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MEMORANDUM

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Re: **FDA Issues Draft Guidance on Refusal of Inspection by Foreign Food Establishments**

The Food and Drug Administration (FDA) recently issued Draft Guidance on its interpretation of what constitutes a refusal of inspection by a foreign food establishment or foreign government. 1/ Though the target audience is foreign food establishments and foreign governments, the Draft Guidance provides insight into FDA's perspective on the legal obligations that apply to all food facility inspections. In particular, FDA describes refusal to permit photography during an inspection as a refusal of inspection. This memorandum provides an overview of the Draft Guidance, including the various actions FDA considers to constitute a refusal of inspection and the repercussions when foreign food establishments or foreign governments refuse inspection. FDA requests that comments on the Draft Guidance be submitted by February 26, 2018. 2/

I. Background

The FDA Food Safety Modernization Act (FSMA) amended the Federal Food, Drug, and Cosmetic Act (FFDCA) to add Section 807(b), which provides that FDA must refuse admission of food into the United States "if it is from a foreign factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, refuses to permit entry of United States inspectors or other individuals duly designated by the Secretary, upon request, to inspect such factory, warehouse, or other establishment." 3/ Section 807(b) also provides that an owner, operator, or agent in charge shall be considered to have refused an inspection if they do not permit an inspection of a factory, warehouse, or other establishment during the 24-hour period after FDA submits an inspection request, or after a time period agreed upon with FDA. With the issuance of this Draft Guidance, FDA is clarifying what additional actions constitute refusal of inspection for purposes of this new statutory provision.

1/ "Refusal of Inspection by a Foreign Food Establishment or Foreign Government: Guidance for Industry," (Dec. 2017), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM586614.pdf.

2/ 82 Fed. Reg. 58410 (Dec. 12, 2017). Comments should be submitted to Docket No. FDA-2017-D-6528.

3/ FSMA § 306.

The Draft Guidance covers inspections of both "facilities" required to register with FDA and farms, using the collective term "establishments" to refer to both types of operations. Although FDA is not required to pre-announce its inspections, its general practice is to contact foreign establishments to schedule the inspection. Before contacting foreign food establishments, FDA sends a written request to the foreign government of the country in which the establishment is located, after which FDA notifies the establishment of its intent to inspect.

II. Refusal of Inspection

FDA explains in the Draft Guidance that it considers a refusal to permit inspection to include statements, actions, and "passive behaviors" that prevent or delay the agency from scheduling or fully conducting an inspection and that are intended to avoid inspection, or are intended to mislead or deceive the FDA investigator. However, FDA generally will not consider minor delays that result from good faith efforts by the establishment to comply with FDA's request to be a refusal of inspection.

A. Refusal of Photographs

Most notably, FDA states that a foreign establishment's or foreign government's refusal to permit FDA to take photographs constitutes a refusal to permit inspection. FDA's inclusion of photography in the Draft Guidance signals that FDA continues to interpret its statutory authorities as providing a right to take photographs. In fact, FDA states in a footnote that failure to permit photography at a *domestic* inspection constitutes a refusal to permit inspection that may result in FDA obtaining an inspection warrant. In support of this latter statement, FDA cites to Section 6-3 of its Regulatory Procedures Manual, which identifies refusal to allow FDA to take photographs as a refusal of inspection and grounds for seeking an inspection warrant.

Although many food companies have longstanding policies that prohibit taking photographs in facilities and take the position that FDA does not have legal authority to take photographs during routine inspections, there are important implications from FDA's statements in the Draft Guidance. As discussed in more detail below, FDA may refuse entry into the country for foods from foreign establishments that refuse inspection, effectively barring them from selling product in the United States. Comparatively, FDA cannot prohibit a domestic establishment that refuses inspection from shipping food throughout the country on those grounds alone. Instead, FDA's remedy would be to bring an injunction or get a warrant forcing the inspection to occur, on the basis that the refusal is a violation of the FFDCA. We are not aware of FDA taking such actions in response to a refusal to permit photographs during a routine domestic facility inspection.

