

Dated: December 29, 2003.

John P. Burke III,

CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0424]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substantial Evidence of Effectiveness of New Animal Drugs

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the 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 (the PRA).

DATES: Fax written comments on the collection of information by February 6, 2004.

ADDRESSES: The Office of Management and Budget is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX 202-395-6974.

FOR FURTHER INFORMATION CONTACT:

Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

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

Substantial Evidence of Effectiveness of New Animal Drugs—21 CFR Part 514 (OMB Control Number 0910-0356)—Extension

Congress enacted the Animal Drug Availability Act of 1996 (ADAA) (Public Law 104-250) on October 9, 1996. As directed by ADAA, FDA published a regulation under § 514.4(a) (21 CFR 514.4(a)), to further define substantial evidence in a manner that encourages the submission of new animal drug applications (NADAs) and supplemental NADAs and encourages dose range

labeling. Under ADAA, substantial evidence is the standard that a sponsor must meet to demonstrate the effectiveness of a new animal drug for its intended use under the conditions suggested in its proposed labeling. Section 514.4(a) gives FDA greater flexibility to make case-specific scientific determinations regarding the number and types of adequate and well-controlled studies that will provide, in an efficient manner, substantial evidence that a new animal drug is effective. FDA believes this regulation will reduce the number of adequate and well-controlled studies necessary to demonstrate the effectiveness of certain combination new animal drugs, will eliminate the need for an adequate and well-controlled dose titration study, and may, in limited instances, reduce or eliminate the number of adequate and well-controlled field investigations necessary to demonstrate by substantial evidence the effectiveness of a new animal drug. Table 1 of this document represents the estimated burden of meeting the substantial evidence standard.

In the **Federal Register** of September 19, 2003 (68 FR 54905), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.4(a)	190	4.5	860	632.6	544,036

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

Dated: December 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-256 Filed 1-6-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0565]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Food and Drug Administration Rapid Response Surveys

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 use of rapid response surveys to obtain data on safety information to support quick-turnaround decision making about potential safety problems or risk management solutions from health care professionals, hospitals and

other user-facilities (e.g., nursing homes, etc.), consumers, manufacturers of biologics, drugs and medical devices, distributors, and importers when FDA must quickly determine whether or not a problem with a biologic, drug, or medical device impacts the public health.

DATES: Submit written or electronic comments on the collection of information by March 8, 2004.

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:

JonnaLynn P. 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.

Generic FDA Rapid Response Surveys (OMB Control Number 0910-0500)—Extension

Section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), requires that important safety information relating to all human prescription drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the act. Under section 519 of the act (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device-related deaths, serious injuries, and malfunctions to FDA, and to require user facilities to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 522 of the act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 903(d)(2) of the act (21 U.S.C. 393(d)(2)) authorizes the Commissioner of Food and Drugs to

implement general powers (including conducting research) to carry out effectively the mission of FDA. These sections of the act enable FDA to enhance consumer protection from risks associated with medical products usage that are not foreseen or apparent during the premarket notification and review process. FDA's regulations governing application for agency approval to market a new drug (21 CFR part 314) and regulations governing biological products (21 CFR part 600) implement these statutory provisions. Currently FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch reporting systems using FDA Forms 3500 and 3500A (OMB control number 0910-0291) and the vaccine adverse event reporting system. FDA is seeking OMB clearance to collect vital information via a series of rapid response surveys. Participation in these surveys will be voluntary. This request covers rapid response surveys for community based health care professionals, general type medical facilities, specialized medical facilities (those known for cardiac surgery, obstetrics/gynecology services, pediatric services, etc.), other health care professionals, patients, consumers, and risk managers working in medical facilities. FDA will use the information gathered from these surveys to obtain quickly vital information about medical product risks and interventions to reduce risks so the agency may take appropriate public health or regulatory action including dissemination of this information as necessary and appropriate.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
200	30 (maximum)	6,000	0.5	3,000

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

FDA projects 30 emergency risk-related surveys per year with a sample of between 50 and 200 respondents per survey. FDA also projects a response time of 0.5 hours per response. These estimates are based on the maximum sample size per questionnaire that FDA can analyze in a timely manner. The annual frequency of response was determined by the maximum number of questionnaires that will be sent to any individual respondent. Some respondents may be contacted only 1 time per year, while other respondents

may be contacted several times annually, depending on the human drug, biologic, or medical device under evaluation. It is estimated that, given the expected type of issues that will be addressed by the surveys, it will take 0.5 hours for a respondent to gather the requested information and fill in the answers.

Dated: December 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-258 Filed 1-6-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225-04-4001]

Memorandum of Understanding Between the Food and Drug Administration and Customs and Border Protection, Department of Homeland Security

AGENCY: Food and Drug Administration, HHS.