

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0334]

DDM

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Center	A. Corbin

Draft Guidance for Industry on the Pediatric Research Equity Act;

Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "How to Comply with the Pediatric Research Equity Act." This draft guidance provides recommendations on how to interpret the requirements of the Pediatric Research Equity Act (PREA), which requires pediatric studies of certain drugs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 approved indications.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send

one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Grace Carmouze, Center for Drug Evaluation and Research (HFD-950),
Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,
301-594-2041, or

Leonard Wilson, Center for Biologics Evaluation and Research (HFM-25),
Food and Drug Administration, 1401 Rockville Pike, suite 200N
Rockville, MD 20852-1448, 301-827-0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “How to Comply with the Pediatric Research Equity Act.” On December 3, 2003, the Pediatric Research Equity Act was signed into law. PREA amends the Federal Food, Drug, and Cosmetic Act (the act) by adding section 505B (21 U.S.C. 355B). In PREA, Congress codified many of the elements of the Pediatric Rule, a final rule issued by FDA on December 2, 1998 (63 FR 66632), and suspended by court order on October 17, 2002. *Association of American Physicians, and Surgeons, Inc. v. FDA*, 226 F. Supp. 2d 204 (D.D.C. 2002). Specifically, PREA, in adding section 505B(a) of the act, requires all

applications (or supplements to an application) submitted under section 505 of the act (21 U.S.C. 355) or section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration to contain a pediatric assessment unless the applicant has obtained a waiver or deferral. PREA also authorizes FDA, under section 505B(b) of the act, to require holders of previously approved applications for marketed drugs and biological products to conduct pediatric studies under certain circumstances, even if the holders are not seeking one of the changes listed under section 505B(a) of the act. This draft guidance only provides recommendations related to studies required under section 505B(a) of the act. This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on how to comply with PREA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501–3520) (the PRA), 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 in this document.

With respect to the following collection of information, FDA invites comment 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 on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Guidance for Industry: How to Comply with the Pediatric Research Equity Act.

Description: The draft guidance provides recommendations to sponsors on how to interpret the requirements of PREA. PREA requires new drug

applications (NDAs) and biologics licensing applications (BLAs) (or supplements to an applications) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration to contain a pediatric assessment unless the applicant has obtained a waiver or deferral. Although PREA applies to both new applications (or supplements to an application) and currently marketed drugs and biological products for which a sponsor is not seeking one of the enumerated changes, the guidance only provides recommendations related to new applications or supplements to applications for drugs and biological products.

Description of Respondents: Sponsors of NDAs or BLAs for human drugs and biological products.

Burden Estimate: FDA is requesting public comments on estimates of annual submissions expected in 2005 (based on the number of submissions received in 2003 and 2004 unless otherwise indicated) as required by the following PREA requirements described in the draft guidance:

Section 505B(a)(1) and (a)(2)—The draft guidance provides recommendations for submitting pediatric studies with applications (or supplements to an application) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration under section 505 of the act or section 351 of the PHS Act. These assessments are required to contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in the relevant pediatric subpopulations and to support dosing and administration for each subpopulation for which the product is safe and effective. FDA estimates that 106 pediatric use assessments will be submitted from 78 applicants and it will take 50 hours to prepare each assessment.

Section 505B(a)(3)—The draft guidance makes recommendations on how to request a deferral of some or all assessments of safety and effectiveness required under PREA. FDA estimates that it will receive 160 requests to defer assessments from 54 applicants and it will take 24 hours to prepare each request.

Section 505B(a)(4)—The draft guidance provides recommendations on how to request a full or partial waiver of the pediatric study requirements. Based on its 2003 and 2004 experience, FDA anticipates that it will receive approximately 110 requests annually from approximately 80 applicants and estimates it will take approximately 8 hours to prepare each request.

Section 505B(e)—The draft guidance makes recommendations for applicants to meet at appropriate times with FDA to discuss plans and timelines for pediatric studies and any planned requests for deferral or waiver of pediatric studies. FDA estimates it will receive 160 submissions associated with meetings to discuss pediatric plans from 95 applicants at 16 hours per meeting submission.

