SheppardMullin

Events

The Biden Administration's FDA: The First Six Months and What to Expect for the Rest of the Year

Webinar
07.22.2021 | 1:30 p.m. - 4:30 p.m EDT

The Biden administration has brought in new policies and personnel to the entire federal health care team. The FDA remains in the news every day as it exercises its vast responsibilities. At the same time, the FDA must restore its reputation, show that it has learned from the pandemic, and be prepared to effect still further changes.

All of which means you have much to do to anticipate, understand, and then comply with what's coming.

Start here, with this special extended edition webinar. Gain insights into what the Biden FDA will look like and the policies and changes it will implement to new drug and device development and approvals. How will recent and ongoing controversies affect your business?

Wayne L. Pines, president of health care at APCO Worldwide and former associate commissioner of the FDA, will lead a team that will explain what we have seen in the first six months of the Biden administration and what to expect going forward, including the answers to your burning questions.

Webinar Takeaways:

- What is likely to change at the FDA under Biden that will affect what you do every day?
- How should you plan now for upcoming changes to be ready for developments later in 2021 and in 2022in drug and device regulation, enforcement, drug pricing and health care innovation?
- What new guidances are likely to be issued later this year?
- Who are the key personnel in Biden's FDA?
- What role will HHS and the White House play under Biden? How important are politics in FDA decision-making?
- What is the agenda for the new CDER director? And how have the agendas changed for the CBER and CDRH directors?
- What regulatory and policy revisions initiated under the pandemic will continue as we return to normal?
- What key elements from CBER's five-year plan do you need to know about?
- How will enforcement under Biden compare to that under Trump?
- Will there be expedited drug and device approvals as a result of the experience with vaccine development?

- What have we learned from recent drug approvals?
- Will there continue to be extensive use of EUAs?
- Will there be expanded opportunities in regenerative medicine?
- What will happen in cannabis regulation?
- What is the current status of software as medical devices?
- What is the status of harmonization efforts with the EU?
- What will PDUFA 2022 bring in terms of new fees but especially new authorities and new responsibilities for FDA?
- And much more!

There's much to do to get — and stay — ahead of the FDA changes. This special extended edition webinar will be invaluable in helping you think about and prepare for the future.

Presented By:

Allison Fulton, *Partner*, Sheppard Mullin

Allison Fulton is a partner in the Sheppard Mullin Washington, D.C. office. She is the Leader of the Life Sciences and FDA Team. Allison advises life sciences companies, including pharmaceutical, medical device, dietary supplement, food, and cosmetic companies, in matters relating to the development, manufacture, and marketing of products regulated by the U.S. Food and Drug Administration (FDA).

Industries

Life Sciences