

and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371); sec. 351 of the Public Health Service Act (42 U.S.C. 262).

2. Section 312.42 is amended by adding new paragraph (b)(1)(v) and by revising paragraph (b)(2)(i) to read as follows:

§ 312.42 Clinical holds and requests for modification.

* * * * *

(b) * * *

(1) * * *

(v) The IND is for the study of an investigational drug intended to treat a life-threatening illness or disease that affects both genders, and men or women with reproductive potential who have the disease being studied are excluded from eligibility in any phase of clinical investigation because of a risk or potential risk of reproductive (i.e., toxicities to reproductive organs) or developmental (i.e., toxicities to potential offspring) toxicity from use of the investigational drug. The phrase "women with reproductive potential" does not include pregnant women. For purposes of this paragraph, "life-threatening illnesses or diseases" are defined as "diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted." The clinical hold would not apply under this paragraph to clinical studies conducted:

(A) Under special circumstances, such as studies of a single-gender population (e.g., studies evaluating the excretion of a drug in semen or the effects on menstrual function); or

(B) In men, as long as a study that does not exclude subjects with reproductive potential has been planned or is being conducted in women.

(2) * * *

(i) Any of the conditions in paragraphs (b)(1)(i) through (b)(1)(v) of this section apply; or

* * * * *

Dated: September 16, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018-AE30

Endangered and Threatened Wildlife and Plants; Public Hearing and Extension of Comment Period on Proposed Endangered Status for Keck's Checker-Mallow

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; notice of public hearing and extension of comment period.

SUMMARY: The Fish and Wildlife Service (Service), pursuant to the Endangered Species Act of 1973, as amended (Act), provides notice of a public hearing and extension of the comment period on the proposed endangered status for *Sidalcea keckii* (Keck's checker-mallow). The comment period is extended to accommodate a public hearing that was requested by California Assemblyman Roy Ashburn, Thirty-Second District.

DATES: The public hearing will be held on Tuesday, October 21, from 6:00 p.m. to 8:00 p.m. in Visalia, California. The comment period closes November 10, 1997.

ADDRESSES: The public hearing will be held at the Visalia Convention Center, 303 East Acequia Street, Visalia, California. Comments and materials concerning this proposal should be sent to the Field Supervisor, U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office, 3310 El Camino Avenue, Suite 130, Sacramento, California 95821-6340. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Ken Fuller of the Sacramento Fish and Wildlife Office (see **ADDRESSES** section) at (916) 979-2120.

SUPPLEMENTARY INFORMATION:

Background

On July 28, 1997, the Service published a rule proposing endangered status for *Sidalcea keckii* in the **Federal Register** (62 FR 40325). The original comment period was to close on September 26, 1997. Section 4(b)(5)(E) of the Act (16 U.S.C. 1531 *et seq.*)

requires that a public hearing be held if it is requested within 45 days of the publication of the proposed rule. In response to a request for a public hearing from California Assemblyman Roy Ashburn, a public hearing will be held in Visalia, California on October 21, 1997, at the Visalia Convention Center. Parties wishing to make statements for the record should bring a copy of their statements to the hearing. Oral statements may be limited in length, if the number of parties present at the hearing necessitates such a limitation. There are no limits to the length of written comments or materials presented at the hearing or mailed to the Service. Written comments carry the same weight as oral comments. The comments period now closes on November 10, 1997. Written comments should be submitted to the Service in the **ADDRESSES** section.

Sidalcea keckii is an annual plant that is known from one population in the hilly annual grasslands of south-central Tulare County. The plant is threatened by agricultural land conversion, urban development, and naturally occurring events. Comments from the public regarding the accuracy of this proposed rule are sought, especially regarding:

(1) Biological, commercial trade, or other relevant data concerning any threat (or lack thereof) to the species listed above;

(2) The location of any additional populations of the species and the reasons why any habitat should or should not be determined to be critical habitat as provided by section 4 of the Act;

(3) Additional information concerning the range, distribution, and population sizes of the species; and

(4) Current or planned activities in the subject area and their possible impacts on the species.

Author

The primary author of this notice is Ken Fuller (see **ADDRESSES** section).

Authority

The authority for this action is the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*).

Dated: September 16, 1997.

Cynthia Barry,

Acting Regional Director, Region 1, Portland, Oregon.

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