

Q – When is carbon dioxide a drug, device, food or industrial gas?

A – The same carbon dioxide can be controlled under various regulations. And the production and quality records/procedures may be different, depending on the application.

Here are the definitions the FDA generally uses to determine how to classify a substance.

Food means:

- Articles used for food or drink for humans or animals;
- Chewing gum;
- Articles used for components of any such articles.

Food additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food

Drug means:

- Articles recognized in the United States pharmacopoeia and national formulary, or any supplement to them;
- Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;
- Articles, other than food, intended to affect the structure or any function of the body of humans or other animals;
- Articles intended for use as a component of any of the foregoing articles, other than devices or their components, parts, or accessories.

Device means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is any of the following:

- Recognized in the United States pharmacopoeia and national formulary, or any supplement to them;
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans or animals;
- Intended to affect the structure or any function of the body of humans or animals, and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or animals and is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

Let's look at some potential applications for carbon dioxide:

| Application | Classification |
|---|-----------------------|
| • Carbon dioxide used to run an industrial laser | Industrial Gas |
| • Carbon dioxide used to run a medical laser | Device Gas |
| • Carbon dioxide used to inflate a body cavity for surgery or inspection | Drug Gas |
| • Carbon dioxide used to make a drug mixture (e.g. 5% CO ₂ /O ₂ | Drug Gas |
| • Carbon dioxide used in a soft drink | Food Gas |
| • Carbon dioxide in a 25% mixture for beer gas | Food Gas |
| • Carbon dioxide used in a "Clinical Blood Gas" mixture | Device Gas |
| • Carbon dioxide used to make a medical "Anaerobic Mixture" | Device Gas |
| • Carbon dioxide used to make a medical "Aerobic Mixture" | Device Gas |

When on doubt, ask the customer to define the intended use in a letter on their letterhead.