

Consultants Update

COVID-19

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December 2, 2020

Discussion Topics

- FDA Update – Food Gas Registration
 - New DUNS Guidance
 - Registration Definitions
 - Retail exemption
- Settled Pressure Test
- Production/Distribution Capacity

FDA Food Registration – DUNS Number







- DUNS number required in 2020's Food Registration
- Formerly FDA DUNS Portal ... now contact D&B directly:
 - Phone at 866-705-5711
 - Website <http://www.dnb.com/duns-number.html>
- DUNS delays??? Use “PENDING” for the DUNS number
- 90 day extension... cancellation
- Registration deadline is 12/31/2020
- New FDA Guidance - <https://www.fda.gov/media/143997/download>

FDA Food Registration Definitions

- **Different from FDA drug registration definitions**
- **“Manufacturer” – filling cylinders, containers, trucks**
- **Ambient Food Storage Warehousing – storing cylinders, containers, etc.**
- **Not for gases:**
 - **Repacking**
 - **Refrigerated warehousing**

FDA Food Registration Definitions

Section 9a: General Product Categories - Food for Human Consumption; and Type of Activity Conducted at the Facility

To be completed by all food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 37	Ambient Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	Refrigerated Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks)	Frozen Food Storage Warehouse / Holding Facility (e.g., storage facilities)	Acidified Food Process or	Low-Acid Food Process or	Interstate Conveyance Caterer / Catering Point	Contract Sterilizer	Labeler / Relabeler	Manufacturer / Processor	Packer / Repacker	Salvage Operator (Reconditioner)	Farm Mixed-Type Facility	Other Activity Conducted (Please Specify)
15.FOOD ADDITIVES, GENERALLY RECOGNIZED AS SAFE (GRAS) INGREDIENTS, OR OTHER													

FDA Food Registration – Retail Exemption

- **If more than 50% of food gas sales are to consumers**
 - **No registration is needed**
- **Consumers**
 - **End user**
 - **Not bars, restaurants, businesses**

Settled Pressure Test

- **Useful operations management tool**
 - **SOP and forms available**
- **Not required by DOT or FDA since 2004**
 - **FDA requirement – cylinder/container has the correct labeled contents (liters/cf)**
- **Tolerance is +/- 3%, per CGA P-77, *Standard For Filling Nonliquefied Gases In DOT/TC Specification Cylinders To A Specified Settled Pressure***

Production/Distribution Capacity

- **Pandemic – Operations/Asset Management**
 - ***CGA SA-35, Safety Alert, Cleaning of Cylinders Returned from Health Care Facilities During a Pandemic***
 - ***CGA SA-36, Safety Alert, Cylinder and Cryogenic Container Issue Related to Cylinder Conversion and Filling During the COVID-19 Crisis***
 - ***CGA M-14, Guideline for Bulk Liquid Oxygen and Bulk Liquid Nitrogen Trailer Change of Grade***
 - ***M-14.1, Bulk Trailer Change of Grade Validation Protocol***
- **GAWDA sample procedures and deviations**

Contact Info

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