quickly and efficiently respond to the request:

•Questions to the agency concerning specific issues regarding the protocol; and

•All data, assumptions, and information needed to permit an adequate evaluation of the protocol, including: (1) The role of the study in the overall development of the drug; (2) information supporting the proposed trial, including power calculations, the choice of study endpoints, and other critical design features; (3) regulatory outcomes that could be supported by the results of the study; (4) final labeling that could be supported by the results of the study; and (5) for a stability protocol, product characterization and relevant manufacturing data.

Description of Respondents: A sponsor, applicant, or manufacturer of a drug or biologic product regulated by the agency under the act or section 351 of the Public Health Service Act (42 U.S.C. 262) who requests special protocol assessment.

Burden Estimate: Table 1 of this document provides an estimate of the annual reporting burden for requests for special protocol assessment.

Notification for a Carcinogenicity Protocol. Based on data collected from the review divisions and offices within CDER and CBER, including the number of notifications for carcinogenicity protocols and the number of carcinogenicity protocols submitted in fiscal years (FY) 2004 and 2005, CDER estimates that it will receive approximately 45 notifications of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately 20 sponsors. CBER estimates that it will receive approximately one notification of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately one sponsor. The hours per response, which is the estimated number of hours that a sponsor would spend preparing the notification and background information to be submitted in accordance with the guidance, is estimated to be approximately 8 hours.

Requests for Special Protocol Assessment. Based on data collected from the review divisions and offices within CDER and CBER, including the number of requests for special protocol assessment submitted in FY 2004 and FY 2005, CDER estimates that it will receive approximately 364 requests for special protocol assessment per year from approximately 143 sponsors. CBER estimates that it will receive approximately 10 requests from approximately 8 sponsors. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for special protocol assessment, including the time it takes to gather and copy questions to be posed to the agency regarding the protocol and data, assumptions, and information needed to permit an adequate evaluation of the protocol. Based on the agency's experience with these submissions, FDA estimates approximately 15 hours on average would be needed per response.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Notification for Carcinogenicity Protocols	21	2.19	46	8	368
Requests for Special Protocol Assessment	151	2.48	374	15	5,610
Total					5,978

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

Dated: July 21, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–12158 Filed 7–28–06; 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; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed survey of physicians' perceptions of the impact of early risk communication about medical products. The purpose of the proposed survey is to improve FDA's understanding of how and when physicians get, and would like to get, information about the risk of medical products, and what factors might influence the likelihood of reporting their patients' adverse experiences. Together with other information, the data from this survey will be used to assess FDA's communication efforts concerning early risk communication about medical products, and inform any potential communication-related changes.

DATES: Submit written or electronic comments on the collection of information by *September 29, 2006*.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (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: Jonna Capezzuto, Office of Management Programs (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 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.

FDA Survey of Physicians' Perceptions of the Impact of Early Risk Communication About Medical Products

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 895 physicians, broken down approximately half and half between primary care practitioners (general practice, family practice, general internal medicine, and pediatricians) and specialists. We expect to identify physician specialty groups that are most likely to have been affected by recent publicity over risks of prescription drugs or medical devices. Such groups may include neurologists, psychiatrists, cardiologists, gastroenterologists, dermatologists, allergists, urologists, obstetricians/gynecologists, and geriatricians. 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 physician focus groups that have recently been completed. The interview will take approximately 15 minutes to administer.

Key information to be collected includes the following topics:

- The impact on physicians, their patients, and their practices of the disclosure of still uncertain, emerging risks associated with medical products.
- How physicians currently receive and ideally would like to receive new risk and benefit information about medical products (for example, at what level of certainty regarding causality and through what communication channels).
- How physicians perceive the credibility of FDA and other potential sources of risk and benefit information, including product sponsors, medical societies, and the media.
- What FDA might do to increase the likelihood that respondents will report to FDA or to manufacturers serious patient reactions that might be side effects of using medical products.

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
27 (Pretests)	1	27	.25	6.75
995 (Screener)	1	995	.025	24.88
895 (Survey)	1	895	.25	223.75

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total				255.38

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

These estimates are based on FDA's and the contractor's experience with previous surveys. The respondents are divided into two groups: Primary care physicians and specialist physicians. We are basing this estimate on 90 percent of the screened physicians being eligible to participate in the survey.

Prior to administering the survey with the entire sample, FDA plans to conduct pretests with up to 27 physicians; these are meant to evaluate the clarity and consistency of the survey questionnaire and interview protocol.

Dated: July 21, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–12159 Filed 7–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0274]

Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining a List of United States Dairy Product Manufacturers/ Processors With Interest in Exporting to Chile

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection 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 the information collection provisions associated with the guidance document entitled ''Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile.''

DATES: Submit written or electronic comments on the collection of information by September 29, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (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: Jonna Capezzuto, Office of Management Programs (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.

Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/ Processors With Interest in Exporting to Chile (OMB Control Number 0910–0509)—Extension

As a direct result of discussions that have been adjunct to the U.S./Chile Free Trade Agreement, Chile has recognized FDA as the competent U.S. food safety authority and has accepted the U.S. regulatory system for dairy inspections. Chile has concluded that it will not require individual inspections of U.S. firms by Chile as a prerequisite for trade, but will accept firms identified by FDA as eligible to export to Chile. Therefore, in the **Federal Register** of June 22, 2005 (70 FR 36190), FDA announced the availability of a revised guidance document entitled ''Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/ Processors With Interest in Exporting to Chile.'' The guidance can be found at *http://www.cfsan.fda.gov/guidance.html*. The guidance document explains that FDA has established a list that is provided to the government of Chile and posted on FDA's Internet site, which identifies U.S. dairy product manufacturers/processors that have expressed interest to FDA in exporting dairy products to Chile, are subject to FDA jurisdiction, and are not the subject of a pending judicial enforcement action (i.e., an injunction or seizure) or a pending warning letter. The term ''dairy products,'' for purposes of this list, is not intended to cover the raw agricultural commodity raw milk. Application for inclusion on the list is voluntary. However, Chile has advised that dairy products from firms not on this list could be delayed or prevented by Chilean authorities from entering commerce in Chile.The revised guidance explains what information firms should submit to FDA in order to be considered for inclusion on the list and what criteria FDA intends to use to determine eligibility for placement on the list. The document also explains how FDA intends to update the list and how FDA intends to communicate any