Chambers AND PARTNERS

< Back to Home

The Pandemic's Effect on FDA Inspections

Jessica Ringel and Amanda J. Klingler, partners in King & Spalding's FDA and Life Sciences team, analyse the lasting effect that the COVID-19 pandemic may have on how the FDA conducts inspections of device manufacturers.

Published on 15 August 2022

Jessica Ringel

Amanda J. Klingler

The COVID-19 pandemic affected many aspects of medical device firms' operations, from supply chain challenges, including shortages of raw materials, to production changes needed to accommodate social distancing and to account for employee illness.

Likewise, the FDA's operations were – and continue to be – greatly affected by the pandemic, as the Agency shifted focus and employee resources to areas of greatest need (eg, COVID-19 vaccines and therapies, SARS-CoV-2 diagnostic tests, personal protective equipment, and ventilators) to help meet the public health need, first in the early days of the COVID-19 pandemic and, later, as the nation learned to live with the virus. Inspections conducted by the Office of

The FDA's normal inspection routines were upended by the pandemic as health and safety needs prevented ORA from sending investigators to conduct routine inspections on-site at manufacturing facilities.

> "In January 2021, the Government Accountability Office took the FDA to task for its inspection backlog."

The limitations of the FDA's authority to conduct medical device inspections via alternative methods came starkly to light. The FDA – and Congress – have already shown sensitivity to this issue, and we expect that the nature of FDA inspections may shift going forward.

FDA inspection activity at the mercy of COVID-19 infection rates

In March 2020, shortly after the global COVID-19 pandemic was officially declared a public health emergency in the United States of America, the FDA announced a halt to nearly all foreign and domestic inspections across all industries, conducting only limited mission-critical inspections. Since then, the pandemic has forced the FDA to take a "start and stop" approach to resuming inspection activity as the waves of the pandemic have ebbed and flowed.

In July 2020, the FDA announced its intent to resume routine inspection activity based on the level of infection in a community, based on its red-yellow-green COVID-19 Advisory Rating system. Due to the continued spread of COVID-19 infection, the FDA was able to conduct relatively few inspections under this system and, at times, put inspection activity on hold, as with an Omicron-related halt in inspections from late December 2021 to early February 2022.

During this time, the FDA's backlog of inspections grew, as both routine and mission critical inspections were continuing at a record low pace. In January 2021, the Government Accountability Office took the FDA to task for its inspection backlog, primarily in relation to drug facilities.

In response, in May 2021, the FDA issued its Resiliency Roadmap, setting forth its plan and priorities for more consistent inspection activity. The FDA also described its alternative tools for oversight of FDA-regulated products, but these tools relied on existing statutory authorities and international partnerships.

Section 704(a)(4) records requests

request records "in advance of, in lieu of, an inspection" – a so-called 704(a)(4) records request. This statutory authority currently applies only to drug manufacturers. Although a 704(a)(4) records request does not constitute an inspection, refusal to comply nevertheless results in the adulteration of drugs made at the facility. Therefore, these "requests" are actually mandatory requirements.

In 2021, the FDA issued three Warning Letters to drug firms that refused to provide the requested records or information. In 2021 and 2022 to date, the FDA has issued 13 Warning Letters to drug firms citing records submitted in response to a 704(a)(4) records request as the basis for the Warning Letter's citations.

> "The FDA will continue to use alternative and remote inspection approaches even after the pandemic subsides."

The FDA does not currently have the statutory authority to issue a 704(a)(4) records request to medical device firms. The House Energy & Commerce Committee included a provision in its draft user fee reauthorisation legislation that would extend the statutory provision to device firms.

However, with the current uncertainty about the final form of the user fee reauthorisation, due to the wide variance between the House and Senate bills is it not clear at this time whether expansion of this statutory authority is imminent.

Remote Regulatory Assessments and Remote Interactive Evaluations

In the absence of 704(a)(4) records requests for device firms, the FDA instituted a voluntary Remote Regulatory Assessment (RRA) process in early 2021. To begin, the FDA sends a letter to a device firm asking whether it agrees to participate in a voluntary RRA, under which ORA investigators electronically collect records and files that the FDA would typically review during an inspection. At the close of the RRA, the investigator meets, virtually, with the firm to discuss the investigator's findings.

The FDA warns that, if the investigator identifies significant deficiencies, the FDA can subsequently conduct an on-site inspection or take other action as warranted. Unlike 704(a)(4) records requests, RRAs are truly voluntary and declining to participate will not result in negative regulatory action. However, it is likely that declining to participate in an RRA would put a firm higher on the list for an inspection relative to firms that choose to co-operate.

In a third type of remote assessment, in April 2021, FDA announced a process for voluntary Remote Interactive Evaluations (RIEs) during the COVID-19 pandemic using live-streaming video,

to drug cGMP inspections and bioresearch monitoring (BIMO) inspections.

New guidance on remote inspections

The FDA recently brought all of these remote strategies together in a draft guidance on Remote Regulatory Assessments released on 22 July 2022. Whereas the remote inspection approaches the FDA implemented earlier in the pandemic were justified by the pandemic-related necessity of using alternatives to in-person inspections, the current guidance looks forward and aims to apply these new approaches in the post-pandemic world.

The FDA states in the draft guidance that "FDA has noted the value of RRAs and concluded that they should be used for certain scenarios outside the current pandemic and for all types of FDA-regulated products." Some key points of this new draft guidance are as follows.

- If an RRA precedes an inspection, the results of the RRA may be included in FDA-483 observations.
- If an RRA follows an inspection, it may be used to confirm corrective actions from the inspection.
- The FDA may use RRAs:
  - when investigators are unable to travel for safety reasons;
  - to support regulatory decisions (eg, follow-up on complaints, verification of corrective actions, and pre-market approvals);
  - to support regulatory meetings, warning letters, import actions, recalls, or other enforcement activities;
  - in advance of an inspection or to prioritise inspections; or
  - to take enforcement action, even without an intervening inspection.
- RRAs can include document requests, virtual meetings, and live or pre-recorded video walkthroughs;
- Declining a voluntary RRA requested instead of a pre-approval inspection may delay submission approval.
- Refusing to provide documents during, or declining, a mandatory RRA is considered refusal of an inspection.
- The FDA encourages a response to RRA observations at the closing meeting and/or within 15 business days.
- The FDA will create a narrative report of the RRA, which is available upon request once the RRA is deemed closed.
- RRA observations, the FDA's narrative report, and firms' responses are subject to release if requested under the Freedom of Information Act (FOIA).

and there are no health or safety restrictions on investigators conducting on-site inspections.

Further, it is expected that the FDA and Congress will seek to strengthen the FDA's statutory authority to use remote assessment and inspection techniques by amending the FDCA to extend mandatory 704(a)(4) record requests to medical device firms and, potentially, to grant the FDA the authority to conduct fully-remote, mandatory inspections.

King & Spalding

65 ranked departments

Learn more about the firm's ranking in Chambers Global 2022

View firm profile >

Chambers Global Practice Guide Medical Devices & Consumer Health Products 2021

Learn more about global developments in medical regulation.

View guide

About our Legal Rankings

Worldwide Law Firms Rankings

Worldwide Lawyers Rankings

About us

Chambers Careers

Privacy

Social

Linkedin

Chambers AND PARTNERS

Youtube

Instagram

Contact Details

165 Fleet Street
London
United Kingdom
EC4A 2AE
View in maps

Contact Us