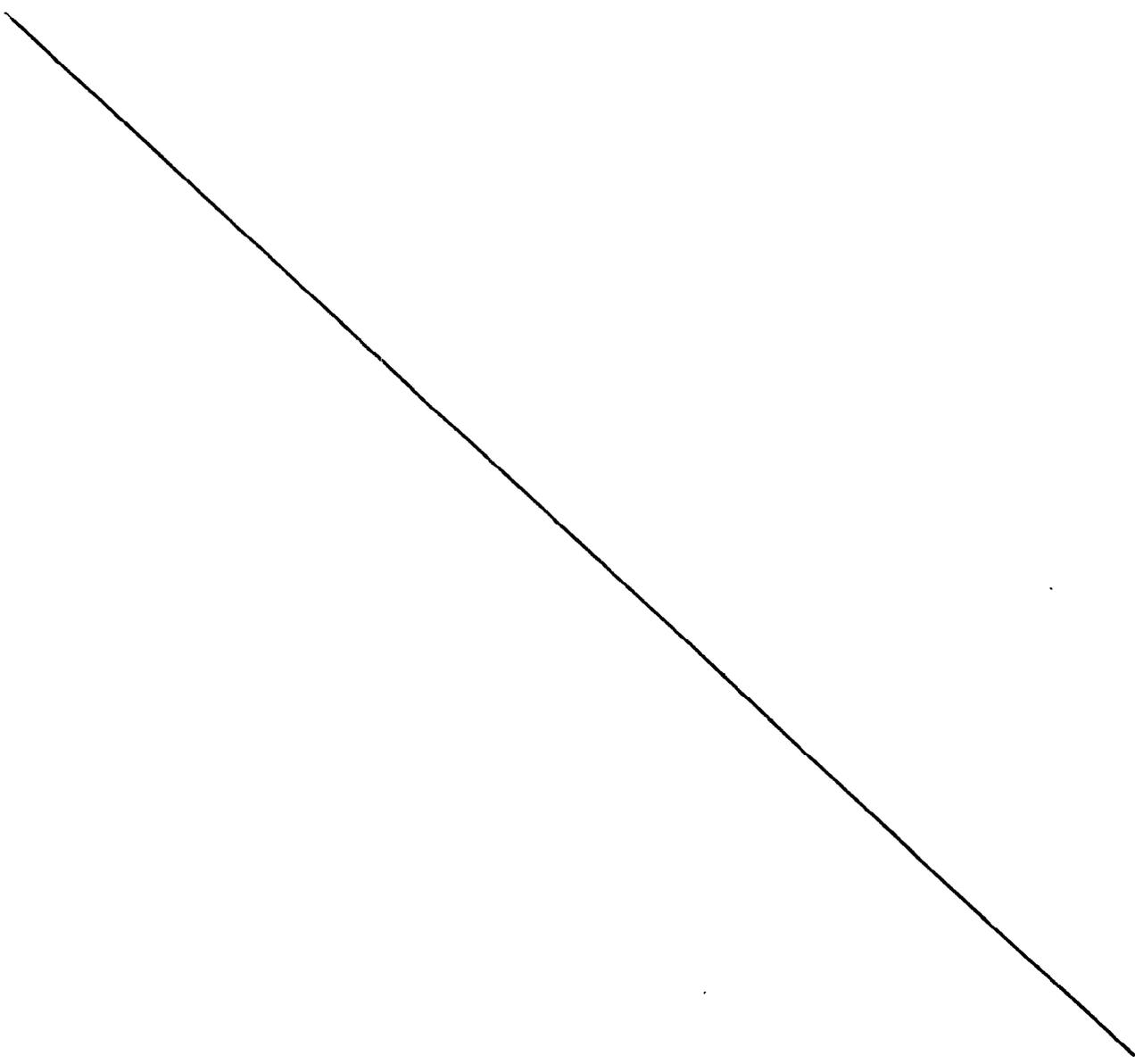
FDA estimates that the collection of information resulting from this draft guidance is as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

PREA Provision	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
505B(a)(1) and (a)(2) Submission of pediatric assessments	78	1.4	106	50	5,300
505B(a)(3) Deferrals	54	3.0	160	24	3,840
505B(a)(4) Full and partial waivers	80	1.4	110	8	880
505B(e) Meetings	95	1.7	160	16	2,560
Total					12,580

In addition, the draft guidance discusses when sponsors may need to report on the status of postmarketing study commitments as part of annual reports submitted under 21 CFR 314.81(b) and 21 CFR 601.70. The burdens

associated with the annual reporting requirements were previously accounted for under OMB number 0910-0001 (expires 5/31/08) (for 21 CFR 314.81(b) and OMB number 0910-0433 (expires 3/31/07) (for 21 CFR 601.70). Furthermore, although labeling submissions are required under certain PREA provisions (e.g., section 505B(a)(4)(D) of the act), the draft guidance does not provide recommendations on these requirements and therefore FDA has not estimated associated burdens.



IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 8/29/05
August 29, 2005



Jeffrey Shuren,
Assistant Commissioner for Policy.

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