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Biologics

FDA: Two Years Too Rigid for Biologics Inspections

By Greg Langlois

In a bit of early spring cleaning, the FDA is revising its regulations to remove a requirement it inspect biological product makers every two years and instead use a risk-based schedule.

Biologics developers such as Spark Therapeutics Inc. and Novartis Pharmaceuticals Corp. with pending biologics license applications can expect an agency inspection less regularly. The agency is changing a regulation requiring it to perform biennial inspections after a change in the law eliminated that requirement. The revision goes into effect June 11.

Snapshot

- Agency eschewing rule requiring biennial biologic manufacturing inspections
- Move to risk-based inspection approach part of cleanup of outdated rules under Trump regulation-reduction push

The move is part of the Trump administration's big push to reduce the cost of regulatory burdens and overall number or regulations. In January 2017, President Donald Trump issued an executive order requiring agencies to identify two regulations to cut for each new one they propose and to offset the costs of new regulations.

The FDA's move likely won't affect the extent and quality of biologics inspections, FDA regulatory attorney Carol Pratt told Bloomberg Law in a Jan. 26 email.

"While this action was in response to the Trump administration's mandate to reduce regulatory burden it does not translate to a reduction in effective regulatory oversight by the FDA of biologics," said Pratt, a partner with Lee & Hayes PLCC and a Bloomberg Law advisory board member. "It is an administrative 'spring cleaning' that will not reduce, and may actually increase, FDA inspections of biologics."

No Longer Required

A 2012 law, the Food and Drug Administration Safety and Innovation Act (FDASIA), removed the every-two-year inspection requirement under the Federal Food, Drug and Cosmetic Act and allowed the FDA to set an inspection schedule based on risk.

"The risk is determined by the nature of the product, as well as the firm's inspectional history," FDA press officer Andrea Fischer told Bloomberg Law in a Jan. 26 email.

She said the risk-based schedule has "been in place and in practice since FDASIA was signed into law."

FDA Flexibility

Basing inspections on risk smartly prioritizes keeping an eye on biologics makers developing the most complex products, industry trade group Pharmaceutical Research and Manufacturers of America said.

"The FDA's move away from a one-size fits all inspection model to a risk-based approach that prioritizes facilities manufacturing vaccines and gene therapies, and those with more complex manufacturing steps will allow for more efficient and improved safety inspections," PhRMA director of public affairs Andrew Powaleny said in a Jan. 26 email to Bloomberg Law. "Some biological medicines are more complex to manufacture than others, and the move will provide more effective oversight of biological facilities while removing barriers and increasing risk-based flexibility."

The FDA issued the regulatory amendment as a direct final rule Jan. 26, with a companion proposed rule. Submit comments on the change by April 11 to https://www.regulations.gov including Docket No. FDA–2017–N–7007.

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