



FDA U.S. FOOD & DRUG
ADMINISTRATION

June 7, 2022

Yongjiang Daniel Li, Ph.D.
Associate Director, Molecular Biology Division
ScienCell Research Laboratories
1610 Faraday Avenue
Carlsbad, CA 92000
Re: Revocation of EUA200079

Dear Dr. Li:

This letter is in response to the request from ScienCell Research Laboratories ("ScienCell"), received on June 2, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit issued on April 3, 2020, and amended on June 5, 2020, September 22, 2020, and September 23, 2021. ScienCell indicated that it has decided to discontinue distribution of the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit and there is not any viable/non-expired product remaining in distribution.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because ScienCell has notified FDA that it has decided to discontinue distribution of the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit and requested FDA revoke the EUA for the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200079 for the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Dated: July 8, 2022.
Lauren K. Roth,
Associate Commissioner for Policy.
[FR Doc. 2022-15160 Filed 7-14-22; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Molecular and Cellular Aspects of Obesity and Metabolic Disease.

Date: July 26, 2022.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Raul Rojas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6185, Bethesda, MD 20892, (301) 451-6319, rojasr@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 12, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-15171 Filed 7-14-22; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R1-ES-2022-N031;
FXES11130100000-223-FF01E00000]

Endangered 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 and survival of endangered species under the Endangered Species Act. We invite the public and local,

State, Tribal, and Federal agencies to comment on these applications. Before issuing 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 August 15, 2022.

ADDRESSES:

Document availability and comment submission: Submit a request for a copy of the application and related documents and submit any comments by one of the following methods. All requests and comments should specify the applicant name and application number (e.g., Dana Ross, ESPER0001705):

- Email: permitsR1ES@fws.gov.
- U.S. Mail: Marilet Zablan, Regional Program Manager, Restoration and Endangered Species Classification, Ecological Services, U.S. Fish and Wildlife Service, Pacific Regional Office, 911 NE 11th Avenue, Portland, OR 97232-4181.

FOR FURTHER INFORMATION CONTACT:

Colleen Henson, Regional Recovery Permit Coordinator, Ecological Services, (503) 231-6131 (phone); permitsR1ES@fws.gov (email). Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

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 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 (CFR) 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 these 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, city, state	Species	Location	Take activity	Permit action
ES22353B	Center for Natural Lands Management, Temecula, CA.	Taylor's Checkerspot (<i>Euphydryas editha taylori</i>).	Oregon and Washington.	Harass by survey, monitor, capture, handle, and release.	Amend.
ES19076C	Guam Department of Agriculture, Mangilao, GU.	Mariana eight-spot butterfly (<i>Hypolimnas octocula marianensis</i>).	Guam	Harass by capture, handle, survey, captive propagation, and release.	Amend.
ES35731D	Pūlama Lānai, Lānai City, HI	Band-rumped storm-petrel (<i>Oceanodroma castro</i>), Hawaiian petrel (<i>Pterodroma sandwichensis</i>).	Hawaii	Harass by survey, monitor, predator control, and salvage.	Amend.
PER0007997	University of Washington Botanic Gardens, Seattle, WA.	<i>Hackelia venusta</i> (Showy stickseed), <i>Sidalcea oregana</i> var. <i>calva</i> (Wenatchee Mountains checkermallow).	Washington ..	Remove/reduce to possession—survey, collect seeds, propagate, outplant, and monitor.	Amend.
PER0042992	Tyler Breech, Idaho State University, Pocatello, ID.	Lost River sucker (<i>Deltistes luxatus</i>), Shortnose sucker (<i>Chasmistes brevirostris</i>).	Oregon	Harass by survey, capture, handle, and release.	New.