

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****[Docket No. 02N-0131]****Agency Information Collection Activities: Submission for OMB Review; Comment Request; FDA Rapid Response Surveys****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

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

DATES: Submit written comments on the collection of information by November 15, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Mark L. Pincus, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1471.

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 Rapid Response Surveys—New Collection

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), regulations governing biological products (21 CFR part 600, *et seq.*), and regulations governing medical devices (21 CFR part 803) 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 (VAERS).

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.

In the **Federal Register** of April 30, 2002 (67 FR 21253), the agency requested comments on the proposed collection of information. FDA received four comments, but only one pertained to the information collection.

For the purpose of clarity and understanding, the comment will be

divided into six sections. The first section is as follows:

The previous notice provides no description of the surveys being proposed, the nature of the information to be sought, the respondents to whom the surveys will be sent, the "triggers" for issuing survey, or proposed use of the results of these surveys.

FDA's response is there have been times when FDA has received notice of medical product problems through its various adverse event-reporting systems and often there is insufficient information to gauge whether or not a significant public health problem exists with respect to a specific medical product. If a significant problem exists, FDA seeks to understand quickly the nature of the problem.

FDA will propose the use of specific FDA Rapid Response Surveys through the submission of a memorandum requesting OMB approval of the survey. Included in this memorandum will be the need for the survey and the timeframe in which FDA needs OMB to make a decision on the survey, and the description of the statistical methods to be used. These include the respondent universe, the sample selection methods, the information collection procedures, the expected response rate and an estimate of the burden. Also included in the request will be a copy of the survey.

Also, if there is a very new problem to FDA, the agency needs to investigate it more before it decides on the proper action. For example, if the results of the survey indicate that problems are more widespread than just a few isolated incidents, the first anticipated action by FDA is to contact the manufacturers or sponsors of the product to discuss the issues. Depending on the manufacturers' responses, the issue could end up in a product recall, or information could be posted on the FDA web site stating that some problems exist with the use of these products. Additionally, the issue may be referred to a center ad-hoc committee or a working group to formulate additional actions. Without first knowing if there is an issue, and what the causes of the problem may be, it is difficult to state the final action. That is why the Rapid Response Survey becomes so important in helping FDA discern the issues.

By going to the manufacturers and sponsors, FDA often needs input from other stakeholders that have firsthand knowledge of the problem and the situation. Here is where the Rapid Response Survey can be invaluable.

The second section of the comment recommends that the notice be reissued with adequate details about the proposed collection of information to

enable the public to understand the proposal so that comments can then be made to the agency based on full knowledge of the proposal.

FDA responds to the comment by stating in the 30-day **Federal Register** notice and in the information collection requirement adequate details about the purpose were added to enable the public to understand the purpose of the proposal. Therefore, FDA is not going to reissue the 60-day **Federal Register** notice, but has considered and responded to all the comments received.

The third section of the comment states that risk management requires the involvement of all stakeholders, including government, industry, health-care professionals, and patients. The role of medical product sponsor appears to be left out of the process.

FDA's response is that medical product sponsors as a stakeholder was omitted inadvertently from the 60-day **Federal Register** notice seeking public comment. They will be included in the 30-day **Federal Register** notice announcing FDA's submission of this information collection to OMB as well as in the justification package sent to OMB.

The fourth section of the comment states that it is unclear to whom the surveys will be directed. Although the notice identifies general groups, there is no discussion of how members of these groups will be identified to participate in the surveys.

The FDA reply is that the agency will determine which groups to which groups will be asked to participate in each particular survey based on the type of medical product problem that

occurred. For instance, if the problem dealt with clinical laboratory devices and a perceived problem with antibody assays for detection of the herpes virus and laboratory information systems mixing up pathology reports, FDA would survey the members of the American Society of Microbiology Division C and facilities that use such information that is retrieved from the MedSun system.

Section five deals with the voluntary nature of the surveys risks the collection of potentially confounded, biased, and unconfirmed information on which, according to the notice, the agency intends to "take: appropriate public health or regulatory action."

FDA responds that usually it expects a 70 percent response rate. The impact of a lower response rate to these surveys will be considered before FDA takes action to improve the response rate. FDA may determine that quicker action—development of a public position paper—can be taken based on consistent responses from each of the surveys conducted. If there is a low response rate with no clear pattern of response, the national organization representing that stakeholder group will send a letter to all respondents reminding them to fill out the survey form.

FDA proposes to draw purposeful samples for these surveys. Since the survey data will not be used for estimates of incidence, there is no need for a probability sample. Because these proposed data collections are qualitative, not quantitative, and because FDA resources for processing incoming data limited, FDA proposes to

keep these data collection efforts to a manageable size.

The response universe will be kept to those stakeholders that have been identified as appropriate respondents. These will be groups that focus on those specialties and have experience and expertise in those areas.

The sixth and final section of the comment stated that the notice doesn't address the mechanism by which the surveys will produce "rapid responses" from those surveyed. Whether the surveys will be conducted by mail, facsimile, telephone, or the Internet, there is a need to validate the source(s) and medical accuracy of the information provided. One of the hallmarks of responsible risk management is confirmation of the information upon which decisions are based. Decision should not be based on information gathered in haste if/when the source and validity of the data have not been confirmed.

FDA's response is depending on the criticality of the survey and the speed in which the data needs to be returned to FDA, respondents can use mail, faxes, or e-mail for their survey responses. More use of Internet based surveys will be made in the future.

FDA will employ great care in determining the validity of the information received. This will be done through the design of the survey instruments and keeping identifiers for followup if the Center has concerns about the data received. After the data has been verified, the respondents identifying information will be deleted.

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 |
|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 200 | 30 (maximum) | 6,000 | .5 | 3,000 |

¹There 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 (30 minutes) 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 one 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 (30 minutes) for a respondent to gather the requested information and fill in the answers.

Dated: October 9, 2002.
Margaret M. Dotzel,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0303]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

AGENCY: Food and Drug Administration, HHS.