Report to Congress

Real-World Evidence in COVID-19 Applications

Required by Section 3629(b) of the
Food and Drug Omnibus Reform Act of 2022

Executive Summary

Section 3629(b) of the Food and Drug Omnibus Reform Act of 2022 (FDORA)[1] requires the Secretary of Health and Human Services to submit a report to Congress no later than 2 years after the end of the COVID-19 public health emergency declared on January 31, 2020, by the Secretary of the Department of Health and Human Services under section 319 of the Public Health Service Act (42 U.S.C. 247d). The report must include the following information:

(1) The number of applications, submissions, or requests submitted for clearance, approval, or authorization under section 505, 510(k), 513(f)(2), or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360c(f)(2), 360e), or section 351 of the Public Health Service Act (42 U.S.C. 262), for which an authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3) was previously granted;
(2) Of the number of applications so submitted, the number of such applications-
    (A) For which real-world evidence was submitted and used to support a regulatory decision; and
    (B) For which real-world evidence was submitted and determined to be insufficient to support a regulatory decision; and
(3) A summary explanation of why, in the case of applications described in paragraph (2)(B), real-world evidence could not be used to support regulatory decisions.

During the January 31, 2020, to September 30, 2024, reporting period, FDA made a regulatory decision regarding 60 applications, submissions, or requests for clearance, approval, or authorization for medical products for the diagnosis, prevention, or treatment of COVID-19, for indications for which FDA had previously granted an emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act. Of these 60 applications, submissions, or requests, 32 included clinical data. In total, 11 of the 32 applications, submissions, or requests with clinical data included real-world evidence that was used to support the regulatory decision. No applications, submissions, or requests included real-world evidence that FDA determined to be insufficient to support the regulatory decision.

[1] Enacted as part of the Consolidated Appropriations Act, 2023, Public Law 117-328.

Table of Contents

Acronym List

CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
COVID-19	Coronavirus disease 2019
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDORA	Food and Drug Omnibus Reform Act of 2022
RWD	Real-world data
RWE	Real-world evidence
U.S.C.	United States Code

I. Background

A. Definitions

The Food and Drug Administration (FDA) defines real-world data (RWD) as data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. RWD can be derived from a variety of sources, including electronic health records, medical claims, and registries.

The FDA defines real-world evidence (RWE) as the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD. Various types of study designs can generate RWE, including non-interventional (observational) studies, externally controlled trials, and randomized trials (e.g., point-of-care trials).

B. Scope of Report

This report includes applications, submissions, or requests for clearance, approval, or authorization of medical products for indications consistent with indications previously granted an authorization for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the diagnosis, prevention, or treatment of COVID-19 and for which FDA made a regulatory decision on or before September 30, 2024.

This report considers RWE that was submitted by the applicant to provide evidence of safety or effectiveness that was necessary for a regulatory decision. Applicants often include or cite other sources of RWD/RWE in their application, submission, or request that are intended to provide additional background information. This report does not address such sources of RWD/RWE.

II. Center for Biologics Evaluation and Research

A. Total Applications, Submissions, or Requests

During the January 31, 2020, to September 30, 2024, reporting period, the Center for Biologics Evaluation and Research (CBER) made a regulatory decision regarding four applications, submissions, or requests for products for which FDA had previously granted an authorization under section 564 of the FD&C Act. All four were for biological products under section 351 of the Public Health Service Act.

No applications, submissions, or requests to CBER included RWE that was submitted to provide evidence of safety or effectiveness that was necessary for a regulatory decision.

B. Real-World Evidence Submitted and Used in Decision

None.

C. Real-World Evidence Insufficient to Support Decision

None.

III. Center for Drug Evaluation and Research

A. Total Applications, Submissions, or Requests

During the January 31, 2020, to September 30, 2024, reporting period, the Center for Drug Evaluation and Research (CDER) made a regulatory decision regarding six applications, submissions, or requests for products for which FDA had previously granted an authorization under section 564 of the FD&C Act: four for drugs under section 505 of the FD&C Act and two for biological products under section 351 of the Public Health Service Act.

Two applications, submissions, or requests to CDER included RWE that was submitted to provide evidence of safety or effectiveness that was necessary for a regulatory decision.

B. Real-World Evidence Submitted and Used in Decision

Two applications, submissions, or requests to CDER included RWE that was used to support the regulatory decision.

C. Real-World Evidence Insufficient to Support Decision

None.

IV. Center for Devices and Radiological Health

A. Total Applications, Submissions, or Requests

During the January 31, 2020, to September 30, 2024, reporting period, the Center for Devices and Radiological Health (CDRH) made a regulatory decision regarding 50 applications, submissions, or requests submitted for clearance, approval, or authorization under section 510(k), 513(f)(2), or 515 of the FD&C Act for devices for which FDA had previously granted an authorization under section 564 of the FD&C Act. Of these 50 applications, submissions, or requests, 28 did not include clinical data. Of the 22 applications, submissions, or requests that included clinical data, 16 were for premarket notification under section 510(k) of the FD&C Act, and 6 were for De Novo classification requests under section 513(f)(2) of the FD&C Act.

Nine applications, submissions, or requests to CDRH included RWE that was submitted to provide evidence of safety or effectiveness that was necessary for a regulatory decision.

B. Real-World Evidence Submitted and Used in Decision

Nine applications, submissions, or requests to CDRH included RWE that was used to support the regulatory decision.

C. Real-World Evidence Insufficient to Support Decision

None.

V. Conclusion

During the reporting period from January 31, 2020, to September 30, 2024, FDA made a regulatory decision regarding 60 applications, submissions, or requests submitted for clearance, approval, or authorization under section 505, 510(k), 513(f)(2), or 515 of the FD&C Act or section 351 of the Public Health Service Act for products for the diagnosis, prevention, or treatment of COVID-19 for which FDA had previously granted an authorization under section 564 of the FD&C Act, including 32 with clinical data. Of the 32 with clinical data, 11 included real-world evidence, and in all cases, the real-world evidence was used to support the regulatory decision.

This report was prepared by FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and Center for Devices and Radiological Health. For further information please contact:

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This report is available on FDA's home page at https://www.fda.gov/.