Consultants Update

COVID-19

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Discussion Topics

- COVID Related FDA/OSHA Guidance – Checklists
- FDA Implementation of Manufacturing Volume Data Reporting Requirements under CARES Act Section 3112(e)
- Food Registration – New DUNS requirement

FDA/OSHA COVID Guidance

8/19/2020

To assist the food industry as it navigates changes to operations related to COVID-19, the FDA has teamed up with OSHA to develop the "Employee Health and Food Safety Checklist for Human and Animal Food Operations During the COVID-19 Pandemic." The checklist pulls from existing guidance provided by the FDA, CDC, and OSHA and serves as a quick reference to help the food industry assess employee health, social distancing, and food safety within workplaces as operations may be impacted by COVID-19.

FDA/OSHA COVID Guidance

Employee Health and Social Distancing Checklist

This 16 page checklist includes considerations for:

- Employee health
  - General
  - Facilities
  - All Personnel
  - For persons who are symptomatic or develop symptoms at work
  - Employee Exposure Investigation & Testing
  - Work Environment Configuration
- Food Safety
  - Food Safety Plan/Hazard Assessment
  - Personnel
  - Suppliers and Incoming Ingredients
  - Current Good Manufacturing Practice (CGMP) Requirements
- 37 Resources – CDC, OSHA, FDA, EPA

FDA/OSHA COVID Guidance - Sample

Employee Health and Food Safety Checklist for Human and Animal Food Operations During the COVID-19 Pandemic *continued*

For persons who are symptomatic or develop symptoms at work:	
☐	Are procedures in place that require symptomatic workers to stay home or go home if they develop symptoms during the work day [6, 9]?
☐	Are procedures in place to physically isolate a symptomatic person from others, including identifying a designated isolation area, prior to the sick person being transported from the facility [9, 20]?
☐	Are procedures in place to provide alternate transportation in a manner that does not expose others if an employee that develops symptoms arrived via shared transportation [5]?
☐	Are procedures in place to collect information about the sick person's contacts (up to 2 days prior to symptom onset) to identify other workers who could be considered exposed (e.g., people who were in close contact with [less than 6 feet from] the symptomatic worker for at least 15 minutes)? (A close contact is defined in CDC's Public Health Guidance for Community-Related Exposure [24].)
☐	Are procedures in place to inform fellow workers of their possible exposure to COVID-19 when a sick person is confirmed infected (maintaining confidentiality as required by the Americans with Disabilities Act [20, 21])?

FDA/OSHA COVID Guidance - Recommendation

- Download the guidance document from GAWDA, FDA or OSHA
- Review the guidance for applicability to your current business continuation plan
- Make changes, as needed

FDA Implementation of Manufacturing Volume Data Reporting Requirements under CARES Act Section 3112(e)

8/24/2020

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FDA Implementation of Manufacturing Volume Data Reporting Requirements under CARES Act Section 3112(e)

This communication is to clarify the timing of FDA's implementation of new reporting requirements for manufacturing volume data under section 3112(e) of the Coronavirus Aid, Relief, and Economic Security (CARES) Act. The effective date of these requirements - September 23, 2020, which is 180 days after the CARES Act was enacted - is the earliest the FDA is authorized to begin collecting these data. The FDA does not intend to begin this collection until it is able to do so through an electronic data submission portal, which will not be ready by September 23.

The CARES Act includes authorities that enhance FDA's ability to identify, prevent, and mitigate possible drug shortages by, among other things, enhancing FDA's visibility into drug supply chains. Specifically, section 3112(e) amends the Federal Food, Drug, and Cosmetic Act to require that each registered drug establishment annually report the "amount of each drug . . . that was manufactured, prepared, propagated, compounded, or processed" by the registrant for commercial distribution. This CARES Act amendment also provides that such "information may be required to be submitted in an electronic format."

FDA staff are working to define the data to be reported, create an electronic portal for the submission of this information, and determine when to begin collecting this information. We will provide further updates as our implementation planning continues.

CARES Act – Data Collection

- We are working with CGA and FDA to
  - make this appropriate for medical gases
  - or exempt the reporting requirement
- Action needed?
  - None right now
  - If the reporting is clarified and the portal is created, then we will let you know how to comply

Food Registrations

- Even numbered years – 10/1 to 12/31
- All food manufacturing and warehousing locations
- New requirement – DUNS numbers
- Also, remember - Attestations

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