| GAWDA | Medical Gas Update |
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| 6 July 2015 | ***FDA's Report to Congress*** |

**Medical Gas Update** – ***FDA files a Report to Congress regarding Updating Regulations for Medical Gases***

**Quick History**

The Medical Gas Safety Act was incorporated into "The Food and Drug Administration Safety and Innovation Act" (FDASIA). The President signed FDASIA into law on July 9, 2012 and it gave the FDA authority to continue operating. Just five of 140 pages covered medical gases. The medical gas portion of FDASIA was the result of years of work from Mike Tiller, CGA President, and CGA's Medical Gas and Regulatory Policy Committee (MGRP).

The medical gas portion of FDASIA had three key provisions. It:

1. created a process whereby designated medical gases were deemed to be "approved"
2. eliminated User Fees for designated medical gases
3. Instructed the FDA to "determine whether any changes to the Federal drug regulations are necessary for medical gases" and make any such changes to the regulations by a certain date

The FDA was to report back to Congress by January 9, 2014.

The FDA held several public meetings where GAWDA and CGA provided specific information about the many drug regulations that are clearly not appropriate for medical gases. CGA also published M-15-2014, *Standard for Appropriate and Effective Regulations for Medical Gases within 21 CFR Parts 201, 205, and 210/211.* CGA M-15 and its companion CGA PS-42, detail the regulatory changes needs and the rationale for those changes. Even though the agency seems to agree with our positions, it is apparently very difficult for the FDA to change regulations.

**Recent Actions**

In response to pressure CGA exerted via language added to a draft appropriations bill in Congress, last month the FDA finally responded to Congress about the necessity of revised medical gas regulations. Predictably, their report states that while some small changes might be useful, the existing "regulatory framework" is adequate. The following paragraph from the Report to Congress summarizes their position:

> "Following extensive deliberation, FDA has determined that although some regulation changes are necessary to implement the medical gas labeling provisions contained in FDASIA, the current regulatory framework is adequate and sufficiently flexible to appropriately regulate medical gases. Although the current regulatory framework applicable to drug products is not a perfect fit in all respects for medical gases, FDA's experience regulating these products over many years supports our conclusion that we can continue to work within this framework to appropriately regulate these products. In addition to the applicable regulations, FDA relies on guidance documents, development of appropriate inspection practices and inspector training, and interaction with industry trade associations, state regulators, and other stakeholders on an as-needed basis in regulating medical gases."

The agency's statements that our industry actually performs better during inspections than other drug manufacturers support this position:

> FDA inspections of the medical gas industry have resulted in a lower rate of cited violations than occurs in the drug industry generally, particularly in recent years. Overall, this inspection history has resulted in a lower regulatory burden on medical gas firms than on many other drug manufacturing firms with regard to inspections (e.g., medical gas firms are inspected less frequently than many other types of drug manufacturers)

We had hoped the agency would agree that specific medical gas regulations are needed. Even though the agency has disagreed with our position in their Report to Congress, we continue to work with key individuals in the agency on issues to help them understand what is appropriate for medical gases.

So, for now, no CGMP regulations are intended to change. We continue to operate under regulations, guidance, draft guidance and enforcement discretion to produce medical gases. After many years of working with the FDA, we generally understand what the agency enforces (until some inspector enforces something else).

If you experience an FDA or state inspection where a new or unusual item or an item inconsistent with CGA M-15 or PS-42 is being enforced, please contact Tom Badstubner (tom@asteriskllc.com). We will work with you to identify potential solutions and help the FDA to be consistent in their application of the rules and industry's published positions. Also, if you would like the full text of FDA's Report to Congress, let Tom know.

Please direct questions to:

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