- Be accompanied by the authorized labeling, if the promotional materials are not subject to Section 502(n) of the Act.
- Be submitted to FDA accompanied by Form FDA-2253 at the time of initial dissemination or first use.

If the Agency notifies Genentech that any descriptive printed matter, advertising or promotional materials do not meet the terms set forth in conditions Q-S of this EUA, Genentech must cease distribution of such descriptive printed matter, advertising, or promotional materials in accordance with the Agency's notification. Furthermore, as part of its notification, the Agency may also require Genentech to issue corrective communication(s).

R. No descriptive printed matter, advertising, or promotional materials relating to the use of Actemra under this authorization may represent or suggest that Actemra is safe or effective when used for the treatment of COVID-19 in hospitalized adults and pediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.

S. All descriptive printed matter, advertising, and promotional material, relating to the use of Actemra under this authorization clearly and conspicuously shall state that:

- Actemra has not been approved, but has been authorized for emergency use by FDA under an EUA, to treat COVID-19 in hospitalized adults and pediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO; and

- The emergency use of Actemra is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Dated: July 30, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–16705 Filed 8–4–21; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; 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 cooperative agreement applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the cooperative agreement applications, the disclosure of which would

constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; CTSA Review.

Date: September 9, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Victor Henriquez, Ph.D., Scientific Review Officer, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20817, 301–435–0813, *henriquv@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: July 30, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–16668 Filed 8–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft NTP Developmental and Reproductive Toxicity Technical Reports on 2-Hydroxy-4-methoxybenzophenone and 2-Ethylhexyl p-Methoxycinnamate; Availability of Documents; Request for Comments; Notice of Peer-Review Meeting

AGENCY: National Institutes of Health, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Division of the National Toxicology Program (DNTP) announces the availability of the Draft NTP Developmental and Reproductive Toxicity Technical Reports on 2-hydroxy-4-methoxybenzophenone and 2-ethylhexyl p-methoxycinnamate scheduled for peer review. The peer-review meeting will be held remotely and will be available to the public for veiwing. Oral and written comments will be accepted; registration is required to access the webcast and to present oral comments.

DATES: Meeting: October 14, 2021, 10 a.m. Eastern Daylight Time (EDT) to adjournment. The meeting may end earlier or later than 5:00 p.m. EDT.

Document Availability: The two draft NTP reports will be available by August 16, 2021 at *https://ntp.niehs.nih.gov/go/36051.*

Written Public Comment Submissions: Deadline is September 30, 2021.

Registration for Oral Comments: Deadline is October 7, 2021.

Registration to View the Webcast: Deadline is October 14, 2021.

ADDRESSES: Meeting web page: The draft reports, preliminary agenda, registration, and other meeting materials will be available at *https://ntp.niehs.nih.gov/go/36051.* Webcast: The URL for viewing the peer-review meeting will be provided to registrants.

FOR FURTHER INFORMATION CONTACT: Email *NTP-Meetings@icf.com.* Dr. Sheena Scruggs, NIEHS/DNTP, is the Designated Federal Official. Phone: (984) 287–3355. Email: *sheena.scruggs@nih.gov.*

SUPPLEMENTARY INFORMATION:

Meeting Attendance Registration: The meeting is available for viewing by the public with time set aside for oral public comment. Registration to view the webcast is by October 14, 2021, at *https://ntp.niehs.nih.gov/go/36051.* The URL for the webcast will be provided in the email confirming registration. Individuals with disabilities who need accommodation to view the webcast should contact Canden Byrd by phone: (919) 293–1660 or email: *NTP-Meetings@icf.com.* TTY users should contact the Federal TTY Relay Service at (800) 877–8339. Requests should be made at least five business days in advance of the event.

Request for Comments: DNTP invites written and oral public comments on the draft reports that address scientific or technical issues. Guidelines for public comments are available at *https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.*

The deadline for submission of written comments is September 30, 2021, to enable review by the peer-review panel and DNTP staff prior to the meeting. Written public comments should be submitted through the meeting website at *https://ntp.niehs.nih.gov/go/36051.* Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP website and the submitter will be identified by name, affiliation, and sponsoring organization (if any). Comments that address scientific/technical issues will be forwarded to the peer-review panel and DNTP staff prior to the meeting.

Oral public comment at this meeting is welcome, with time set aside for the presentation of oral comments on the draft reports. The agenda will allow for two oral public comment periods—one comment period per report (up to 6 commenters, up to 5 minutes per speaker). Persons wishing to make an oral comment are required to register online at *https://ntp.niehs.nih.gov/go/36051* by October 7, 2021. Registration is on a first-come, first served basis. Each organization is allowed one time slot per report. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Commenters will be notified approximately one week before the peer-review meeting about the actual time allotted per speaker.

If possible, oral public commenters should send a copy of their slides and/or statement or talking points to Canden Byrd by email: *NTP-Meetings@icf.com* by October 7, 2021. Written statements can supplement and may expand the oral presentation.

Meeting Materials: The draft NTP reports and preliminary agenda will be available on the NTP website at *https://ntp.niehs.nih.gov/go/36051* prior to the meeting. NTP expects that the draft reports should be available on the website by August 16, 2021. Additional information will be posted when available or may be requested in hardcopy from Canden Byrd by phone: (919) 293–1660 or email: *NTP-Meetings@icf.com.* Individuals are encouraged to access the meeting web page to stay abreast of the most current information regarding the meeting.

Following the meeting, a report of the peer review will be prepared and made available on the NTP website.

Background Information on NTP Peer-Review Panels: NTP panels are technical, scientific advisory bodies established on an ''as needed'' basis to provide independent scientific peer review and advise NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. DNTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide their name and best form of contact to