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Certifier	<i>[Signature]</i>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1336]

**Draft Guidance for Industry: Pediatric Oncology Studies in Response to a Written Request; Availability**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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Pediatric Oncology Studies in Response to a Written Request." The draft guidance document provides assistance to applicants intending to respond to a written request from FDA for pediatric studies for a drug that may show potential health benefits in children with cancer. The draft guidance discusses the kind of information applicants should include in their pediatric studies, which, if responsive to a written request, may make the applicant's drug eligible to qualify for an additional 6 months of marketing exclusivity. This guidance is part of the agency's pediatric initiative to generate new knowledge to assist practitioners in the care of children with cancer and to help provide pediatric patients early access to emerging new drugs.

**DATES:** Submit written comments on the draft guidance to ensure their adequate consideration in preparation of the final document by *[insert date 90 days after date of publication in the Federal Register]*.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:** Submit written requests for single copies of "Pediatric Oncology Studies in Response to a Written Request" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Manufacturers Assistance and Communications Staff (HFM-42), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 208521448.

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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:**

Terrie L. Crescenzi, Center for Drug Evaluation and Research (HFD-104), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-7337, FAX 301-827-2520, e-mail: [crescenzit@cder.fda.gov](mailto:crescenzit@cder.fda.gov), or

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:**

**I. Background**

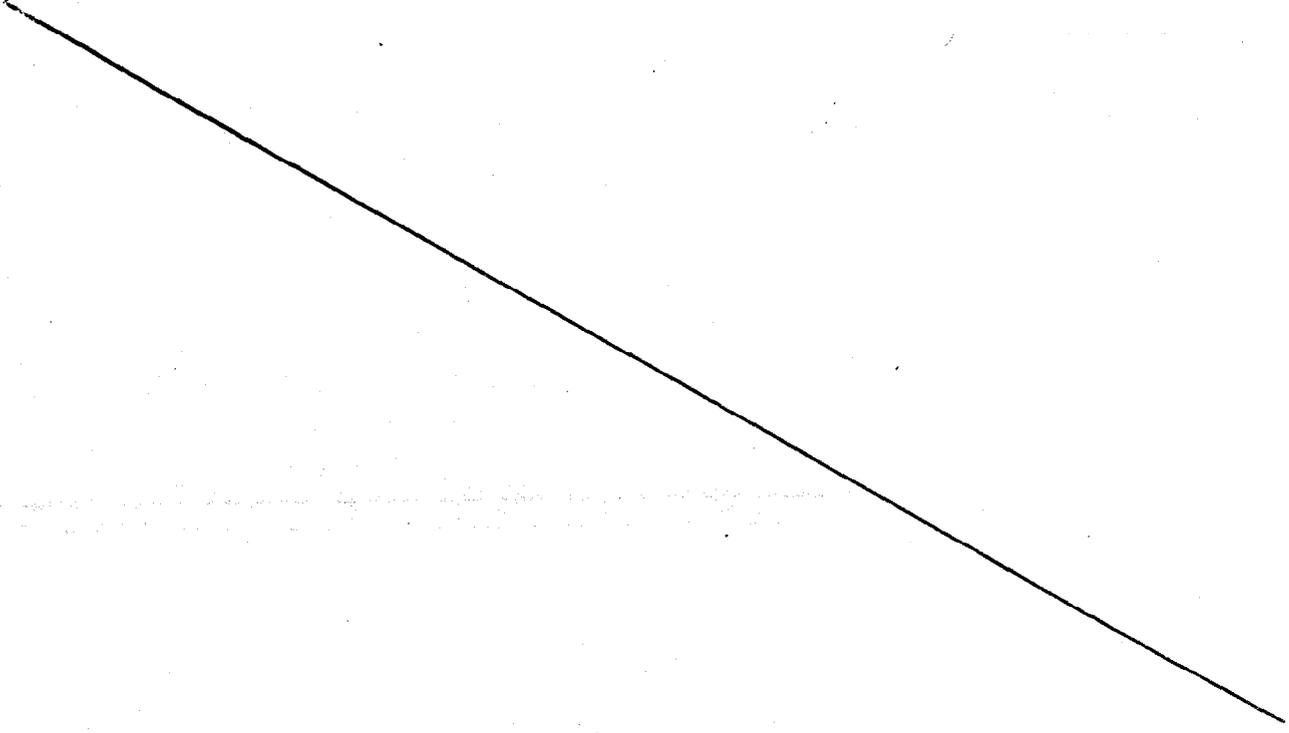
FDA is announcing the availability of a draft guidance for industry entitled "Pediatric Oncology Studies in Response to a Written Request." Section 111 of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act), signed into law by President Clinton on November 21, 1997, created section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a), which permits certain marketing applications to obtain an additional 6 months of marketing exclusivity if the sponsor submits requested information relating to the use of the drug in the pediatric population. The statute permits the agency to issue a written request for pediatric studies under section 505A(a) or (c) of the act. A written request is a specific document in which the agency requests submission of certain studies. The studies are designed to provide information on the health benefits of a drug in the pediatric population.

Because the study of oncology drugs in pediatric populations merits special consideration, the agency is publishing this guidance to assist sponsors who wish to undertake pediatric oncology studies.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on pediatric oncology studies. 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 statute, regulations, or both.

## **II. Comments**

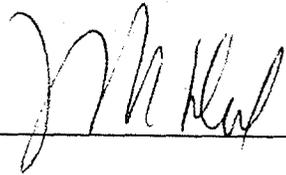
Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of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



**III. Electronic Access**

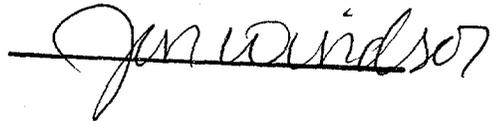
Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cder/pediatrics>, and at <http://www.fda.gov/cber/guidelines.htm>.

Dated: 6/14/00  
June 14, 2000



Margaret M. Dotzel  
Associate Commissioner for Policy

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**



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