The NDA regulations at 21 CFR 314.50, which define what must be submitted in an application, do not explicitly define a ''full report,'' but require, among other things, submission of a ''description and analysis of each controlled clinical study pertinent to a proposed use of the drug'' and of ''any other data or information relevant to an evaluation of the safety and effectiveness of the drug product.''

In 1988, FDA issued ''Guidelines for the Format and Content of the Clinical and Statistical Sections of New Drug Applications'' (hereinafter referred to as the Clin/Stat Guideline), which described the contents of a full report of a study. This guidance called for full study reports for studies that contributed effectiveness data as well as safety information. For other studies, sponsors were advised to submit abbreviated reports of the effectiveness results.

In 1996, the International Conference on Harmonisation of the Technical Requirements for Registration of Pharmaceuticals (ICH) ''Guidelines for the Structure and Content of Clinical Study Reports'' (ICH E3) provided an updated description of the contents of a full study report and specific provisions for submitting less-than-full study reports.

Applicants have not used the provisions to submit less-thanfull study reports contained in both the Clin/Stat Guideline and ICH E3 as often as they could have because of difficulties experienced in deciding when a full study report is required by the reviewing body. For example, clinical drug and biologic product development programs often include numerous clinical studies and resulting data that are not intended to contribute to the evaluation of the effectiveness of a product for a particular use and are not needed to support information included in labeling. Accordingly, such studies may be submitted as abbreviated reports or synopses, and this guidance is intended to facilitate their submission.

In developing the guidance, FDA identified the following three issues on which it is specifically seeking public comment:

(1) In describing the format of an abbreviated study report, the draft guidance references selected sections of the study report format in ICH E3 and states that the abbreviated report should include these sections. An alternative approach considered by the agency was to recommend that all of the sections in the ICH E3 clinical study report format be included, but that some of them contain detailed information while others contain only minimal information. Which of these approaches is preferable, or is there another approach that the agency should consider?

(2) The draft guidance indicates that, in general, applicants should submit full reports of negative studies (studies adequately designed to evaluate efficacy that failed to demonstrate efficacy), but provides for the submission of abbreviated reports of such studies in some cases with agreement from the relevant review division. Should abbreviated reports of negative studies be recommended, and, if so, should more detailed information be provided on these trials than is contemplated by the proposed abbreviated report format?

(3) The draft guidance states that in the case of products that are the subject of very limited drug development programs (those with fewer than six studies from any phase of development designed to determine effectiveness including dose comparison trials), full reports of all studies ordinarily should be provided. The rationale for this provision is that, in such programs, even studies less central to the proposed application (e.g., related indication, different dosage form) often form a substantive proportion of the total clinical data base. The agency is seeking comment on whether the proposed definition of ''very limited drug development programs'' is appropriate. Should full reports of all studies be provided for drug development programs with fewer or more than six studies designed to determine effectiveness, or can commenters propose an alternative definition of ''very limited drug development programs?''

This draft guidance represents the agency's current thinking on submission of full study reports, abbreviated reports, and synopses of information related to effectiveness for new drugs and biological products. 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 submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. 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: August 11, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–25102 Filed 9–15–98; 4:19 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Receipt of Application for Endangered Species Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Receipt of Application for Endangered Species Permit.

SUMMARY: 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.*).

DATES: Written data or comments on these applications must be received, at the address given below, by October 21, 1998.

FOR FURTHER INFORMATION CONTACT: Documents and other information submitted with these applications are available for review, *subject to the requirements of the Privacy Act and Freedom of Information Act*, 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, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (Attn: David Dell, Permit Biologist). Telephone: 404/679–7313; Facsimile: 404/679–7081.

SUPPLEMENTARY INFORMATION:

Applicant: J. D. Wilhide, Arkansas State University, TE002413–0

The applicant requests authorization to take (capture, band, and harass during surveys) the endangered gray bat, *Myotis grisescens*, Indiana bat, *Myotis sodalis*, and Ozark big-eared bat, *Corynorhinus townsendii ingens*, throughout the species' range in Arkansas, for the purpose of enhancement of survival of the species.

Applicant: William Post, Miccosukee Tribe, Miami, Florida, TE002414–0.

The applicant requests authorization to take (harass during surveys) the endangered Cape Sable seaside sparrow, *Ammodramus maritimus mirabilis*, throughout the species range in Everglades National Park, for the purpose of enhancement of survival of the species.

Applicant: Cecil Lamar Comalander, Jr., Milliken Forestry Company, Inc., Columbia, South Carolina, TE002412–0.

The applicant requests authorization to take (capture, band, and harass during surveys) the endangered red-cockaded woodpecker, *Picoides borealis*, throughout the species range in South Carolina, for the purpose of enhancement of survival of the species.

