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/.

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, approved[1], 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

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.

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