Consultants Update

COVID-19

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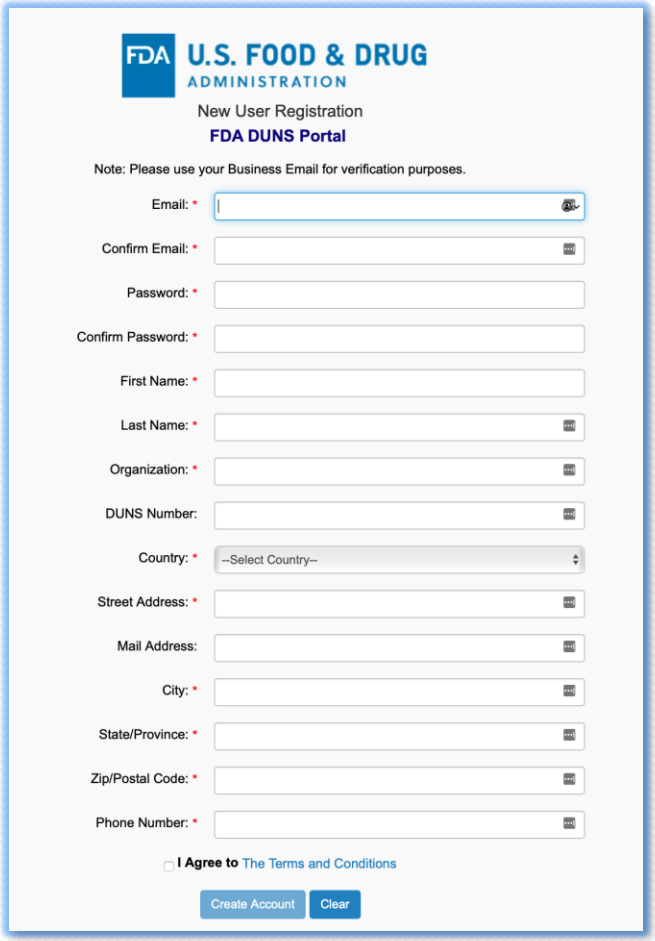
Discussion Topics

- FDA Update – Food Gas Registration
- Cannabis oil contamination
- Emergency Use Oxygen
- Annual Records Review

FDA Food Registration

- **New requirement for DUNS numbers … Registration**
  - **Production locations**
  - **Warehouse locations**
  - FDA message…
    - In accordance with 21 CFR 1.232(a)(2), effective October 1, 2020, all facilities must include a unique facility identifier (UFI)... FDA recognizes the Data Universal Numbering System D-U-N-S (DUNS) number as an acceptable UFI. DUNS numbers are assigned and managed by Dun & Bradstreet and is available free of charge. Please visit the FDA DUNS Portal at https://fdadunslookup.com/ in order to obtain or verify your DUNS number.
- **Attestation renewals**
- **Deadline 12/31/2020**

FDA DUNS Portal



CGA PS-64 – Cannabis Oil Contamination

- **CGA PS-64 – recently published**
  - **“Handling Carbon Dioxide Cylinders Previously Used In Cannabis Extraction Or With Food Products Containing Cannabis”**
- **Carbon Dioxide used in oil extraction**
- **Cylinders could become contaminated if oil backs up into your cylinder**
  - **Personnel and food safety risks**
  - **HARPC to assess and establish preventive controls**
- **Follow CGA G-6.3 for suggested mitigation strategies**

Emergency Use Oxygen

When can I sell medical oxygen without a prescription?

- **Used for oxygen deficiency and resuscitation**
- **Must have the "emergency use" statement on the label**
- **Evidence of current training**
  - **Use of emergency oxygen including providing oxygen to both breathing and non-breathing patients, and safe use and handing of emergency oxygen equipment.**
  - **Training may be obtained from any nationally recognized professional organization, such as the National Safety Council, the American Heart Association, the American Red Cross, etc.**

What training courses/certifications would qualify a person to buy medical oxygen for emergency use?

- American Safety and Training Institute (ASTI)
  - Emergency Oxygen Administration/Bloodborne Pathogens
- American Red Cross
  - Emergency Oxygen Administration
- American Safety and Health Institute (ASHI)
  - Emergency Oxygen

- S.C.U.B.A. divers who hold a valid certificate in the following nationally recognized S.C.U.B.A. diving certifying organization programs may purchase, possess, and use medical oxygen for the purpose of emergency care or treatment at the scene of a diving emergency:
- Diver alert network (DAN):
  - Oxygen first aid for scuba diving injuries;
- International association of nitrox and technical divers:
  - Oxygen provider course;
- Professional association of diving instructors (PADI):
  - Emergency first response;
  - Oxygen first aid;
  - Rescue diver course;
  - Tec deep diver;
- Scuba schools international:
  - Medic first aid emergency oxygen administration;
- Technical diving international-S.C.U.B.A. diving international:
  - Diver advanced development program as a CPROX administrator;
- National association of underwater instructors (NAUI)
  - First aid;
  - Rescue scuba diver;
  - Advanced rescue scuba diver;
  - First aid instructor;
  - Oxygen administration; and
  - Instructor
- YMCA:
  - SLAM rescue;

Annual Records Review

21 CFR Subpart J-Records and Reports - 211.180(e) General requirements.

(e)Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. Written procedures shall be established and followed for such evaluations and shall include provisions for:

(1) A review of a representative number of batches, whether approved or rejected, and, where applicable, records associated with the batch.

(2) A review of complaints, recalls, returned or salvaged drug products, and investigations conducted under § 211.192 for each drug product.

Annual Records Review

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Annual Records Review **Product:** _____

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1. Were records found to be readily accessible?

   Yes _____ or No _____

2. Which batch production and control records were reviewed?

   _____

   _____

3. Which Lot Distribution and Shipping Records were reviewed?

   _____

   _____

4. Were the critical equipment validation status, changes (MOC), complaint file, recalls, investigation and deviation records reviewed?

   Yes _____ or No _____

5. Are changes needed in drug product specifications or manufacturing or control procedures to ensure processes remain in control?

   Yes _____ or No _____

6. Enter the date and name of the person conducting the Annual Records Review:

   _____ _____

   Date Name (signature)

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Contact Info

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