docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–827–4659.

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 these topics: (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.

Voluntary Registration of Cosmetic Product Establishments—21 CFR Part 710 (OMB Control Number 0910–0027)—Extension

The Federal Food, Drug, and Cosmetic Act (the act) provides FDA with the responsibility for assuring consumers that cosmetic products in the United States are safe and properly labeled. Cosmetic products that are adulterated under section 601 of the act (21 U.S.C. 361) or misbranded under section 602 of the act (21 U.S.C. 362) may not be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, FDA has developed the Voluntary Cosmetic Registration Program (VCRP). In 21 CFR part 710, FDA requests that establishments that manufacture or package cosmetic products register with the agency on Form FDA 2511 entitled ''Registration of Cosmetic Product Establishment.'' The term ''Form FDA 2511'' refers to both the paper and electronic versions of the form. The electronic version of Form FDA 2511 is available on FDA's VCRP Web site at *http://www.cfsan.fda.gov/~dms/cos-regn.html*. FDA's online registration system, intended to make it easier to participate in the VCRP, was made available industry-wide on December 1, 2005. The agency strongly encourages electronic registration of Form FDA 2511 because it is faster and more convenient. A registering facility will receive confirmation of electronic registration, including a registration number, by e-mail, usually within 7 business days. The online system also allows for amendments to past submissions. Submission of the paper version of Form FDA 2511 remains an option as described in *http://www.cfsan.fda.gov/~dms/cos-reg2.html*. However, due to the high volume of online participation, the VCRP is allocating its limited resources primarily to electronic registrations.

Because registration of cosmetic product establishments is not mandatory, voluntary registration provides FDA with the best information available about the locations, business trade names, and types of activity (manufacturing or packaging) of cosmetic product establishments. FDA places the registration information in a computer database and uses the information to generate mailing lists for distributing regulatory information and for inviting firms to participate in workshops on topics in which they may be interested. FDA also uses the information for estimating the size of the cosmetic industry and for conducting onsite establishment inspections. Registration is permanent, although FDA requests that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Part	Form	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
710	FDA 2511	135	1	135	0.2	27

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

FDA bases its estimate on its review of the registrations received over the past 3 fiscal years. The total annual responses (averaged over fiscal years 2004 through 2006) is 9 times the previous total reported in 2004 (for fiscal years 2000 through 2003) due to increased participation by cosmetic companies, because of a renewed industry commitment to the program, and implementation of the online registration system on December 1, 2005. Due to the ease of online registration, FDA estimates that the hours per response have declined from 0.4 hours to 0.2 hours. Thus, the total estimated hour burden for this information collection is 27 hours, which is 4.5 times the previous level reported in 2004.

Dated: July 13, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–14013 Filed 7–18–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0527]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Threshold of Regulation for Substances Used in Food-Contact Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Threshold of Regulation for Substances Used in Food-Contact Articles'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 22, 2007 (72 FR 13499), 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 0910–0298. The approval expires on June 30, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: July 12, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–14014 Filed 7–18–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0283]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; FDA Survey of Physicians' Perceptions of the Impact of Early Risk Communication About Medical Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 20, 2007.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number ''0910–NEW'' and title, ''FDA Survey of Physicians' Perceptions of the Impact of Early Risk Communication about Medical Products.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

FDA Survey of Physicians' Perceptions of the Impact of Early Risk Communication about Medical Products (OMB Control Number 0910–NEW)

The authority for FDA to collect the information derives from the FDA Commissioner's authority, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

FDA engages in a number of communication activities to inform health care providers about new risks of regulated medical products, including prescription drugs, biologics, and medical devices (for example, pacemakers, implantable cardiac defibrillators, contact lenses, infusion pumps). More recently, FDA's communication activities have also included the general public. Activities include, but are not limited to, communications in medical journals, through the press (press releases, public health advisories), letters to health care providers sent out in cooperation with product manufacturers, and notifications and information sheets about recalls, withdrawals, and new product safety information on FDA's Internet site.

Extensive publicity regarding serious side effects from certain commonly used prescription drugs, as well as certain implantable medical devices, has spurred public pressure to make risk information available sooner. In opposition to such public pressures, however, at least some prescribers and medical societies have suggested that early disclosure of potential side effects (emerging risks) may have unintended negative effects on patient care. For FDA to plan informed programmatic communication activities we need better empirical data about the impact of disseminating emerging risk information on providers and patient care. In addition, only limited research addresses specific barriers to physicians reporting patient adverse events either to FDA or product manufacturers. Further, we have no data evaluating FDA's efforts to improve reporting.

Given differing perspectives on the value and timing of providing risk information to medical experts and the public at large, FDA believes it is important to assess how well it is communicating with physicians--the health care provider group with primary responsibility for deciding whether to use medical products to address patient problems. This information is critical both to plan programmatic communication activities and to improve the effectiveness of our reporting systems. Therefore, FDA plans to conduct a survey of a nationally representative group of physicians about these issues.

The survey will collect information from respondents through computer-assisted telephone interviews conducted by experienced interviewers. FDA expects to have a final sample of 900 physicians, broken down approximately half and half between primary care practitioners (general practice, family practice, general internal medicine, and pediatricians) and specialists. The physician specialty groups identified for inclusion in the survey are office-based allergists, dermatologists, endocrinologists, nephrologists, certain oncologists, ophthalmologists, certain surgeons, psychiatrists, pulmonologists and rheumatologists. These groups were chosen to provide a reasonable cross-section of specialists who use both drugs and medical devices that might have been the focus of relatively recent publicity concerning emerging risk information. Procedures will be used to ensure production of a sample of physicians that is reasonably representative of the population within the United States. The design of the interview questions will be guided by the results of a series of 6 physician focus groups. The interview will take approximately 15 minutes to administer.

Key information to be collected includes the following topics: