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Events

The Biden Administration's FDA: What's Happened and What to Expect

Webinar
09.02.2021 | 1:30 p.m. - 4:30 p.m.
Event Sponsor: The Regulatory Affairs Professionals Society (RAPS)

The Biden administration has brought in new policies and personnel to the federal health care team. The FDA remains in the news every day as it exercises its vast responsibilities over drugs and devices. At the same time, the FDA must restore its reputation, show that it has learned from the pandemic, manage some of the most challenging issues and decisions it has ever faced, and be prepared to effect still further changes. All of which means we all need to gain perspective and understanding what's happened thus far in 2021 and anticipate, understand and then comply with what's coming for the rest of the year and beyond.

This special extended edition webinar features five expert speakers with decades of experience working for and with FDA. Their interactive session will enable you to gain insights into what the Biden team has done so far and the policies and changes it will bring to new drug and device development and approvals. How will recent and ongoing policy changes and controversies affect your business? What permanent changes will we see as we again shift gears into how FDA interacts with industry, Congress, the media and the patient/consumer communities?
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.

LEARNING OBJECTIVES/WEBINAR TAKEAWAYS:

- What has changed at the FDA under Biden that has and 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 2022 in drug and device regulation, enforcement, drug pricing and health care innovation?
- What new guidances are likely to be issued this year and next?
- 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?
- What are the agendas for the CBER and CDRH directors?
- What regulatory and policy revisions initiated under the pandemic will continue as we return to normal?
- What are the key elements from CBER's five-year plan?
- How will enforcement under Biden compare to that under the previous administration?

- What have we learned from recent drug approvals?
- Will there continue to be extensive use of EUAs?
- How will the timetables for drug and device approvals change as a result of the experience with vaccine development?
- What is the plan for virtual inspections and catching up on delayed inspections?
- 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 enforcement and policy changes will occur for the promotion of drugs and devices?
- What will PDUFA 2022 bring in terms of new fees but especially new authorities and new responsibilities for FDA?
- And much more!

Presented By:

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).

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