DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0265]

Guidance for Industry on Qualifying for Pediatric Exclusivity; Availability; Request for Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for submissions.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act.'' FDA is also requesting the submission of proposed pediatric study requests. This guidance is intended to assist industry in interpreting newly enacted 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 This guidance will remain in effect until superseded by regulations or new guidance.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: Written comments may be submitted on the guidance by October 5, 1998. General comments on agency guidance documents are welcome at any time. Sponsors of applications for marketed drugs that appear in the priority section of the ''List of Approved Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population'' (the list) (see Docket No. 98N–0056) (63 FR 27733) for which any exclusivity or patent period expires on or before March 31, 1999, should submit proposed pediatric study requests to the appropriate new drug review division with a facsimile copy to Khyati N. Roberts (address below) on or before August 31, 1998, for expedited consideration.

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 See the **Supplementary Information** section of this document for electronic access to the draft guidance.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: Khyati N. Roberts, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779, FAX 301–594–5493, e-mail ''robertsk@cder.fda.gov'', or David W. Feigal, Center for Biologics Evaluation and Research (HFM–6), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0376, FAX 301–827–0440, e-mail ''feigal@cber.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a 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 (Pub. L. 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, and (11) treatment of information submitted in support of a request for pediatric exclusivity.

This guidance document is being implemented immediately without prior public comment because the guidance is needed to implement the Modernization Act. However, the agency wishes to solicit comment from the public, and it is providing a 90-day comment period and establishing a docket for the receipt of comments. FDA will also consider comments on pediatric exclusivity submitted to Docket No. 98N–0056 (containing the ''List of Approved Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population'') before July 7, 1998.

This guidance document 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.

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. Request for Proposed Pediatric Study Requests

Sponsors of applications for marketed drugs that appear in the priority section of the list (see Docket No. 98N–0056) for which any exclusivity or patent period expires on or before March 31, 1999, should submit proposed pediatric study requests to the appropriate new drug review division with a facsimile copy to Khyati N. Roberts (address above) on or before August 17, 1998, for expedited consideration. These sponsors should label their proposals ''Proposed Pediatric Study Request—Expiration on or Before March 31, 1999.'' FDA will endeavor to issue Written Requests on or before October 15, 1998, for adequate proposals or as soon thereafter as possible. FDA will ask sponsors of proposals that are submitted before August 31, 1998, and that are not adequate to resubmit their proposal. The resubmitted proposal will be processed based on the date of resubmission. Other proposed pediatric study requests may also be submitted during this period, but they will be processed in the order described in the guidance. As FDA gains experience with this process, it may provide additional guidance regarding the timing of a proposed pediatric study request.

III. 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 IND regulations (21 CFR part 312) submitted to 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.

IV. 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: June 24, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–17876 Filed 7–6–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications.

The following applicants have applied for permits to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*).

PRT–844263

Applicant: Dr. Brenda Molano-Flores, Illinois Natural History Survey/Midewin National Tallgrass Prairie, Wilmington, Illinois.

The applicant requests a permit to take (collect infructescence, flowers, and leaf tissue samples) endangered Leafy Prairie Clover (*Dalea foliosa*) plants located in the Midewin National Tallgrass Prairie (Federal jurisdiction). Activities are proposed for scientific research aimed at survival and enhancement of the species in the wild.

PRT–842503

Applicant: Robert Mies and Kimberly Williams, The Organization for Bat Conservation, Williamston, Michigan.

The applicant requests an amendment to permit number PRT–842503 to take (capture, handle, band) endangered Indiana Bat (*Myotis sodalis*) at locations within the States of Region 3 (Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin) where they occur. Activities are proposed for scientific research aimed at survival and enhancement of the species in the wild.

Written data or comments should be submitted to the Regional Director, U.S. Fish and Wildlife Service, Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056, and must be received within 30 days of the date of this publication.

Documents and other information submitted with these applications are available for review by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056. Telephone: (612/713–5332); FAX: (612/713–5292).

Dated: June 25, 1998.

Matthias A. Kerschbaum,

Acting Assistant Regional Director, IL, IN, MO (Ecological Services), Region 3, Fort Snelling, Minnesota.

[FR Doc. 98–17860 Filed 7–6–98; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO–310–1310–01–24–1A]

Extension of Currently Approved Information Collection; OMB Approval Number 1004–0034

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) is announcing its intention to request extension of approval for the collection of information from those persons who wish to transfer interest in oil and gas or geothermal leases by assignment of record title, or transfer operating rights (sublease) in oil and gas or geothermal leases under the terms of the mineral leasing laws.

DATES: Comments on the proposed information collection must be received by September 8, 1998, to be considered.

ADDRESSES: Comments may be mailed to: Regulatory Management Team (420), Bureau of Land Management, 1849 C Street NW, Room 401 LS Bldg., Washington, D.C. 20240.

Comments may be sent via Internet to: !WO140attmail.com. Please include ''Attn: 1004–0034'' and your name and return address in your Internet message.

Comments may be hand delivered to the Bureau of Land Management Administrative Record, Room 401 L Street, NW, Washington, D.C.

Comments will be available for public review at the L Street address during regular business hours (7:45 A.M. to 4:15 P.M., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Barbara Gamble, Fluids Minerals Group, (202) 452–0340.

SUPPLEMENTARY INFORMATION: In accordance with 5 CFR 1320.12(a), the BLM is required to provide 60-day notice in the **Federal Register** concerning a collection of information contained in published current rules to solicit comments on (a) whether the proposed collection of information is