B. Refusals by Foreign Establishments

The following are additional examples of activities by a foreign establishment (including by the owner, operator, or agent in charge) that FDA would consider refusal of inspection:

- Barring the FDA investigator from an area where food is manufactured, processed, prepared, packed, or held. Note that it is not clear whether this extends only to areas where food is manufactured for U.S. shipment, or if it extends to the full facility.

- Refusing to allow the FDA investigator to collect evidence to document potential violations, including collecting environmental samples or other samples relating to observations of insanitation or collecting food labels and labeling (in addition to photographs).

- Refusing or limiting access to records relevant to the inspection, including failing to produce records within the requested timeframe or editing records to remove information relevant to the inspection.

- Not responding to FDA within 24 hours after an initial written inspection request (subject to certain circumstances such as receipt of the request on a non-business day).

- Not agreeing to an inspection start date without giving a reasonable explanation.

- Agreeing to an inspection start date and then requesting a later date without giving a reasonable explanation. However, unforeseen events that prevent an establishment from operating (e.g., severe weather) would not be considered a refusal of inspection, though FDA may require documentation of the event. A request to delay should include the earliest possible date an inspection can be scheduled. For instance, if the inspection must be rescheduled because the establishment is temporarily closed, FDA will expect the establishment to provide the date it will reopen.

- Establishing unreasonable preconditions to allowing the inspection.

- Preventing or interfering with completion of some aspects of the inspection.

- Delaying an FDA investigator from conducting an inspection either before or after entry into the establishment (e.g., leaving the FDA investigator in a conference room or other waiting area for an unreasonable period of time without access to necessary documentation or a responsible individual).

- Not allowing an inspection because of the absence of staff members without a reasonable explanation.

- Limiting observation of the manufacturing process to an unreasonably short period of time.

Though the Draft Guidance focuses on foreign food establishments, it suggests FDA would consider the same actions by a domestic establishment to constitute a refusal of inspection. As discussed above, however, FDA has stronger enforcement authority against foreign establishments that refuse inspection than domestic establishments that may engage in the same activities because of its ability to refuse entry for imports.

C. Refusals by Foreign Governments

In addition to the activities above, the following are some of the key activities by a foreign government that FDA would consider refusal of inspection:

- Denying an investigator entry into the country (e.g., denying a visa) without a reasonable explanation.

- Refusing to allow FDA to schedule an inspection without providing a reasonable alternative date or time.

- Delaying scheduling an inspection without a reasonable explanation for the delay.

- Preventing FDA from entering the establishment.

- Refusing inspection of specific types of food facilities.

III. FDA Import Alert

As discussed above, under section 807(b) of the FFDCA, FDA will refuse admission into the United States for food from a foreign establishment that refuses to permit an inspection. The agency uses Import Alert 99-32 (Detention Without Physical Examination of Products from Firms Refusing FDA Foreign Establishment Inspection) to identify foreign food establishments that have refused an inspection (or whose government refused the inspection). Food offered for import from these establishments is subject to refusal of admission. To be removed from the Import Alert, the establishment needs to request and permit an FDA inspection. FDA cautions that in some situations, it may be at least a year before FDA can return to inspect an establishment that refused and then later requests an inspection.

Where a foreign government has refused an inspection and the government maintains its refusal after further dialog with FDA, the agency will add each foreign food establishment for which the foreign government refused a request to inspect to the Import Alert. FDA will advise the foreign government that it will remove an establishment from the Import Alert when the foreign government provides FDA with written notification that it can schedule and inspect the establishment. If the foreign government sustains its refusal of multiple requests to inspect foreign food establishments in the country, FDA will ask the foreign government if its refusal applies to all establishments in the country. If so, FDA may include all foreign food establishments in the country on the Import Alert.

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We will continue to monitor developments related to FDA inspections and FSMA implementation. Please contact us if you have any questions.