FDA Postpones Ex-US Facility Inspections

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U.S. Food and Drug Administration (FDA) Commissioner Stephen M. Hahn, M.D., announced that FDA is postponing foreign inspections through April 2020 in response to the COVID-19 outbreak. Manufacturers, including contract manufacturers, anticipating post-approval inspections may welcome the news, given other pressing issues facing ex-US facilities (i.e., facilities located outside the US) in light of COVID-19. Companies with planned pre-approval inspections, however, may find the news distressing.

The postponement will impact companies with pre-approval inspections that are planned now through April because a delayed inspection could mean a delay in product approval. FDA typically will not approve a new drug, biologic, or certain medical devices without a successful pre-approval inspection. Pre-approval inspections are product specific and are conducted to determine whether a facility is capable of manufacturing the new product and that data submitted in the product application are accurate and complete.

FDA will consider conducting foreign inspections that are deemed “mission critical” on a case-by-case basis. The Commissioner did not elaborate on the criteria for “mission critical,” but it could include a pre-approval inspection for a life-saving drug or biologic with no alternative in the marketplace. Preapproval inspections for products intended to diagnose or treat COVID-19 also likely would be deemed “mission critical.”
The FDA based its decision on a number of factors, including State Department Level 4 travel advisories, Centers for Disease Control and Prevention travel recommendations, and access restrictions being imposed on foreign visitors by certain countries. FDA reported that it will monitor the situation closely and be ready to resume foreign inspections as soon as feasible.

To read the statement by Commissioner Hahn, click here.

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