

United States Food and Drug Administration

Authorization of Medical Products for Use Emergencies

OMB Control No. 0910-0595

No Material or Non-Substantive Change to a Currently Approved Collection (83-C)

FDA is requesting a non-substantive/non-material change to the referenced collection to include the Emergency Use Authorization (EUA) Fact Sheet Templates. The EUA Fact Sheet Templates were developed as a tool to facilitate FDA's ability to make investigational therapeutic products available during public health emergencies. While these templates were initially developed after EUA experiences from the 2009 H1N1 outbreak, the COVID-19 response produced many lessons learned and best practices for EUAs that have now been incorporated into these templates. The COVID-19 response experience made these templates more widely known by sponsors, who are requesting FDA provide these templates to facilitate the development of the fact sheets for EUA submissions across many chemicals, biological, radiological, and nuclear (CBRN) threats, including and beyond COVID-19. While the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients and Parents/Caregivers are statutorily required communication components of an EUA submission under section 564 of the FD&C Act, the utilization of these fact sheet templates is not required. Sponsors may choose to use these templates as an EUA development tool or may choose to submit their own fact sheets in any other format.

When time is of the essence in a public health emergency, posting the fact sheet templates on the external FDA website, for optional use by sponsors, would expedite sponsors' ability to obtain and draft EUA fact sheets as quickly as possible, potentially making life-saving investigational products available sooner to support public health.

We plan to update our webpage at [Emergency Use Authorization](#) to include information regarding the EUA Fact Sheet Template. In response to many sponsor requests, we developed the following template documents to help facilitate the preparation, submission, and authorization of an EUA request:

1. Fact Sheet for Healthcare Providers Template
2. Fact Sheet for Patients and Parents/Caregivers Template

We do not believe the templates require an adjustment or revision to the currently approved information collection. Included in our current estimate is the average burden among respondents, where use of any of the individual templates reflect effort by FDA to manage the information presented for review; to make the FDA review process for EUA products more efficient; to present the information in a standardized format for healthcare providers' ease of use; and to facilitate information collection relevant to EUA submissions and associated records.