

with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Michelle Sollenberger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1673, Silver Spring, MD 20993-0002, 240-402-0981.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Good ANDA Submission Practices." This draft guidance is intended to assist

applicants preparing to submit ANDAs to FDA. It highlights common, recurring deficiencies that may lead to a delay in the approval of an ANDA. This draft guidance also makes recommendations to applicants on how to avoid these deficiencies so that applicants can submit ANDAs that may be approved in the first review cycle. This draft guidance has been developed as part of FDA's "Drug Competition Action Plan," which, in coordination with the Generic Drug User Fee Amendments (GDUFA I and II) (Pub. L. 112-144 and Pub. L. 115-52, respectively) and other FDA activities, is expected to increase competition in the market for prescription drugs, facilitate entry of high-quality and affordable generic drugs, and improve public health.

In conjunction with this draft guidance, FDA is issuing a *Good ANDA Assessment Practices Manual of Policies and Procedures*, which establishes good ANDA assessment practices for the Office of Generic Drugs and the Office of Pharmaceutical Quality to increase their operational efficiency and effectiveness. This draft guidance and the *Manual of Policies and Procedures* are intended to build upon the success of the GDUFA program and to help reduce the number of review cycles for an ANDA to attain approval.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on good ANDA submission practices. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This draft guidance is not subject to Executive Order 12866.

##### **II. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information that 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 the draft guidance have been approved under OMB control numbers 0910-0001 and 0910-0786.

##### **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> or <https://www.regulations.gov>.

Dated: December 26, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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#### **DEPARTMENT OF THE INTERIOR**

##### **Fish and Wildlife Service**

[FWS-R1-ES-2017-N161;  
FXES11140100000-189-FF01E00000]

##### **Proposed Graysmarsh Safe Harbor Agreement for the Taylor's Checkerspot Butterfly, Clallam County, Washington**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** Graysmarsh, LLC, hereafter referred to as the applicant, has applied to the U.S. Fish and Wildlife Service (Service, us) for an enhancement of survival permit (permit) pursuant to the Endangered Species Act of 1973, as amended. The permit application includes a draft safe harbor agreement (SHA). The permit would authorize incidental take of the endangered Taylor's checkerspot butterfly. We have prepared a draft environmental action statement (EAS) for our preliminary determination that the SHA and permit decision may be eligible for categorical exclusion under the National Environmental Policy Act (NEPA). We invite the public to review and comment on the permit application, draft SHA, and the draft EAS.

**DATES:** To ensure consideration, please send your written comments by February 5, 2018.

**ADDRESSES:** You may view or download copies of the draft SHA, and draft EAS and obtain additional information on the internet at <http://www.fws.gov/wafwo/> or obtain hard copies or a CD-ROM by calling the phone number listed below. You may submit comments or requests for more information by any of the following methods:

- **Email:** [wfwocomments@fws.gov](mailto:wfwocomments@fws.gov). Include "Graysmarsh SHA" in the subject line of the message.
- **U.S. Mail:** Mark Ostwald, U.S. Fish and Wildlife Service, Washington Fish and Wildlife Office, 510 Desmond Drive, Southeast, Suite 102, Lacey, WA 98503.
- **In-Person Drop-off, Viewing, or Pickup:** Call 360-753-9564 to make an appointment (necessary for viewing/pickup only) during regular business

hours at Washington Fish and Wildlife Office (address above).

**FOR FURTHER INFORMATION CONTACT:**

Mark Ostwald, U.S. Fish and Wildlife Service (by mail at the address in ADDRESSES), telephone 360-753-9564. If you use a telecommunications device for the deaf (TDD), please call the Federal Relay Service at 800-877-8339.

**SUPPLEMENTARY INFORMATION:**

Graysmarsh, LLC, hereafter referred to as the applicant, has applied to the U.S. Fish and Wildlife Service (Service, us) for an enhancement of survival permit (permit) pursuant to section 10(a)(1)(A) of the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*; ESA), as amended. The permit application includes a draft safe harbor agreement (SHA), which covers 1,105 acres managed by the applicant in Clallam County, Washington. The proposed term of the permit and the SHA is 50 years. The permit would authorize incidental take of the endangered Taylor's checkerspot butterfly (*Euphydryas editha taylori* (TCB)) in exchange for habitat conservation actions that are expected to provide a net conservation benefit for the species. We have prepared a draft environmental action statement (EAS) for our preliminary determination that the SHA and permit decision may be eligible for categorical exclusion under the National Environmental Policy Act (43 U.S.C. 4321 *et seq.*; NEPA). We invite the public to review and comment on the permit application, draft SHA, and the draft EAS.

