Safety Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Food Safety Survey" 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 August 18, 2000 (65 FR 50541), 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