



A Client's Guide to FDA Inspections

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Recent FDA Inspection Highlights & Developments

- FDA issued Review and Update of Device Establishment Inspection Processes and Standards; Draft Guidance for Industry, describing the agency's timeframe for device establishment inspections, standard communication methods, and other practices for investigators and device establishments.
- The agency issued Nonbinding Feedback After Certain FDA Inspections of Device Establishments; Draft Guidance for Industry and Food and Drug Administration Staff, explaining how, under specified circumstances, device establishment operators may submit a request for nonbinding feedback to FDA regarding actions the firm has proposed to take to address certain inspectional observations on a Form FDA 483.
- Under the Mutual Recognition Agreement between FDA and the European Union, FDA has continued to recognize additional European drug regulatory authorities as being capable of conducting inspections of manufacturing facilities that meet FDA requirements, expanding the agency's ability to accept inspections completed by foreign regulators.
- FDA implemented two protocols, for sterile drug surveillance inspections and the other sterile pre-approval drug inspections, developed as part of the agency's New Inspection Protocol Project (NIPP). The new protocols additional structured tools for conducting inspections, as well as completing establishment inspection reports.
- FDA's Office of Pharmaceutical Quality published Understanding CDER's Risk-Based Site Selection Model from its Manual of Policies and Procedures, identifying the internal criteria FDA uses to prioritize manufacturing sites for routine quality-related surveillance inspections.
- FDA has continued its implementation of the Food Safety Modernization Act (FSMA), conducting an increased number of inspections verifying compliance with the Foreign Supplier Verification Program rule, the Preventive Controls for Human Food rule and other FSMA requirements.

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A Food and Drug Administration (FDA) investigator has just knocked on your door and announced that he or she will now inspect your facility. What happens before, during and after this inspection, and what should your firm do to prepare for each stage?

Here are answers to a number of frequently asked questions about FDA inspections and compliance actions. These answers are designed to be generally applicable, rather than addressing a specific type of product.

Q. Who conducts FDA inspections?

A. Almost all FDA inspections are conducted by Consumer Safety Officers in the Office of Regulatory Affairs (ORA).¹ Consumer Safety Officers, colloquially called investigators, are trained to conduct inspections for a specific FDA-regulated commodity. They report to ORA supervisors within the same specialty—for example, drug specialists oversee drug investigators. Investigators in the Office of International Programs (OIP) perform some inspections in locations in which FDA has a foreign office.² These OIP investigators are usually on temporary assignment from the ORA, are specialized, and have received the same training as those in ORA. Occasionally, experts from the relevant FDA product center accompany ORA investigators. FDA's Office of Criminal Investigation does not participate in regulatory inspections.

Q. Has FDA's Program Alignment initiative changed who inspects my facility?

A. On May 15, 2017, FDA implemented its Program Alignment initiative, which is a reorganization of ORA that shifts management of inspections and compliance from a geographic structure to one based on commodity.³ Before Program Alignment, although most investigators were specialized by commodity, some performed inspections of facilities in their geographic area, regardless of commodity type. Also



prior to Program Alignment, an investigator could report to a specialist in a different commodity because the two worked in the same geographic district. Now, all investigators and supervisors are specialists in the facilities that they oversee.⁴

If a firm had been inspected by nonspecialists, the identity of the investigator in future inspections has likely changed. Also, because Program Alignment changed investigators' supervisors, if a firm wishes to dispute an investigator's actions or conclusions, the relevant ORA officials have also changed.

Q. What types of inspections does FDA conduct?

A. In FY 2018, FDA conducted more than 16,000 domestic inspections and 3,500 foreign inspections, and contracted with states to perform more than 18,500 inspections.⁵

There are four basic types of inspections of manufacturing facilities:

- **Pre-approval inspections:** Part of the process that FDA uses to evaluate whether to approve some medical products for sale in the United States, such as most prescription drugs and high-risk, "Class III" devices. Because there is no preapproval process for food, pre-approval inspections are not part of FDA's food program.

1 See *ORA Overview*, FDA, <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ucm409371.htm> (Aug. 12, 2014); *Consumer Safety Officer Positions at FDA*, FDA, <https://www.fda.gov/AboutFDA/WorkingatFDA/CareerDescriptions/ucm113286.htm> (Mar. 28 2018).

2 *Office of International Programs*, FDA, <https://www.fda.gov/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/officeofinternationalprograms/default.htm> (Oct. 23 2018).

