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:

1. The impact on physicians, their patients, and their practices of the disclosure of still uncertain, emerging risks associated with medical products.

2. How physicians currently receive and ideally would like to receive new risk information about medical products (for example, at what level of certainty regarding causality and through what communication channels).

3. How physicians perceive the trustworthiness of FDA and other potential sources of risk information, including product sponsors, medical societies, and the media.

4. 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.

In the **Federal Register** of July 31, 2006 (71 FR 43200), FDA published a 60-day notice requesting public comment on the information collection provisions. Comments were received from five public entities consisting of two corporations and three associations. Comments supported FDA's belief in the value of conducting the survey. None of the comments addressed specific survey questions. FDA agrees with the comments concerning the study methodology.

- Questions should be clear and not leading or ambiguous.
- FDA should conduct pre-tests.
- The sample size will be sufficient to provide statistically relevant information for the two stratified segments of physicians and the combination of these segments.

After carefully considering them, FDA determined that other comments would require changes that would reduce the utility of study results by diluting the study's focus, omitting important topic areas, or making the questionnaire excessively long and thereby reducing response rates. These comments included the following:

- Including other health care providers ''who prescribe drugs.''
- Getting more detail about particular source categories.
- Omitting questions about how respondents report adverse events or product problems.

FDA agreed with the value of adding some questions that ask about the inclusion of other information, including benefits, in communications about newly emerging product risks.

FDA also received feedback from experts in the fields of risk communication and health literacy on the study and the proposed questionnaire at an ''Effective Risk Communication'' Think Tank Workshop. FDA revised the survey questionnaire in response to this feedback, the feedback received through the public comments, and eight cognitive interviews conducted in May 2007.

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	.3	8.1
1,000 (Screener)	1	1,000	.025	25.0
900 (Survey)	1	900	.25	225.0
Total				258.1

[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 13, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–14015 Filed 7–18–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007P–0052]

Determination That Brethine (Terbutaline Sulfate) Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that Brethine (Terbutaline Sulfate) Injection was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for terbutaline sulfate injection if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal