

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 00D-1595]

DMB

Display Date	12/1/07
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Certifier	<i>[Signature]</i>

**Draft Guidance for Industry on Recommendations for Complying With the Pediatric Rule; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Recommendations for Complying With the Pediatric Rule (21 CFR 314.55(a) and 601.27(a)).” The draft guidance provides recommendations for sponsors of new drug applications (NDA’s) and biologics license applications (BLA’s) on how to meet the requirements of the final rule requiring manufacturers to assess the safety and effectiveness of new drugs and biological products in pediatric patients (pediatric rule).

**DATES:** Submit written comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**  
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Elaine C. Esber, Center for Biologics Evaluation and Research (HFM-30), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0641, FAX 301-827-0644, e-mail [esber@cber.fda.gov](mailto:esber@cber.fda.gov).

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance for industry entitled "Recommendations for Complying With the Pediatric Rule (21 CFR 314.55(a) and (601.27(a))." In the **Federal Register** of December 2, 1998 (63 FR 66632), FDA published the pediatric rule. Under the pediatric rule, applications for new active ingredients, new indications, new dosage forms, new dosing regimens, and new routes of administration must contain a pediatric assessment unless the applicant has obtained a waiver or deferral of pediatric studies (21 CFR 314.55(a) and 601.27(a)). The rule became effective on April 1, 1999. Under the compliance dates in the final rule, pediatric assessments must be included in applications after December 2, 2000, for: (1) NDA's; (2) BLA's; and (3) abbreviated new drug applications (ANDA's) that are based on suitability petitions for a change in active ingredient, dosage form, or route of administration.<sup>1</sup> This draft guidance describes how the pediatric rule will be implemented. Areas covered include an overview of pediatric assessments, pediatric plans, waivers and deferrals, compliance issues, pediatric exclusivity, and the role of FDA's Pediatric Advisory Subcommittee.

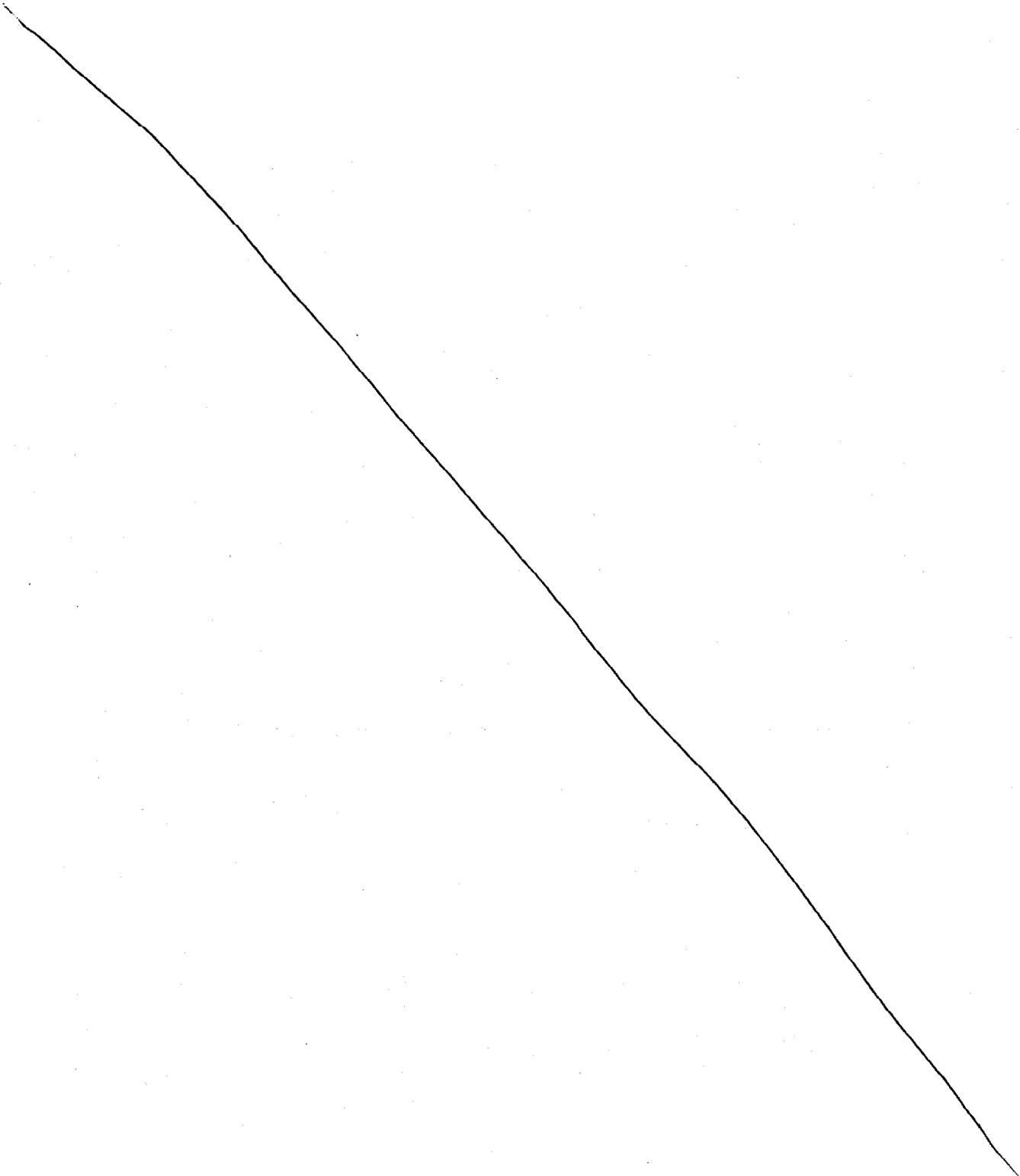
This Level 1 draft guidance is being issued consistent with FDA's good guidance regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on how to comply with the pediatric rule. It does not create or confer any rights

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<sup>1</sup> On November 4, 1999, FDA received a citizen petition raising issues associated with the relationship between the pediatric rule and ANDA suitability petitions. The issues raised in the petition are still under consideration by the agency. Therefore, this guidance does not address pediatric studies associated with suitability petitions.

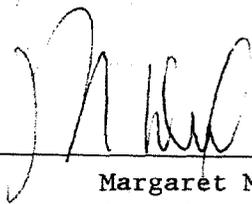
for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found



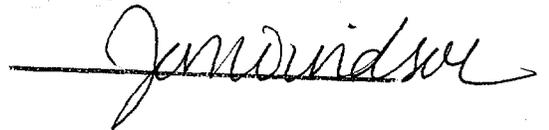
in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11-22-00  
November 22, 2000.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

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