3 *Program Alignment and ORA*, FDA, <https://www.fda.gov/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/ucm549087.htm> (Aug. 31, 2017).

4 *Id.*

5 FDA, *Fiscal Year 2020: Justification of Estimates for Appropriations Committees* (Mar. 2019).

- **Post-approval inspections:** Product specific inspections that take place following approval, intended to evaluate commercial-scale processes, process validation lifecycle, manufacturing changes and any changes in perceived product risks.
- **Surveillance inspections:** Routine assessments of whether a facility is complying with FDA's rules and regulations. FDA conducts these inspections after a product is on the market.
- **For-cause inspections:** Occur in response to a specific trigger, such as a recall, an outbreak, laboratory testing results or information from a whistle-blower. FDA also performs for-cause inspections to verify that a firm has taken corrective actions that rectify a problem that FDA had previously identified. These inspections are also called "follow-up inspections."⁶

FDA also conducts inspections of FDA-regulated research pursuant to its Bioresearch Monitoring Program.⁷ These inspections cover clinical trials, nonclinical testing laboratories and bioequivalence facilities. FDA also performs inspections of tobacco manufacturing facilities and contracts with states, territories and third-party entities to inspect tobacco retailers.

Additionally, FDA conducts Foreign Supplier Verification Programs (FSVP) inspections for importers of foreign food for human and animal consumption that are subject to FDA safety standards.⁸ FSVP inspections are based on the review of records, rather than observations of food production.⁹ A modified inspection form, FDA Form 483A, is used to capture FSVP inspection observations.¹⁰ Inspections began in June 2017, with 285 inspections completed in FY 2017.¹¹

Q. How does FDA decide where to inspect?

- 6 See *What Is a Compliance Follow-up Inspection?*, FDA, <https://www.fda.gov/food/complianceenforcement/inspections/ucm211823.htm#q31> (Sept. 19, 2018).
- 7 See *Bioresearch Monitoring General Information*, FDA, <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/BioresearchMonitoring/ucm052023.htm> (Mar. 22, 2018).
- 8 See 21 U.S.C. § 384a(c)(4).
- 9 *What Do Importers Need to Know About FSVP*, FDA, <https://www.fda.gov/food/guidanceregulation/fsma/ucm560689.htm> (Aug. 20, 2018).
- 10 *Form FDA 483a*, FDA, <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM493415.pdf> (Feb. 2016).
- 11 Sharon Lindan Mayl, *AFDO Annual Educational Conference FSMA Imports and Systems Recognition*, FDA, http://www.afdo.org/resources/Documents/2018Conference/1530-1615_Fsma%20Imports%20and%20Systems%20Recognition_Sharon%20Mayl.pdf (June 2018).

A. FDA uses risk-based models to determine where to conduct surveillance inspections.¹² The models differ based on commodity, but, generally, inspections are more frequent when the product is riskier (for example, a sterile injectable drug versus an over-the-counter tablet), the site has a poor compliance history and the site has not recently been inspected by FDA or other trusted regulators. ORA and the product centers collaborate in choosing where to inspect. FDA considers similar factors when deciding whether to conduct preapproval inspections.

For-cause inspections usually occur promptly after a triggering event, particularly if the agency determines that there is a significant public health risk.

Under limited circumstances, FDA may waive a preapproval inspection for approval of some medical products.

In some areas, the law establishes a minimum inspection frequency. For example, (FSMA) contains a series of food inspection mandates.

Q. Will my inspection be announced ahead of time?

A. Not necessarily. Many FDA inspections are unannounced.

Q. How should a firm prepare for an inspection?

A. Although most inspections are unannounced, firms often can anticipate that they will be inspected in the near future, depending on the factors described above.

The specifics of preparation depend on the type of inspection. Generally, firms should have procedures in place for responding to FDA inspections—for example, specifying who will be the lead for interacting with the investigator, where the investigator will review documents, and which legal counsel or technical expert the firm would consult if a problem were to arise.

Q. What happens during an inspection?

A. At the beginning of an inspection, the investigator will present his or her credentials. Additionally, domestic establishments will receive a "Notice of Inspection" (FDA Form 482).

