E. Inspections

1. Background

FDA conducts inspections of establishments that manufacture, process, pack, or hold FDA-regulated products, before approving products and/or after products are on the market, to determine the establishment's compliance with laws administered by FDA.[1] Upon completing the inspection, if objectionable conditions are observed, FDA provides the owner of the establishment with a document, called an FDA Form 483, which includes the name of the firm and the date(s) of inspection, and lists the observations made by the investigator during the inspection.[2]

FDA provides initial classification of the inspection based on the observations noted during the inspection, the investigator's report, and FDA District Office supervisory personnel review. With the exception of instances where procedures indicate that the relevant product center has the right of final classification, the final classification of the inspection is made by the FDA District Office. An inspection classification reflects the compliance status of the establishment at the time of the inspection, based on the observations documented. The conclusions of the inspection are reported as Official Action Indicated (OAI), Voluntary Action Indicated (VAI), or No Action Indicated (NAI).

An **OAI** inspection classification occurs when significant objectionable conditions or practices were found and regulatory action is warranted to address the establishment's lack of compliance with statute(s) or regulation(s).

A **VAI** inspection classification occurs when objectionable conditions or practices were found that do not meet the threshold of regulatory significance. Inspections classified with VAI violations are typically more technical violations of the FDCA.

An **NAI** inspection classification occurs when no objectionable conditions or practices were found during the inspection or the significance of the documented objectionable conditions found does not justify further actions.

If no enforcement action is contemplated, or after enforcement action is concluded,[3] FDA provides inspected establishments with a final inspection report, called an Establishment Inspection Report (EIR), which includes:

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[1] *See* FDCA § 704.

[2] FDCA § 704(b).

[3] FDA's Information Disclosure Manual, Section III.D, explains how to determine whether an EIR is "closed," such that it no longer qualifies as a law enforcement record protected from public release under FOIA Exemption (b)(7)(A), 5 U.S.C. § 552(b)(7)(A). Among other things, "[a]n EIR is considered closed when FDA has concluded its review of the firm's activities and decides that no additional administrative or regulatory action is warranted or dictated. This generally does not occur until after FDA has issued a Warning Letter to the firm and

- Brief history of prior inspectional findings, including any action taken by FDA or corrective action taken by the firm in response to a previous inspection

- The investigator's narrative report

- Any refusals, voluntary corrections, or promises made by the firm's management

- Copies of forms the FDA issued to the firm during the inspection, including the FDA Form 483

FDA proactively posts inspection reports (FDA Form 483s and EIRs) in the ORA Electronic Reading Room when a high level of public interest is anticipated.[4] Also, FDA may post in the ORA Electronic Reading Room "frequently requested" inspection reports as defined by the Electronic Freedom of Information Act Amendments of 1996. FDA redacts non-public information, such as trade secrets, from the inspection report before posting it.

2. Summary of Public Comments

Several comments from both industry and consumer groups requested that FDA make all inspection reports available online in a timely fashion. Some comments suggested that inspection results should be posted within 24 hours after an inspection of a food facility is completed; another comment requested that FDA inspectional observations be posted and available for review within 30 days of the inspection being concluded. A comment from a consumer group suggested that FDA disclose a summary page of key inspection results after each food facility inspection and noted that this format appeared to be used successfully in another country.

Some comments specifically noted that the reports should only be posted after proprietary information has been redacted. A comment from industry noted that "these inspectional findings help industry to understand the expectations of the agency and are significant tools for industry to ensure that compliance training and programs are in step with FDA." Many comments bemoaned the time it takes to obtain inspection information through the FOIA process.

An industry comment suggested FDA provide additional information about inspection trends and "FDA's concerns that may drive inspectional observations and other citations."

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the firm has responded." However, "[m]ere issuance of the Warning Letter does not close the EIR record, because a Warning Letter is informal and advisory and is not final agency action."

[4] *See* ORA FOIA Electronic Reading Room, *available at* http://www.fda.gov/AboutFDA/CentersOffices/ORA/ORAElectronicReadingRoom/default.htm.

3. Considerations

The Task Force recognizes that disclosing more information about FDA's inspectional findings will be helpful to industry seeking to comply with applicable laws and regulations. In addition, additional disclosures may provide the public with a better understanding of the supply chain for FDA-regulated products and inform decisions, by both consumers and industry, about which firms to purchase products from.

The Task Force considered the risk that the public may draw conclusions about firms based solely on the list of observations from the investigator's report though FDA may conclude that observations noted in a FDA Form 483 do not affect the public health and further action is not required. In addition, the Task Force considered that in FY 2008, FDA conducted approximately 14,800 inspections of foreign and domestic facilities that resulted in the issuance of an EIR. With additional funding, the Agency will conduct more inspections in the future, which will likely result in the issuance of more inspection reports.

The Task Force considered whether the usefulness of the inspection information would diminish if it was not provided in a timely fashion.

4. Draft Proposal(s) for Public Comment

DRAFT PROPOSAL 6:

FDA should disclose the name and address of the entity inspected, the date(s) of inspection, type(s) of FDA-regulated product involved, and the final inspectional classification—Official Action Indicated (OAI), Voluntary Action Indicated (VAI), or No Action Indicated (NAI)—for inspections conducted of clinical trial investigators, Institutional Review Boards (IRB), and facilities that manufacture, process, pack, or hold an FDA-regulated product that is currently marketed. The disclosure of this information should be timed so as not to interfere with planned enforcement actions.

Reasoning: Disclosing information about the findings from establishment inspections increases public understanding about some of the ways FDA works to protect the public health. Disclosure of FDA's determination about the compliance status of establishments provides the public with a basis and rationale for enforcement actions FDA pursues against an establishment.

Public disclosure of this information makes firms accountable not only to FDA, but to the public at large. Disclosure of inspectional classification information may serve as an incentive to firms to correct violations.

Further, other firms are provided with information that will help them make more informed decisions about companies they choose to do business with. If FDA, for example, has concluded that a distributor has had significant objectionable conditions at its facility, this is important information to convey to manufacturers, schools, federal agencies, and other entities that may contract with that distributor. Market pressures may create incentives for firms to correct violations quickly or prevent violations from occurring in the future.

DRAFT PROPOSAL 7:

FDA should generate, and share with the public, information about the most common inspectional observations of objectionable conditions or practices that are made during inspections of FDA-regulated establishments and post that information online on a regular basis.

Reasoning: FDA should disclose summary information about common violations associated with FDA-regulated products; this is a method to provide firms with information that can be used to inform compliance efforts.