**Background**

SHAs are intended to encourage private or other non-Federal property owners to implement beneficial conservation actions for species listed under the ESA. SHA permit holders are assured that they will not be subject to increased property use restrictions as a result of their proactive actions to benefit listed species. Incidental take of listed species is authorized under a SHA permit pursuant to the provisions of section 10(a)(1)(A) of the ESA. For an applicant to receive a permit through an SHA, the applicant must submit an application form that includes the following:

(1) The common and scientific names of the listed species for which the applicant requests incidental take authorization;

(2) A description of how incidental take of the listed species pursuant to the SHA is likely to occur, both as a result of management activities and as a result of the return to baseline; and

(3) A description of how the SHA complies with the requirements of the Service's Safe Harbor policy.

For the Service to issue a permit, we must determine that:

(1) The take of listed species will be incidental to an otherwise lawful activity and will be in accordance with the terms of the SHA;

(2) The implementation of the terms of the SHA is reasonably expected to provide a net conservation benefit to the covered species by contributing to its recovery, and the SHA otherwise complies with the Service's Safe Harbor Policy (64 FR 32717, June 17, 1999);

(3) The probable direct and indirect effects of any authorized take will not appreciably reduce the likelihood of survival and recovery in the wild of any listed species;

(4) Implementation of the terms of the SHA is consistent with applicable Federal, state, and tribal laws and regulations;

(5) Implementation of the terms of the SHA will not be in conflict with any ongoing conservation or recovery programs for listed species covered by the permit; and

(6) The applicant has shown capability for and commitment to implementing all of the terms of the SHA.

The Service's Safe Harbor Policy (64 FR 32717) and the Safe Harbor Regulations (68 FR 53320, 69 FR 24084) provide important terms and concepts for developing SHAs. The Service's Safe Harbor policy and regulations are available at the following website: <http://www.fws.gov/endangered/laws-policies/regulations-and-policies.html>.

**Proposed Action**

The applicant has submitted a draft SHA for the TCB that covers approximately 1,105 acres of land (enrolled property) in Clallam County, Washington. The enrolled property is primarily operated as a commercial lavender and berry farm ("u-pick farm"), and a private recreational area and homestead. There are also some non-agricultural areas of mowed grasslands, marsh, and forest.

The applicant worked closely with the Service to establish the baseline and develop the SHA. Habitat surveys for the TCB have shown there are 40.5 acres of TCB baseline habitat within the enrolled property. The baseline habitat contains three habitat types: Upland grass and forb occupied by the covered species (15.3 acres), and a buffer consisting of emergent marsh/wetland (18.7 acres) and beach upland (6.5 acres). For specific details about baseline conditions, see the draft SHA.

Within the 40.5 acres, the applicant will perform habitat management activities for the benefit of the TCB. Within the area occupied by the TCB, the applicant will maintain and potentially enhance habitat. This will include annual hand removal of Scotch broom (*Cytisus scoparius*) until it is considered eradicated. Additional non-desirable vegetation may also be removed if necessary. Plantings of certain vegetation to benefit the TCB may also occur. The applicant will maintain fencing and signage to impede illegal public trespass onto baseline habitat.

The applicant will conduct annual surveys of the TCB during its flight period and also monitor the status of baseline habitat relative to the metrics described in the SHA. Additional monitoring will also include observations regarding public access, describing any research and data collection, and any emerging issues that could influence the success of the SHA. The applicant will monitor and report in years 1, 3, and 5 of the SHA, and every 3 years thereafter (except for adult TCB surveys, which will be conducted annually).

These activities will require the applicant to enter habitat occupied by the TCB as needed over the course of the year, but mainly during the spring flight season for the TCB. Depending on the timing, these activities could result in take of TCB larva and possibly adult butterflies, mainly as a result of inadvertent trampling. Continued removal of Scotch broom and other invasive plant species and the planting of target host plants could result in temporary disturbance of TCB habitat and also result in take if TCB is present in the affected areas. The timing and extent of these activities will occur in a manner to minimize incidental take. There is also a low potential for take of TCB to occur within other areas of the property as a result of interactions between agricultural activities and adult butterflies. Examples of the potential for incidental take include inadvertent harm during routine agricultural operations, mainly associated with annual seeding (plowing and disking) of barley, mowing lawns, moving and replacing irrigation lines, and managing and harvesting berries.

