

have been approved under OMB control number 0910–0078; the collections of information in part 807, subpart E (Premarket Notification Procedures), have been approved under OMB control number 0910–0120; the collections of information under 21 CFR part 801 (Device Labeling) have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR 860, subpart D (De Novo Classification) have been approved under OMB control number 0910–0844.

III. References

The following reference is on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. CMS, “ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model,” available at <https://www.cms.gov/priorities/innovation/innovation-models/access> (last accessed on December 1, 2025).

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–22190 Filed 12–5–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–5791]

Revocation of Emergency Use of a Drug Product During the COVID–19 Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Genentech, Inc. (Genentech) for Actemra (tocilizumab). FDA revoked this Authorization on August 8, 2025, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocation, including an explanation of the reasons for the revocation, are reprinted in this document.

DATES: The authorization is revoked as of August 8, 2025.

ADDRESSES: Submit written requests for a single copy of the revocation to the Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, 6th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Andrea Gormley, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., 2nd Floor, Silver Spring, MD 20993–0002, 301–796–2210 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations.

On June 24, 2021, FDA issued an Authorization to Genentech for Actemra (EUA 099), subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on August 5, 2021 (86

FR 42850), as required by section 564(h)(1) of the FD&C Act.

The authorization of a drug for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. The Revocation

On August 8, 2025, the Agency approved a supplemental Biologics License Application (BLA) to BLA 125276, which expanded the approved indication for COVID–19 to the following: ACTEMRA® (tocilizumab) is an interleukin–6 (IL–6) receptor antagonist indicated for the treatment of: Coronavirus Disease 2019 (COVID–19), Hospitalized adult and pediatric patients aged 2 years and older with coronavirus disease 2019 (COVID–19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Based on this approval, FDA concluded that BLA 125276 for Actemra is an adequate, approved, and available alternative to Actemra’s emergency use for the treatment of COVID–19 for the purposes of section 564(c)(3) of the Act. Accordingly, FDA revoked EUA 099 for Actemra, pursuant to section 564(g)(2) of the Act. The revocation in its entirety follows and provides explanations of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

III. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet at: <https://www.regulations.gov/>.

BILLING CODE 4164–01–P



August 8, 2025

Hoffman-La Roche, Ltd.
C/O Genentech, Inc.
Attention: Dhushy Thambipillai
Regulatory Program Manager
1 DNA Way, Building 45-1
South San Francisco, CA 94080

RE: Emergency Use Authorization 099

Dear Ms. Thambipillai:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA) authorizing the emergency use of Genentech, Inc.'s ("Genentech") Actemra (tocilizumab), issued initially on June 24, 2021, and amended on October 27, 2022 and December 21, 2022.

The authorization of a drug 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 revised or revoked when the criteria under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

FDA has determined that the criteria for issuance of the authorization for Actemra under section 564(c) of the Act are no longer met. Under section 564(c)(3) of the Act, an EUA may be issued only if FDA concludes there is no adequate, approved¹, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.

On August 8, 2025, the Agency approved a supplemental Biologics License Application (BLA) to BLA 125276, which expanded the approved indication for COVID-19 to the following:

¹ In the context of section 564, the term "approved" refers to a product that is approved, licensed, or cleared under section 505, 510(k), or 515 of the Act or section 351 of the Public Health Service Act. See section 564(a)(2) of the Act.

ACTEMRA® (tocilizumab) is an interleukin-6 (IL-6) receptor antagonist indicated for the treatment of:

Coronavirus Disease 2019 (COVID-19)

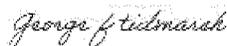
Hospitalized adult and pediatric patients aged 2 years and older with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Based on this approval, FDA has concluded that BLA 125276 for Actemra is an adequate, approved, and available alternative to Actemra's emergency use for the treatment of COVID-19 for the purposes of section 564(c)(3) of the Act.

Accordingly, FDA revokes EUA 099 for Actemra, pursuant to section 564(g)(2) of the Act. As of the date of this letter, the Actemra that was authorized by FDA for emergency use under EUA 099 is no longer authorized by FDA.

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

Sincerely,



George F. Tidmarsh, M.D., Ph.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-22211 Filed 12-5-25; 8:45 am]

BILLING CODE 4164-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Product-Specific Guidance on Estradiol; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a new draft guidance for industry entitled “Draft Guidance on Estradiol” and a revised draft guidance for industry entitled “Draft Guidance on Estradiol.” The new draft guidance and the revised draft guidance, when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for estradiol vaginal inserts and estradiol vaginal tablets.

DATES: Submit either electronic or written comments on the draft guidance by February 6, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2007-D-0369 for “Draft Guidance on Estradiol.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states