§ 201.66(c) and (d), which averages to 8.5 submissions per respondent. The agency estimated that each submission will take an average of 2 hours to prepare for a total of 1,040 hours annually. The burden was also expected to be a one-time burden.

Since the final rule was issued on March 17, 1999, the agency has extended the May 16, 2001, compliance date by 1 year to May 16, 2002 (with a corresponding extension of the May 16, 2002, compliance date for products with annual sales of less than $25,000 to May 16, 2003) (65 FR 38191, June 20, 2000). During this time, the agency has published only one major final rule (which has had its effective date extended from May 21, 2001, to December 31, 2002) (65 36319, June 8, 2000) and several minor amendments to existing final rules. These monograph amendments have an effective date of May 16, 2002, so that the relabeling required by the amendments may be coordinated with the relabeling required by the OTC drug product labeling final rule. For these reasons, the agency believes that the numbers of affected products in the different categories discussed in the collection of information in the final rule are little changed. Accordingly, the agency is listing the same number of respondents, annual frequency per response, and total annual responses in this notice.

The agency believes the hours per response and total hours may be less than the numbers stated in the final rule for several reasons. First, respondents have made a number of inquiries already since the final rule was issued in 1999. The agency's experience with these inquires made to the agency is that inquiries have been less than 2.5 or 4 hours per response, generally averaging 0.25 to 0.5 hour per inquiry. Second, the agency issued a draft guidance for industry entitled ''Labeling Over-the-Counter Human Drug Products; Updating Labeling in ANDA's'' (66 FR 11174, February 22, 2001), which included a number of labeling examples to assist holders of ANDAs for OTC drug products and manufacturers of reference listed drugs for the ANDAs to implement the new OTC drug product labeling regulation. This guidance should have reduced some of the hours per response and total hours for some NDA and ANDA holders. However, the agency is not currently able to estimate how much the time has been reduced. Accordingly, the agency is listing the same hours per response and total hours in this notice as appeared in the final rule.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.66	400	31.43	12,573	4	50,292
201.66	400	66.8	26,737	2.5	66,842
201.66(c) and (d)	61	8.5	522	2	1,044
201.66(e)	25	4	100	24	2,400
Total					120,578

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

Dated: September 21, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–24160 Filed 9–26–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0400]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients

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 regulations requiring manufacturers to assess the safety and effectiveness of new drugs and biological products in pediatric patients.

DATES: Submit written or electronic comments on the collection of information by November 26, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (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: Karen Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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: (1) Whether the proposed collection of information is necessary for the proper performance of FDA'sfunctions, 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.

Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients (OMB Control No. 0910–0392)—Extension

FDA regulations require pediatric studies of certain new drugs and biological products to ensure that those products that are likely to be commonly used in children or that represent a meaningful therapeutic benefit over existing treatments contain adequate pediatric labeling for the approved indications at the time of, or soon after, approval. (These regulations were issued in the **Federal Register** of December 2, 1998 (63 FR 66632).) Many new drugs and biological products represent treatments that are the best available treatment for children, but most of them have not been adequately tested in the pediatric population. As a result, product labeling frequently fails to provide directions for safe and effective use in pediatric patients. The regulations are intended to increase the number of new drugs and biological products, with clinically significant use in children, that carry adequate labeling for use in that subpopulation. Specifically, the regulations are intended to address the following concerns: (1) Avoidable adverse drug reactions in children—drug reactions that occur because of the use of inadvertent drug overdoses or other drug administration problems that could have been avoided with better information on appropriate pediatric use; and (2) undertreatment of children with a potentially safe and effective drug because the physician either prescribed an inadequate dosage or regimen, prescribed a less effective drug, or did not prescribe a drug, due to the physician's uncertainty about whether the drug or the dose was safe and effective in children.

The regulations contain the following reporting requirements that are subject to the PRA:

21 CFR 201.23(a)—Applicants submit a supplemental application containing data adequate to assess whether the drug product is safe and effective in pediatric populations; applicants develop a pediatric formulation for FDA approval.

21 CFR 201.23(c)(1)—Applicants request a full or partial waiver of § 201.23(a).

21 CFR 312.47(b)(1)(iv)—Sponsors submit background information on the sponsor's plan for Phase 3, including plans for pediatric studies, including a time line for protocol finalization, enrollment, completion, and data analysis, or information to support any planned request for waiver or deferral of pediatric studies.