Inspections vary by the type of product and the size and complexity of the facility. For example, in a drug manufacturing facility inspection, FDA will often examine six systems—quality, production, facilities and equipment, laboratory controls, materials, and packaging and labeling. In a food inspection, FDA

¹² See, e.g., FDA, *Office of Pharmaceutical Quality: Understanding CDER's Risk-Based Site Selection Model; Manual of Policies and Procedures* (Sept. 2018).

will determine whether a firm has complied with the appropriate preventive controls described in the regulations implementing FSMA or with the Hazard Analysis Critical Control Point rules that apply to seafood and juice. In device inspections, FDA focuses largely on compliance with the Quality Systems Regulation. In practically any type of inspection, investigators will examine relevant records and processes, such as the standard operating procedures for recalls, laboratory test results, whether production employees are properly trained and attired and follow procedure, whether a facility is appropriately sterile or clean, and whether a firm monitors its operations and takes appropriate corrective action. Investigators will talk to employees and collect records, will sometimes obtain product samples or environmental samples and may take photographs. Usually, one or two FDA investigators conduct an inspection; additional investigators might be involved in inspections that are more complex.

A firm employee or employees should accompany the investigator during the inspection to respond to questions or information requests. It is important for the firm to take notes of the information requested and provided and what has transpired.

At the end of each day, the investigator usually summarizes any problems that he or she detects. The firm should point out any areas in which it disagrees with the investigator as soon as the investigator raises them.

Q. How does the inspection end?

A. At the conclusion of the inspection, the investigator will issue a form entitled "Inspectional Observations," known as FDA Form 483 or simply a 483, when, "in the investigator's 'judgment', conditions or practices observed, indicate that any food, drug, device or cosmetic have been adulterated or are being prepared, packed or held under conditions whereby they may become adulterated or rendered injurious to health."¹³ The investigator issues the 483 at a closeout meeting, which concludes the inspection. If the firm disagrees with an item on the 483, it should voice that disagreement at or before the closeout.

Inspections vary considerably in length, depending on the size and complexity of the facility and what the investigator finds. FDA must conduct inspections "at reasonable times and within reasonable limits and in a reasonable manner."¹⁴

Q. Are there limits on the types of records that FDA may request during an inspection?

¹³ FDA, *Investigations Operation Manual*, § 5.2.3 (2018)
¹⁴ 21 U.S.C. § 374(a).



A. Yes. The types of records that FDA may request is quite broad, but there are limitations, set forth in 21 U.S.C. § 374, that vary by commodity. For example, FDA has limited authority to obtain certain financial data, sales data, pricing data, personnel data and research data.

Q. How should a firm respond to FDA information requests during an inspection?

A. It is important to provide truthful and complete responses to lawful FDA questions and information requests. FDA inspections are governed by laws that make it a crime to obstruct, or provide material false information in, federal proceedings.

If a firm believes that an investigator has overstepped, the firm should seek counsel promptly. If a firm declines to provide information that FDA may lawfully request or causes an unreasonable delay to FDA's ability to obtain information or complete its inspection, FDA could initiate enforcement action.¹⁵ It is therefore important that a firm's objection have a strong legal and factual basis.

¹⁵ See FDA, *Guidance for Industry: Circumstances that Constitute Delaying, Denying, Limiting or Refusing a Drug Inspection* (Oct. 2014).

Q. If a firm raises a significant objection with an investigator and continues to disagree with the investigator's response, are there means to appeal to others in FDA during an inspection?

A. There are both formal and informal ways to resolve a dispute with an investigator, through ORA, the relevant product center or elsewhere in FDA—depending on the nature of the dispute.

Q. What is the significance of a 483? Are 483s public documents?

A. Technically, 483s do not have independent legal force. FDA states that a 483 “does not constitute a final Agency determination” of whether there has been a violation of law.¹⁶ FDA considers the 483, along with other evidence and documents and the firm's response, when determining whether compliance action is warranted.

However, FDA releases 483s under the Freedom of Information Act, upon request. If it believes that a 483 would generate significant interest, it may release the document proactively. FDA will redact protected information on 483s, such as trade secrets and commercial confidential information. The bottom line is that 483s will often become public and appear on the Internet, where they can affect the perception of, consumer confidence in and stock price of a company, even if there is no subsequent compliance action. Additionally, state regulatory agencies may decide to initiate investigations or inquiries based on an issued 483. Therefore, it is important for a company to raise objections and make its case before the investigator issues a 483.

Q. If a firm receives a 483, what are the next steps for the firm?

A. A firm has 15 working days to respond in writing to a 483. If a firm believes that there is a clear factual error in a 483, it can ask FDA to amend the document. Because most observations on a 483 involve some degree of interpretation, however, the FDA rarely amends them.

