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MEMORANDUM

From: Joseph A. Levitt
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Date: July 13, 2020

Re: COVID-19 Update: FDA Prepares to Resume Domestic Inspections

Dr. Stephen M. Hahn, the Commissioner of Food and Drugs for the Food and Drug Administration (FDA) issued a statement on July 10, 2020, describing the agency's intentions and approach to resuming domestic inspections in light of the COVID-19 pandemic. ^{1/} After temporarily suspending inspections in March 2020, FDA is working toward restarting on-site inspections during the week of July 20, 2020. However, this timeline will depend on the data about the coronavirus trajectory in a given state and locality, and the rules and guidelines that are in place by state and local governments. FDA also notes that, for the foreseeable future, domestic inspections will continue to be pre-announced to FDA-regulated businesses. Note that this announcement is not limited to the food industry, but the impacts for the food industry are the focus of this memorandum.

As background, in March, FDA announced that it would temporarily postpone all domestic routine surveillance facility inspections. ^{2/} Importantly, FDA continued to conduct mission-critical inspections and engaged in alternative forms of review where legally permitted (e.g., remote inspections for the Foreign Supplier Verification Programs regulation). Under this policy, inspections were typically pre-announced.

Since the agency temporarily suspended domestic inspections, it has been monitoring reopening criteria to determine when and where to resume domestic inspections, prioritizing the inspections based on risk and other factors. To ensure investigators have the most up-to-date information on a locality, FDA has developed a rating system to help determine when and where it is safe to conduct prioritized domestic inspections. The COVID-19 Advisory Rating System (COVID-19 Advisory Level) uses real-time data to qualitatively assess the number of COVID-19 cases in a local area based on state and national data. The COVID-19 Advisory Level data will also be available to the state partners who conduct inspections on FDA's behalf under contract.

^{1/} FDA Statement, *Coronavirus (COVID-19) Update: FDA prepares for resumption of domestic inspections with new risk assessment system* (July 10, 2020), available at <https://bit.ly/328mczE>.

^{2/} See *HL Memo - COVID-19 Update: FDA Temporarily Postpones Routine Domestic Inspections* (March 19, 2020), available at <https://bit.ly/2W6TsDQ>.

The COVID-19 Advisory Level is based upon three metrics:

1. The “Phase of the State”; ^{3/}
2. Statistics measured at the county level to gauge the current trend; and
3. Statistics measured at the county level to gauge intensity of infection.

FDA will identify the appropriate regulatory activities that can occur within the given geographic region based on these three metrics and other issues or services affecting a region (e.g., availability of public transportation). There are three main categories of regulatory activities (i.e., types of inspections) that can occur at the county level:

- Mission critical inspections only;
- All inspections with caveats to help protect staff who have self-identified as being in a vulnerable population; and
- Resumption of all regulatory activities.

In order to move to the next less restrictive category for types of inspections, FDA must see downward trends in new cases of COVID-19 and hospitalizations in a given area.

Finally, FDA states: “for the foreseeable future, **prioritized domestic inspections will be pre-announced to FDA-regulated businesses.**” FDA explains that pre-announcing inspections will help ensure safety for FDA and the regulated establishment, as well as ensuring the appropriate staff are on-site to assist FDA staff with inspection activities.

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We will continue to monitor the impacts on the food industry from COVID-19. Should you have any questions or if we can be of assistance with your COVID-19 response strategy, please do not hesitate to contact us.

^{3/} As defined by the White House Guidelines for Opening Up America Again (2020), available at <https://www.whitehouse.gov/openingamerica/>.