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ALERT

The End of an Era: FDA Announces Disposition Plans for COVID-19 Related Guidance Documents

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The COVID-19 pandemic presented the U.S. Food and Drug Administration (FDA or Agency) with a monumental task of shifting its operations and the way it approached the regulation of critical drugs, medical devices, and biologic products. Because policies and practices were changing faster than formal rulemaking would allow, the Agency utilized guidance documents to keep stakeholders informed of these policies, including the ever-important enforcement policies. But as the sun finally sets on the COVID-19 Public Health Emergency (PHE) that was the vehicle for enacting many of the changes at FDA, the Agency is now faced with a new herculean problem: disposition of the more than 70 COVID-19 guidance documents that remain in effect.

On March 13, 2023, the FDA shifted this disposition task into gear. The FDA published a notice in the Federal Register that outlined its current plans for the COVID-19 guidance documents, dividing the documents into four tables: Table 1 contains 22 documents that will no longer be in effect upon expiration of the PHE, Table 2 contains 22 documents that will be in effect for 180 days after the expiration of the PHE, Table 3 lists 24 documents that will be in effect for 180 days after the expiration of the PHE but will be revised, and Table 4 contains four documents that are COVID-19 related, but are not tied to the PHE expiration. We will provide a brief summary of the tables, and highlight those documents that may be of particular interest to stakeholders.

Authors

Ann M. Begley
Partner
202.719.4585
abegley@wiley.law

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So Long and Goodbye: Guidance Documents That Will Expire With the PHE

Table 1 contains a list of guidance documents that will no longer be in effect once the PHE expires. These documents were developed to address specific issues and circumstances that will no longer be present when the PHE expires. It is important to note that five of the guidance documents in Table 1 have recommendations that will continue after the PHE expiration, but those recommendations have been included in other guidance documents (e.g., the Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the COVID-19 Public Health Emergency), and therefore the stand-alone document is no longer necessary. Important guidance documents included in Table 1:

- Manufacturing Considerations for Licensed and Investigational Cellular and Gene Therapy Products During COVID-19 Public Health Emergency (CBER)
- Development of Abbreviated New Drug Applications During the COVID-19 Pandemic-Questions and Answers (CDER)
- Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications-Questions and Answers (CDER)
- Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency (CDER)
- COVID-19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products (CDER)

Not Quite Finished: Guidance Documents That Will Remain in Effect for 180 Days After the PHE Expiration

Table 2 lists the 22 guidance documents that FDA intends to revise to allow for the document and its recommendations to remain in effect for an additional 180 days (November 7, 2023) after the PHE expiration. The Agency has stated that while these guidance documents are directly related to the PHE, the policies and recommendations contained within these guidance documents warrant a "wind-down" period. A review of the guidance documents included in the list makes the need for the transition period readily apparent, as the list is dominated by medical device enforcement policies. It is expected that FDA will revise the guidance documents to allow companies to withdraw or cease distribution of those devices that do not comply with all relevant medical device regulations from the market. It is also possible that these enforcement policies will be linked with the soon-to-be-finalized guidance document, Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the COVID-19 Public Health Emergency. Important guidance documents included in Table 2:

- Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers (CDER)
- Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency, Guidance for Industry and Health Care Professionals (CDER)
- Enforcement Policy for Face Shields, Surgical Masks, and Respirators During the COVID-19 Public Health Emergency (CDRH)

- Enforcement Policy for Gowns, Other Apparel, and Gloves During the COVID-19 Public Health Emergency (CDRH)
- Enforcement Policy for Modifications to FDA Cleared Molecular Influenza and RSV Tests during the COVID-19 Public Health Emergency (Revised) (CDRH)

Change is Coming: Guidance Documents That Will Remain in Effect for 180 Days After the PHE Expiration but Will Be Revised

The FDA has identified 24 guidance documents relating to the COVID-19 PHE that will undergo revision during the 180-day extension period after the PHE expiration in Table 3. FDA suggests that the guidance documents could be revised to align with the expiration of certain Emergency Use Authorizations (EUAs) that were issued in response to the PHE. The list includes guidance documents related to the EUAs for vaccines, as well as clinical trials conducted under the COVID-19 PHE, and drug development of COVID-19 treatments. FDA has signaled a return to "business as usual" but there is likely a need for further transition from policies that impact long-term situations such as drug development programs and clinical trials. There could be serious impacts to a change in the conduct of a clinical trial while it is in progress which could impact the study outcomes, and therefore a measured approach such as FDA seems to suggest is more appropriate. Interestingly, FDA will not be soliciting comments prior to the revisions as is the normal course, but indicates that it will evaluate and incorporate comments it receives as appropriate. Important guidance documents included in Table 3:

- Emergency Use Authorization for Vaccines to Prevent COVID-19 (CBER)
- FDA Guidance on Conduct of Clinical Trials of Medical Products During COVID-19 Public Health Emergency (CDER)
- Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational New Drugs and Biological Products During the COVID-19 Public Health Emergency-Guidance for IRBs and Clinical Investigators (CDER)
- Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency-Guidance for Industry (CDER)
- Supplements for Approved Premarket Approval or Humanitarian Device Exemption Submissions During the COVID-19 Public Health Emergency (Revised) (CDRH)

Here for the Long Haul: COVID-19 Related Guidance Documents Not Impacted by the PHE Expiration

The final table, Table 4, includes four guidance documents that FDA believes are not dependent on the PHE expiration. These guidance documents will continue to be in effect after the expiration. The guidance documents included are more generally applicable to COVID-19 which will continue to be relevant, such as the policy to evaluate the impact of mutations, which will be needed as COVID-19 will continue to evolve. The guidance documents are as follows:

- Product-Specific Guidance for Chloroquine and Hydroxychloroquine (CDER)
- Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic (CDER)
- Policy for Coronavirus Disease-2019 Tests (Revised) (CDRH)
- Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests (CDRH)

The pandemic was a period of upheaval and rapid changes for the FDA, as well as the rest of the world, but the expiration of the PHE signals a return to calmer times. The discontinuation of the COVID-19 guidance documents will likely be met with some hesitation by industry, as manufacturers and sponsors scramble to prepare regulatory applications that were delayed or exempted during the pandemic. We look forward to additional guidance from the FDA as it implements these guidance document transitions.