21 CFR 312.47(b)(2)—Sponsors submit information on the status of needed or ongoing pediatric studies.

21 CFR 314.50(d)(7)—Applicants submit a pediatric use section, describing any investigations of the drug for use in pediatric populations.

21 CFR 314.55(a)—Applications contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in pediatric subpopulations and to support dosing and administration information.

21 CFR 314.55(b)—Applicants request a deferred submission of some or all assessments of safety and effectiveness required under § 314.55(a).

21 CFR 314.55(c)—Applicants request a full or partial waiver of the requirements under § 314.55(a).

21 CFR 314.81(b)(2)(i)—Applicant's annual report includes a brief summary of whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population have been initiated.

21 CFR 314.81(b)(2)(vi)(*c*)—Applicant's annual report includes an analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information.

21 CFR 314.81(b)(2)(vii)—Applicant's annual report includes a statement whether postmarketing clinical studies in pediatric populations were required or agreed to, and if so, the status of these studies.

21 CFR 601.27(a)—Applications for new biological products contain data that are adequate to assess the safety and effectiveness of the biological product for the claimed indications in pediatric subpopulations, and to support dosing and administration information.

21 CFR 601.27(b)—Applicants request a deferred submission of some or all assessments of safety and effectiveness required under § 601.27(a).

21 CFR 601.27(c)—Applicants request a full or partial waiver of the requirements under § 601.27(a).

21 CFR 601.28(a)—Sponsors submit to FDA a brief summary stating whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated.

21 CFR 601.28(b)—Sponsors submit to FDA an analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information.

21 CFR 601.28(c)—Sponsors submit to FDA a statement on the current status of any postmarketing studies in the pediatric population performed by, on or behalf of, the applicant.Based on the number of submissions the agency has received as a result of the December 2, 1998, final rule (63 FR 66632), FDA estimates that the PRA burden to comply with the regulations will be as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.23(a)	2	1	2	48	96
201.23(c)	0	0	0	0	0
312.47(b)(1)(iv)	103	1.2	122	16	1,952
312.47(b)(2)	102	1.3	130	16	2,080
314.50(d)(7)	47	1	73	50	3,650
314.55(a)	25	1	25	48	1,200
314.55(b)	65	1	65	24	1,560
314.55(c)	90	1	90	8	720

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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
314.81(b)(2)(i)	100	1	100	8	800
314.81(b)(2)(vi)(*c*)	100	1	100	24	2,400
314.81(b)(2)(vii)	100	1	100	1.5	150
601.27(a)	2	1	3	48	144
601.27(b)	5	1	5	24	120
601.27(c)	3	1	4	8	32
601.28(a)	69	1	69	8	552
601.28(b)	69	1	69	24	1,656
601.28(c)	69	1	69	1.5	103.5
Total					17,215.5

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

Dated: September 21, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–24162 Filed 9–26–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0399]

Agency Information Collection Activities; Proposed Collection; Comment Request; 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 continued 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, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Rapid Response Surveys to obtain data from health professionals and medical-device-user facilities when FDA must quickly determine whether or not a problem with a medical device impacts the public health.

DATES: Submit written and electronic comments on the collection of information by November 26, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (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: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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 below.

With respect to the following collection of information, FDA invites comments on: (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.

Rapid Response Surveys (OMB Control Number 0910–0457)—Extension

Under section 519 of the Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device related deaths, serious injuries, and malfunctions, and 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 (the Commissioner) to implement general powers (including conducting research) to effectively carry out the mission of FDA. These sections of the act enable FDA to enhance consumer protection from risks associated with medical device usage that are not foreseen or apparent during the premarket notification and review process. FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch Reporting Systems using FDA form 3500 and 3500A (OMB control number 0910–0281).

FDA received a 1-year OMB approval on February 5, 2001, to implement Emergency Health Surveys (since that time, renamed ''Rapid Response Surveys''), via a series of surveys, thus implementing section 705(b) of the act and the Commissioner's authority as specified in section 903(d)(2) of the act. To date, FDA has initiated one Rapid