A written 483 response can have a significant impact on whether FDA takes further compliance action. The 483 response should address all of FDA's observations. It should indicate which ones have been corrected already and provide a timetable and plan for correcting the others. The response can go beyond the specific observations and address the firm's overall corrective action plan and commitment to quality and compliance. A firm may request that FDA post the 483 response on FDA's website, if FDA has posted the 483.

¹⁶ FDA Form 483 Frequently Asked Questions, FDA, <https://www.fda.gov/iceci/inspections/ucm256377.htm> (July 24, 2017).



Q. If a firm receives a 483, what are the next steps for FDA?

A. The investigator prepares an Establishment Inspection Report (EIR), which provides substantially more detail than a 483. If the investigator took product or environmental samples, FDA will obtain laboratory analysis.

After the EIR is written, FDA will classify the inspection as No Action Indicated (NAI), Voluntary Action Indicated (VAI), or Official Action Indicated (OAI). The internal FDA process involves an ORA recommendation and, often, review by the applicable product center. An NAI inspection is often one in which the investigator did not issue a 483, though, sometimes, a 483 is issued, and, later in the process, FDA determines that the observations were not serious and classifies the inspection as NAI. VAI inspections may lead to inspection follow-up or more frequent reinspections, but typically no additional compliance actions. OAI inspections often lead to compliance actions for food and postmarket medical products and recommendations to withhold product approval for preapproval inspections.

After FDA has classified an inspection as NAI or VAI, it provides the firm with a copy of the EIR. For OAI inspections, firms do not receive the EIR until the relevant compliance action has been undertaken or the matter has otherwise been closed (such as with a decision to withhold product approval).

Q. How will FDA's Concept of Operations agreement for the Integration of FDA Facility Evaluation and Inspection Program for Human Drugs affect human drug facility inspections?

A. On June 7, 2017, FDA's Center for Drug Evaluation and Research (CDER) and the ORA entered into

a Concept of Operations (ConOps) agreement to coordinate efforts and workflow for inspections at domestic and international facilities for human drugs (excluding compounding and biomedical research monitoring).¹⁷ ConOps is intended to complement the changes made under FDA's Program Alignment, helping to vertically integrate CDER and ORA's efforts in pre-approval, post-approval, surveillance and for-cause inspections for human drug facilities.¹⁸ As part of this agreement, CDER and ORA established timelines for communicating the findings of inspections to firms. Inspectional classification should now be communicated within 90 days follow the inspection closing via issuance of a decisional letter (also known as a FMD-145 letter).¹⁹ FDA has expressed a goal of achieving this timeline in 90 percent of applicable inspections.²⁰

Additionally, under ConOps, for-cause inspection follow-up actions, such as warning letters, should be complete within six months post-inspection.²¹ As of July 2018, 81 percent of FDA's enforcement/advisory actions were issued within six months of the close of the inspection.²²

For further information on ConOps, please see our related [Food and Drug Law Alert](#).

Q. What types of compliance or enforcement actions does FDA take?

A. FDA takes many different types of compliance or enforcement actions.

There are three types of judicial enforcement actions—the seizure of unlawful product; an injunction (usually ordering a firm to cease operations, abide by rigorous conditions or disgorge profits); and criminal prosecution. These actions usually involve companies that have had poor inspection histories; have, in FDA's view, caused a significant risk to public health; or have engaged in fraud or deliberate misconduct. The Department of Justice represents FDA in court. A criminal prosecution may occur even if FDA is also seeking a civil remedy.

FDA increasingly uses administrative enforcement tools, which vary by commodity. Under FSMA, FDA may issue administrative orders for the detention of product, mandatory recalls or the suspension of a company's registration (which has the effect of causing it to cease operations). In the device area, FDA may impose civil monetary penalties, order mandatory recalls and detain product. For drugs, FDA may detain product, and order mandatory recalls for controlled substances, but the other remedies are not available. FDA rarely pursues mandatory recalls because it will first indicate to a firm that it thinks that a recall is needed, and, if the firm refuses, FDA will post a strongly worded patient or consumer alert on the Internet. Firms usually agree to an FDA request to initiate a recall. For more information, see [A Client's Guide to FDA Recalls](#).

A powerful tool that FDA uses for imported products is Detention without Physical Examination, colloquially known as an "import alert." If it "appears" that there has been a violation of the Federal Food, Drug and Cosmetic Act, FDA may bar import of the affected product.²³ FDA has used this authority to bar whole categories of product from a geographic area—for example, raw and cooked shrimp from India²⁴—or from a specific company. FDA generally issues firm-specific alerts for medical products, but issues both firm-specific and geographic alerts for food. FDA employs import alerts when there is an imminent public health risk (usually coupled with a product recall), but also when there are long-term or systemic compliance problems. Products remain on import alert until FDA believes that the relevant compliance problem has been resolved. Most of the time, FDA believes that a re-inspection is necessary before it lifts an import alert. When companies have corrected the problems that FDA has identified, they should proactively argue for the lifting of the import alert.

