

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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[Docket No. 01 N-04001

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 *[insert date 60 days after date of publication in the **Federal Register**]*.

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’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.

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 3 14.50(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 § 3 14.55(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 3 14.81(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 3 14.81 (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 BURDEN¹

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
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: 9-21-01
September 21, 2001.

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Margaret M. Dotzel

Margaret M. Dotzel,
Associate Commissioner for Policy,

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Suzette N. Reese