The Food and Drug Administration is taking on a “marathon strategy” in place of its originally adopted sprint mentality for the review, authorization and approval of a novel coronavirus vaccine, according to the agency’s Center for Biologics Evaluation and Research (CBER) Director Peter Marks.

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Marks, who is responsible for overseeing the vaccine approval process, said the agency learned that keeping up the speed of review for COVID-19-related products established at the beginning of the pandemic was not sustainable in the long term.

“We were originally trying to turn things around ... within a few days,” Marks said during a National Health Research Forum panel earlier this month. “We realized that you can’t continue at that pace with the number of submissions.”

This review time was shortened with the FDA's emergency use authorization (EUA) guidance, which included hydroxychloroquine for hospitalized COVID-19 patients. The drug was revoked after the agency had determined it was unlikely effective and could pose health risks.

It also included the quick authorization of effective treatments like remdesivir and even 3D-printed masks to address nationwide shortages in personal protective equipment.

“In March, April and May, I thought that we’d get to a point over the summer that we would have adjusted or there might have been some plateau, but there’s really been very little cessation in the frenetic activity that we’ve had,” Marks explained. “For many of these products, [authorization] is now more like a week or so. And for some products that are less urgent, we have them on standard timelines.”

Marks noted that the agency has also adapted since its shift to mass telework. Its product offices have been working nonstop hours to handle the influx of COVID-19-related drug applications on top of its normal product review work. He's also observed that the pandemic has taken a toll on the agency’s workforce and limited resources.

“We came into this pandemic in a bad place in terms of being under-resourced in certain areas. We were barely adequately resourced in vaccines, and we were certainly not adequately resourced for cell and gene therapies. For us to keep this up, we will need to really amp up the resources we have because there’s only so long we can have people working at 150% effort.”
Still, the faster turnaround time in producing EUA guidance for the potential coronavirus vaccine and drug therapeutics has helped shorten this load significantly, Marks said.

“In terms of efficiency, getting guidance moving fast is a good thing. In part, for us, many of our guidances are on highly technical topics that, if you take too long to write them, you have to start writing them again,” he explained. “It’s beneficial to us because we take less time, but it’s also beneficial for industry because they actually get the advice sooner.”

The agency will also soon release new EUA guidance for a COVID-19 vaccine to further ensure its safety and efficacy.

“I think we can say, unequivocally, that it’s not just going to be a typical EUA that 'may be effective,'” Marks said, in reference to the upcoming guidance. “We could call it an 'EUA-Plus' or you could call it a little less than a [standard biologics license approval], but the difference is it’s going to look more like, in terms of the data required, a [biologics license application]. What we are going to be looking for are the data on efficacy and safety and the quality manufacturing information that indicate to us that we have a product that’s going to do what we intend it to do.”

Marks added that the vaccine would have a "reasonably large-size safety data set that will be evaluated by FDA" and that it will be "taken to a public advisory committee meeting so that people can see that it’s looking more like a [BLA] than a typical EUA." It would also need to undergo safety surveillance monitoring to ensure nothing was overlooked in the short term, he said.

Moving through this timeline, Marks said that the agency and industry will also need to invest in technologies, such as continuous manufacturing, for the mass public distribution of the vaccine and related treatments.

“We are going to need to be thinking about how we can have a robust and flexible manufacturing technology that can adapt to not necessarily even another pandemic, but what will invariably be the next thing that will come along where we would need to make something quickly that we would not have been making previously," he said. "We may have to find ways to work with industry so that we’re never at a loss [for] the flexibility to move very quickly into the production of a novel vaccine or a novel therapeutic."
coronavirus
IT transformation
FDA
innovation
Food and Drug Administration
vaccine
Standard