

regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: March 7, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04572 Filed 3–12–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2018–N140;
FXES11130300000–189–FF03E00000]

Endangered and Threatened Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered or threatened species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before April 12, 2019.

ADDRESSES: *Document availability and comment submission:* You may, within 30 days of the date of publication of this notice (see **DATES**), submit requests for copies of the applications and related documents, and submit any comments by one of the following methods. All requests and comments should specify the applicant name(s) and application number(s) (e.g., TXXXXXXX):

- *Email:* permitsR3ES@fws.gov.

Please refer to the respective permit number (e.g., Application No. TXXXXXXX) in the subject line of your email message.

- *U.S. Mail:* Regional Director, Attn: Carlita Payne, U.S. Fish and Wildlife Service, Ecological Services, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437–1458.

FOR FURTHER INFORMATION CONTACT:

Carlita Payne, 612–713–5343; permitsR3ES@fws.gov. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications for permits under section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The requested permits would allow the applicants to conduct activities

intended to promote recovery of species that are listed as endangered or threatened under the ESA.

Background

With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activity. The ESA's definition of "take" includes such activities as pursuing, harassing, trapping, capturing, or collecting in addition to hunting, shooting, harming, wounding, or killing.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. These activities often include such prohibited actions as capture and collection. Our regulations implementing section 10(a)(1)(A) for these permits are found in the Code of Federal Regulations at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild. The ESA requires that we invite public comment before issuing such permits. Accordingly, we invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE06130D	Claudio Gratton, Madison, WI.	Rusty patched bumble bee (<i>Bombus affinis</i>).	WI	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, hold, release.	New.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE99056B	Marion Wells, Springfield, MO.	Add Curtis pearlymussel (<i>Epioblasma florentina curtisii</i>), fat pocketbook (<i>Potamilus capax</i>), Neosho mucket (<i>Lampsilis rafinesqueana</i>), scaleshell mussel (<i>Leptodea leptodon</i>), spectaclecase (mussel) (<i>Cumberlandia monodonta</i>), winged mapleleaf (<i>Quadrula fragosa</i>) to existing permitted species: Clubshell (<i>Pleurobema clava</i>), fanshell (<i>Cyprogenia stegaria</i>), northern riffleshell (<i>Epioblasma torulosa rangiana</i>), pink mucket (pearly-mussel) (<i>Lampsilis abrupta</i>), purple cat's paw pearlymussel (<i>E. obliquata obliquata</i>), rabbitsfoot (<i>Quadrula cylindrica cylindrica</i>), rayed bean (<i>Villosa fabalis</i>), sheepnose mussel (<i>Plethobasus cyphus</i>), snuffbox mussel (<i>E. triquetra</i>), white catspaw (pearlymussel) (<i>E. o. perobliqua</i>).	Add new location—MO—to existing authorized location: OH.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, temporary hold, tag, release, relocate.	Amend.
TE08501D	Alyssa Roberts, Independence, IA.	Rusty patched bumble bee (<i>Bombus affinis</i>).	IA, IL, IN, MI, MN, MO, OH, WI.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, hold, release.	New.

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**.

Authority: Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Lori H. Nordstrom,

Assistant Regional Director, Ecological Services, Midwest Region.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

**[FWS-R3-ES-2018-N156;
FXES11130300000-190-FF03E00000]**

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SUPPLEMENTARY INFORMATION: