

NewsBREAK | March 10

FDA Issues COVID-19 PHE Guidance

- On Mar. 10, FDA issued guidance regarding which FDA guidance documents will extend beyond the ending of the public health emergency (PHE).
- The PHE is expected to end on May 11, 2023.
- Twenty-two guidance documents will expire when the PHE ends on May 11, 2023. See Table 1 of the new guidance for a list of these documents.
- Twenty-two guidance documents will continue in effect for 180 days after the PHE declaration expires, then will no longer be in effect. This provides a wind-down period for these requirements. See Table 2 of the new guidance.
- Twenty-four guidance documents will continue in effect for 180 days after the PHE declaration expires, during which time FDA plans to further revise these documents. See Table 3 of the new guidance.
- Four guidance documents' duration is not tied to the COVID-19 PHE and will remain in effect when the COVID-19 PHE declaration expires. See Table 4 of the new guidance.

Table 4.--Other COVID-19-Related Guidance Documents

Docket No.	Lead Center	Title of Guidance
FDA-2007-D-0369	CDER	Product-Specific Guidances for Chloroquine and Hydroxychloroquine
FDA-2008-D-0610	CDER	Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic
FDA-2020-D-0987	CDRH	Policy for Coronavirus Disease-2019 Tests (Revised)*
FDA-2020-D-0987	CDRH	Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests*

See the guidance for additional requirements.

More on This Topic

- [Guidance document](#)
- [COVID-19-Related Guidance Documents](#)

For questions, please reach out to [Tyler Thorne](#).