

UNITED STATES FOOD AND DRUG ADMINISTRATION

Emergency Use Authorizations

OMB Control No. 0910-0595

Request for Non-Substantive/Non-Material Change:

FDA is requesting a non-substantive/non-material change to the referenced collection to reflect authorization of emergency use of in vitro diagnostics for the detection and/or diagnosis of infection with the monkeypox virus (MPOX), including in vitro diagnostics that detect and/or diagnose infection with non-variola Orthopoxvirus, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Additionally, section 319 of the Public Health Service Act, recently added by the 21st Century Cures Act, allows, among other things, the Secretary of the Department of Health and Human Services (DHHS) to determine that circumstances of a public health emergency (PHE) may necessitate a waiver from PRA requirements. On August 4, 2022, the DHHS Secretary determined that, as a result of the consequences of the outbreak of MPOX cases across multiple states, a PHE exists, and that the circumstances of the PHE necessitate such a waiver.¹

We have updated our Emergency Use Authorization (EUA) webpage at [Emergency Use Authorization](#) to include information regarding the MPOX PHE. In response to the PHE we have also developed the following MPOX-specific template documents to help facilitate the preparation, submission, and authorization of an EUA request:

1. EUA Summary Template for Developers of Molecular Diagnostic Tests for Monkeypox
2. EUA Template for Developers of Molecular Diagnostic Tests for Monkeypox
3. EUA Summary Template for Developers of Antigen Diagnostic Tests for Monkeypox
4. EUA Template for Developers of Antigen Diagnostic Tests for Monkeypox

We do not believe the templates introduce any burden to the currently approved estimate associated with the information collection. Included in our current estimate is the average burden among respondents, where use of any of the individual templates reflects effort by FDA to reduce burden on respondents to facilitate information collection relevant to EUA submissions and associated records.

Submitted: December 2022

¹ [FDA-PHE-PRA-Waiver-Notice-monkeypox-outbreak-8-19-2022.pdf \(hhs.gov\)](#)