**National Environmental Policy Act Compliance**

The development of the draft SHA and the proposed issuance of an enhancement of survival permit is a Federal action that triggers the need for compliance with the NEPA (42 U.S.C. 4321 *et seq.*). We have prepared a draft

EAS to analyze the impacts of permit issuance and implementation of the SHA on the human environment in comparison to the no-action alternative. We have made a preliminary determination that issuing the permit and implementing the SHA would have minor or negligible impacts to the environment, and thus the proposed SHA and permit actions are eligible for categorical exclusion under NEPA. The basis for our preliminary determination is contained in the EAS, which is available for public review (see **ADDRESSES**).

### Public Comments

You may submit your comments and materials by one of the methods listed in the **ADDRESSES** section. We request data, new information, or comments from the public, other concerned governmental agencies, Tribes, the scientific community, industry, or any other interested party via this notice on our proposed Federal action.

### Public Availability of Comments

All comments and materials we receive become part of the public record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comments, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All comments received from organizations, businesses, or individuals representing organizations or businesses are available for public inspection in their entirety. Comments and materials we receive will be available for public inspection by appointment, during normal business hours, at our office (see **ADDRESSES**).

### Next Step

The Service will evaluate the permit application, draft SHA, and public comments submitted thereon to determine whether the permit application meets the requirements of section 10(a)(1)(A) of the ESA and NEPA regulations. The final NEPA and permit determinations will not be completed until after the end of the 30-day comment period and full consideration of all comments received during the comment period. If we determine that all requirements are met, we will issue the applicant an enhancement of survival permit under section 10(a)(1)(A) of the ESA.

### Authority

We provide this notice pursuant to section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*), its implementing regulations (50 CFR 17.22), and NEPA (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1506.6).

**Theresa E. Rabot,**

*Deputy Regional Director, Pacific Region, U.S. Fish and Wildlife Service.*

[FR Doc. 2017-28490 Filed 1-3-18; 8:45 am]

**BILLING CODE 4333-15-P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

**[Docket No. FWS-HQ-IA-2017-0095; FXIA16710900000-178-FF09A30000]**

### Endangered Species Receipt of Permit Applications

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of receipt of permit applications.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, invite the public to comment on applications to conduct certain activities with foreign endangered species, marine mammals, or both. With some exceptions, the Endangered Species Act (ESA) prohibit activities with listed species unless Federal authorization is acquired that allows such activities. The ESA also requires that we invite public comment before issuing these permits.

**DATES:** We must receive comments by February 5, 2018.

**ADDRESSES:** *Document availability:* The applications, as well as any comments and other materials that we receive, will be available for public inspection online in Docket No. FWS-HQ-IA-2017-0095 at <http://www.regulations.gov>.

*Submitting Comments:* You may submit comments by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments on Docket No. FWS-HQ-IA-2017-0095.

- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: Docket No. FWS-HQ-IA-2017-0095; U.S. Fish and Wildlife Service Headquarters, MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041-3803.

When submitting comments, please indicate the name of the applicant and the PRT# at the beginning of your comment. We will post all comments on <http://www.regulations.gov>. This generally means that we will post any personal information you provide us

(see **SUPPLEMENTARY INFORMATION** for more information).

**FOR FURTHER INFORMATION CONTACT:** Joyce Russell, 703-358-2280.

### SUPPLEMENTARY INFORMATION:

#### I. Public Comment Procedures

*A. How do I comment on submitted applications?*

You may submit your comments and materials by one of the methods listed under *Submitting Comments* in the **ADDRESSES** section. We will not consider comments sent by email or fax, or to an address not in the **ADDRESSES** section.

Please make your requests or comments as specific as possible, confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES** or comments delivered to an address other than those listed above in **ADDRESSES**).

*B. May I review comments submitted by others?*

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. 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 ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

*C. Who will see my comments?*

If you submit a comment via <http://www.regulations.gov>, your entire comment, including any personal identifying information, will be posted