FDA frequently issues warning letters and untitled letters. Warning letters document serious compliance problems and warn companies that failure to correct the deficiencies could result in a more serious compliance measure, such as a judicial enforcement action. Firms have 15 working days to respond to a warning letter and describe the corrective actions that it has undertaken. It is important for firms to prepare thorough and timely responses, in consultation with outside technical and legal experts, as needed. FDA routinely posts warning letters on its website. FDA almost always conducts a follow-up inspection to verify that a company has taken appropriate corrective action. Untitled letters document less serious compliance issues. Although FDA does not post all untitled letters on its website, it releases them upon a

¹⁷ FDA, *Integration of FDA Facility Evaluation and Inspection Program for Human Drugs: A Concept of Operations*, 1 (June 6, 2017), <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAs/UCM574362.pdf>.

¹⁸ *Questions and Answers: Integration of FDA Facility Evaluation and Inspection Program for Human Drugs: A Concept of Operations*, FDA, <https://www.fda.gov/drugs/developmentapproval-process/manufacturing/ucm576309.htm> (Sept. 27, 2018).

¹⁹ *Id.* at 6. Also consistent with FDA's GDUFA II commitment re surveillance inspection classification, and GDUFA and PDUFA application timeframe for PAIs.

²⁰ *Questions and Answers: Integration of FDA Facility Evaluation and Inspection Program for Human Drugs: A Concept of Operations*, FDA, <https://www.fda.gov/drugs/developmentapproval-process/manufacturing/ucm576309.htm> (Sept. 27, 2018).

²¹ FDA, *supra* note 16, at 8.

²² FDA, *supra* note 5 at 235.

²³ 21 U.S.C. § 381(a).

²⁴ *Import Alert 16-35*, FDA, https://www.accessdata.fda.gov/cms_ia/importalert_43.html (Mar. 8, 2019).

Freedom of Information Act request.

Q. How long does FDA's compliance process take?

A. When FDA believes that there is a public health emergency, it will act quickly. These situations typically involve FDA requests for a voluntary recall, mandatory recall, administrative detention or suspension of registration. If an import alert is meant to address an imminent risk, FDA will issue it quickly. If it is a response to a more systemic concern, FDA's decision-making process may take weeks or months.

FDA sometimes issues warning letters and untitled letters many months after inspections. They are posted on the Internet rather quickly, making it important that firms be prepared to respond publicly. If time passes after a 483 response and a firm has still not heard from FDA, it should inform the agency of any material changes to its 483 response, such as additional corrective measures. During this quiet interval, a warning letter could be under consideration and new information could be pivotal.

The consideration of possible judicial actions by FDA and the Department of Justice is usually time consuming, as are criminal investigations.

Q. How does enactment of the FDA Reauthorization Act of 2017 (FDARA) affect device establishment inspections?

A. Under FDARA, medical device manufacturers may request nonbinding feedback from FDA under certain circumstances following an FDA inspection of a device

establishment.²⁵ Specifically, feedback regarding the firm's proposed responsive actions may be requested when FDA's observations, as documented on an applicable 483, involve a public health priority, that implicate systemic or major actions, or relate to emerging safety issues.²⁶

The agency has stated that situations qualifying for agency feedback include observations that: (1) require resolution due to conditions that have resulted in, or will likely result in, the release of violative product that may cause death or serious injury; (2) indicate that quality system/subsystem deficiencies, when considering all pertinent factors, have resulted in, or will likely result in, the production of nonconforming, violative, and/or defective finished devices; or (3) relate to an emerging safety issue that, if unresolved, is likely to result in release of devices that would likely cause death or serious injury.²⁷

A request for feedback should be submitted within 15 working days following the issuance of a 483, parallel to the timeline for a 483 response. The agency must provide the requested feedback within 45 days of the request.²⁸ The nonbinding feedback will indicate if the firm's proposed actions, if implemented appropriately, would be adequate, partially adequate, or inadequate, with any necessary explanations and recommendations.²⁹

Q. Aside from the compliance actions mentioned above, if an FDA inspection produces a worrisome result, what other consequences should a firm anticipate?