Applicant: Stephen Hoffman, Hawkwatch International, Inc., Salt Lake City, Utah, TE002404–0.

The applicant requests authorization to take (capture, band, and collect feathers) the endangered peregrine falcon, *Falco peregrinus*, throughout the species range in the Florida Keys, Monroe County, Florida, for the purpose of enhancement of survival of the species.

Applicant: Andrea Christman, Withlacoochee Forestry Center, Brooksville, Florida, TE002507–0.

The applicant requests authorization to take (harass during installation of artificial cavities) the endangered red-cockaded woodpecker, *Picoides borealis*, throughout the species range in Florida, for the purpose of enhancement of survival of the species.

Dated: September 3, 1998.

Sam D. Hamilton,

Regional Director.

[FR Doc. 98–25125 Filed 9–18–98; 8:45 am]

BILLING CODE 4310–55–P

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–697830

Applicant: Assistant Regional Director for Ecological Services, Region 3, U.S. Fish and Wildlife Service, Ft. Snelling, Minnesota; William F. Hartwig, Regional Director.

The applicant requests an amendment to his permit for take activities of listed species in Region 3 to add the Illinois cave amphipod (*Gammarus acherondytes*), a recently listed species, for scientific purposes and the enhancement of propagation or survival of the species in the wild, in accordance with listing, recovery outlines, recovery plans, and/or other Service work for the species.

PRT–838055

Applicant: Ecological Specialists, St. Peters, Missouri; Heidi L. Dunn, President.

The applicant requests an amendment to her permit for take (capture and release; collect dead specimens) activities of listed freshwater mussels to add to the scope of permitted activities the states of Illinois, Missouri, Ohio, and West Virginia and the following species: fat pocketbook [*Potamilus* (=*Proptera*) *capax*], orange-foot pimple back pearlymussel (*Plethobasus cooperianus*), and pink mucket pearlymussel [*Lampsilis abrupta* (=*orbiculata*)]. Take activities are currently authorized in Iowa, Minnesota, and Wisconsin for Higgins' eye pearlymussel (*Lampsilis higginsi*) and winged mapleleaf mussel (*Quadrula fragosa*) for biological survey purposes. On September 2, 1998, a notice was published in the **Federal Register** seeking comments on an amendment request to add authorization for take activities in the state of Indiana for clubshell (*Pleurobema clava*), fanshell [(*Cyprogenia stegaria* (=*irrorata*)], and northern riffleshell (*Epioblasma torulosa rangiana*). Activities are proposed to document presence or absence of the species for the purpose of survival and enhancement of the species in the wild.

PRT–TE002722–0

Applicant: Voyageurs National Park, International Falls, Minnesota; Barbara West, Superintendent.

The applicant requests a permit to take (capture, radio-collar, and release) gray wolf (*Canis lupus*) in Voyageurs National Park, Minnesota. 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 Program, 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 Program, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056. Telephone: (612/713–5332); FAX: (612/713–5292).

Dated: September 11, 1998.

Matthias A. Kerschbaum,

Acting Program Assistant Regional Director, Ecological Services, Region 3, Fort Snelling, Minnesota.

[FR Doc. 98–25126 Filed 9–18–98; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of a Technical/ Agency Draft Recovery Plan for Juglans Jamaicensis (West Indian Walnut or Nogal) for Review and Comment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability.

SUMMARY: The Fish and Wildlife Service (Service) announces the availability for public review of a draft recovery plan for *Junglans jamaicensis* (West Indian walnut or nogal). In Puerto Rico this large tree is known from only 14 individuals at one locality near Adjuntas. The species is threatened by land-clearing for agriculture and rural development. The Service solicits review and comment from the public on this draft plan.

DATES: Comments on the draft recovery plan must be received on or before November 20, 1998 to receive consideration by the Service.

ADDRESSES: Persons wishing to review the recovery plan may obtain a copy by contacting the Field Supervisor, Boquerón Field Office, P.O. Box 491, Boquerón, Puerto Rico 00622 (Telephone 787/851–7297). Comments and materials are available on request for public inspection, by appointment, during normal business hours at the above-mentioned address.

FOR FURTHER INFORMATION CONTACT: Ms. Susan R. Silander at the address and telephone shown above.

SUPPLEMENTARY INFORMATION:

Background

Restoring an endangered or threatened animal or plant to the point where it is again a secure, self-sustaining member of its ecosystem is a primary goal of the U.S. Fish and Wildlife Service's endangered species program. To help guide the recovery effort, the Service is working to prepare recovery plans for most of the listed species native to the United States. Recovery plans describe actions considered necessary for the conservation of the species, establish criteria for the recovery levels for the