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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0265]

Guidance for Industry on Qualifying for Pediatric Exclusivity; Availability; Revised

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry entitled "Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act." FDA is publishing this revised guidance to assist industry in interpreting provisions of the Food and Drug Administration Modernization Act of 1997 (Modernization Act). This guidance will remain in effect until superseded by regulations or new guidance.

DATES: Comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of "Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act" 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 20852-1448. Send one self-addressed adhesive label to assist in processing your requests. Submit written comments on the 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 See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the draft guidance.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-2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-7337, FAX 301-594-6197, e-mail "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".

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a revised guidance for industry entitled "Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act." Section 111 of the Modernization Act (Public Law 105-115), 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). Section 505A of the act permits certain applications to obtain an additional 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits information relating to the use of the drug in the pediatric population. FDA plans to issue regulations through notice-and-comment rulemaking to implement the pediatric exclusivity provisions of the Modernization Act. The agency is publishing this procedural guidance to explain how the agency intends to implement section 505A of the act in the interim. The guidance will be updated as appropriate. This guidance will remain in effect until superseded by regulations or new guidance.

This guidance describes FDA's current thinking on how sponsors may qualify for pediatric exclusivity under section 505A of the act. The guidance includes the following topics: (1) Whether studies for certain drugs will be requested under section 505A(a) or (c), (2) the definition of pediatric studies, (3) the content and format of an FDA request for pediatric studies, (4) how an applicant can obtain an FDA written request, (5) the content of a written agreement for the conduct of pediatric studies, (6) the definition of commonly accepted scientific principles, (7) the filing

of reports of studies, (8) acceptance of studies by FDA, (9) scope and nature of pediatric exclusivity, (10) publication of exclusivity determinations, (11) treatment of information submitted in support of a request for pediatric exclusivity, (12) how pediatric studies required under FDA regulations may qualify for pediatric exclusivity, and (13) what happens after January 1, 2002, the sunset date for the pediatric exclusivity provisions of the Modernization Act.

This level 1 guidance document is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on the implementation of section 505A of the act and pediatric exclusivity. 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.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). 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 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.

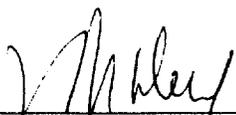
II. Paperwork Reduction Act of 1995

This notice contains no new collections of information. The information requested for proposed pediatric studies is already covered by the collection of information on investigational new drug application regulations (21 CFR part 312) submitted to the Office of Management and Budget (OMB) for review and clearance. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB approved the information collection and assigned OMB control number 0910–0014. The approval expires on December 31, 1999.

III. Electronic Access

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

Dated: 9/28/99
September 28, 1999



Margaret M. Dotzel
Acting Associate Commissioner for Policy

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