A. The collateral consequences of a bad inspection depend on factors such as the risk to consumers and patients, whether product is contaminated and whether FDA uncovers fraud. Firms can be subject to tort and contract liability and investigations by Congress or state legislators. Foreign and state regulators and licensing authorities could take action based on FDA inspection results. Firms may also have to disclose inspection results and subsequent actions to shareholders. As soon as a firm anticipates troubling inspection results, it should consult counsel to evaluate next steps, not just with FDA, but in these other areas.



²⁵ See 21 U.S.C. § 374(h)(2)

²⁶ *Id.*

²⁷ FDA, *Nonbinding Feedback After Certain FDA Inspections of Device Establishments; Draft Guidance for Industry and Food and Drug Administration Staff*, 6 (Feb. 19, 2019) <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm631397.pdf>.

²⁸ *Id.* at 7.

²⁹ *Id.*

Q. How does FDA collaborate with foreign regulators regarding inspections?

A. Under the Food and Drug Administration Safety and Innovation Act (FDASIA), enacted in 2012, FDA gained the ability to enter into agreements to recognize pharmaceutical inspections completed by foreign regulators, if FDA determined the foreign regulators were able to perform inspections that met FDA requirements.³⁰ Mutual recognition of inspections with other countries helps to increase the efficient use of agency resources and provides a practical means of overseeing an increasing number of manufacturing facilities outside the United States.

On November 1, 2017, updated provisions of a Mutual Recognition Agreement between FDA and the European Union came into force, covering medicinal products for human use (including marketed finished pharmaceuticals and marketed biologics).³¹ Since the agreement came into force, FDA has conducted capability assessments of European Union countries in phases, with completion anticipated in 2019.³² Thus far, FDA has recognized 22 European Union countries as capable of performing inspections meeting FDA requirements.³³ In the future, as a result of the Mutual Recognition Agreement, FDA will generally not conduct routine drug manufacturing inspections in European Union countries with a capable inspectorate and will instead rely on the inspection reports of the European regulators. Likewise, European regulators will rely on FDA's inspection reports of United States-based drug manufacturing facilities that ship products to European Union countries.

FDA engages in a similar process for food safety. Under systems recognition, FDA completes assessments of foreign countries' food safety regulatory system, evaluating whether the foreign regulatory framework provides similar protections as FDA requirements.³⁴ If a foreign country's system is determined to be comparable, FDA and the foreign regulatory agency work together to allow for a more efficient use of resources by decreasing duplicative border checks and verification activities for exported foods. FDA has recognized Australia, Canada and New Zealand as having comparable food safety systems to the United States.³⁵



FDA also participates in the Medical Device Single Audit Program (MDSAP), which allows a single regulatory audit of a medical device manufacturer's quality management system to satisfy the requirements of multiple regulatory jurisdictions.³⁶ Participating countries are Australia, Brazil, Canada, Japan and the United States.³⁷ Following the completion and evaluation of a successful three-year pilot, FDA now accepts MDSAP audit reports as a substitute for routine agency inspections.³⁸

FDA also engages in memoranda of understanding and other cooperative arrangements with foreign governments regarding pharmaceutical and medical device inspections, as well as good manufacturing practices.³⁹

As a result of these types of agreements, an unfavorable FDA inspection will likely lead to follow-up by some foreign regulators, while an unfavorable foreign inspection by a recognized or partner country would invite increased FDA scrutiny.

³⁰ See 21 U.S.C. § 384e.

³¹ FDA, *Frequently Asked Questions / The Mutual Recognition Agreement*, 6 (July 2017), <https://www.fda.gov/downloads/InternationalPrograms/Agreements/UCM544394.pdf>.

³² *Mutual Recognition Agreement (MRA)*, FDA, <https://www.fda.gov/internationalprograms/agreements/ucm598735.htm> (Feb. 28, 2019).

³³ *Id.*

³⁴ *International Cooperation*, FDA, https://www.fda.gov/Food/InternationalInteragencyCoordination/InternationalCooperation/default.htm#systems_recognition (Oct. 4, 2018).

³⁵ *Id.*

³⁶ *Medical Device Single Audit Program (MDSAP)*, FDA, <https://www.fda.gov/medicaldevices/internationalprograms/mdsap/lot/> (Apr. 1, 2019).

³⁷ *Id.*

³⁸ *Id.*

³⁹ *See Memoranda of Understanding and Other Cooperative Arrangements*, FDA, <https://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/default.htm> (Mar. 18, 2019).

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