

UNITED STATES FOOD AND DRUG ADMINISTRATION

Emergency Use Authorizations

OMB Control No. 0910-0595

Request for Non-Substantive/Non-Material Change:

In our recent renewal of the information collection we revised its scope to include activities attendant to the use of agency templates found at [Coronavirus Disease 2019 \(COVID-19\) Emergency Use Authorizations for Medical Devices | FDA](#). Since OMB approval on September 6, 2022, we have developed additional templates as follows:

Pre-Emergency Use Authorization (EUA)/EUA Interactive Review Template For Non-IVD Products; (see [EUA Template Non-IVD Products](#)).

Surgical Masks EUA Template for Addition to Appendix A (to support addition of a surgical mask to the list of authorized surgical masks in Appendix A under the Surgical Masks EUA; see [Personal Protective Equipment EUAs | FDA](#))

Ventilator, Ventilator Tubing Connectors, and Ventilator Accessories Pre-Emergency Use Authorization (EUA)/EUA Interactive Review Template (see [Ventilators and Ventilator Accessories EUAs | FDA](#)).

Although we do not provide individual burden estimates for each of the templates we develop, among their intended purposes is to facilitate the processing of an EUA. We believe that the cumulative estimates currently proffered and approved include any burden that respondents would incur upon utilizing any of the individual templates.

Submitted: September 2022