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Domestic In-Person Inspection Work Could Be Back To Normal This Summer, Woodcock Says

by Derrick Gingery

Foreign facility visits may take longer to reach usual levels because of the ongoing coronavirus outbreaks in other countries.

The pandemic-starved US Food and Drug Administration facility inspection program is poised to resume full unencumbered operations in the US later this year.

But Acting FDA Commissioner Janet Woodcock told the Senate Appropriations Subcommittee on Agriculture, Rural Development, FDA and Related Agencies that normal foreign facility inspections may take longer to reach pre-pandemic levels.

"We are committed to getting our inspectional program back and running fully by this summer to the extent we can domestically," she said during a 10 June hearing on the FDA's fiscal year 2022 budget request. "We probably can."

For foreign inspections, "it's going to depend on the state of the country and whether we can actually get into the country," Woodcock added. "I can't commit to having a full inspection program fully operating by the fall because we may have parts of the world where the pandemic is still raging."

Travel and safety restrictions to limit the spread of coronavirus forced the FDA to postpone many in-person facility

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By Bowman Cox

11 Jun 2021
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inspections in FY 2020 and FY 2021, which in some cases has delayed application decisions.

Woodcock said 68 applications now are on hold because they are awaiting an in-person inspection that now cannot be completed, which is in line with the recent agency report on inspection program resiliency. Most of the delayed inspections are for human drug manufacturers. (Also see "*Forty-Eight US FDA Drug Application Decisions Delayed By Pandemic's Deferred Inspections*" - Pink Sheet, 5 May, 2021.)

awaiting US FDA inspection resumption; GSK sotrovimab EUA gets root cause provision; API GMP compliance work acknowledged; Aziyo recalls bone matrix associated with tuberculosis outbreak, and other matters in this latest update.

Read the full article here

Among the areas that remain off-limits for FDA officials is India. A recent spike in COVID-19 infections caused the agency to suspend its restart of in-person facility inspections there. Work once again is being done remotely. (Also see "*India's COVID-19 Surge Forced Another Abrupt Stop Of US FDA In-Person Inspections*" - Pink Sheet, 21 May, 2021.) In-person work has resumed in China. (Also see "*US FDA Resumes China, India Inspections In Bid To Keep Drug Approvals On Schedule*" - Pink Sheet, 26 Jan, 2021.)

How A Rubber Band Explains The Effect Of Inspection Delays

Most of the delayed inspections are surveillance inspections. Woodcock said those regular and routine visits will continue, but will not be as frequent at first.

"If you think about a rubber band with marks on it and this is how often we'd like to inspect that plant, what's happened is we've stretched that rubber band and for every plant there's going to be more time between inspections than there ordinarily normally is," she said.

In its *budget request congressional justification*, the agency estimates that human drug program inspections will largely return to pre-pandemic levels during FY 2022. Interestingly, the agency is predicting 1,360 foreign inspections will be conducted that year, which would be the most in more than a decade. (Also see "*US FDA's Inspection Volume Projected To Return To Normal Levels In FY 2022 As Backlog Looms*" - Pink Sheet, 2 Jun, 2021.)

The news should make sponsors happy, as many have been pleading for FDA visits to their facilities, only to be rebuffed. (Also see "*Drug Manufacturers Beg US FDA To Inspect Facilities, But Still Find Difficulties*" - Pink Sheet, 1 Mar, 2021.)

Alternative Tools Helped FDA Avoid Many In-Person Inspections

The agency has employed alternative tools when possible throughout the pandemic to avoid

some in-person inspections. Options such as remote record requests saved the agency from about half of the needed pre-approval facility inspections during the final two quarters of FY 2020 and first two quarters of FY 2021. (Also see "*FDA Avoided Half Of ANDA Pre-Approval Inspections During COVID By Using Alternative Tools*" - Pink Sheet, 3 May, 2021.)

FDA officials also are interested in conducting remote site visits using video conferencing and other technology. The agency will select the facilities that will qualify for remote visits at first. (Also see "*Remote Site Visits Will Help US FDA Keep Reviews On Track During Remainder Of Pandemic*" - Pink Sheet, 14 Apr, 2021.)