Medical Gas Regulation – Public Workshop II – February 9, 2018

FDA Questions for Consideration by Stakeholders

Stakeholders are invited to provide their thoughts on the questions below during the workshop, or via written comments submitted to the docket within 90 days after the workshop. For instructions on submitting comments, please see the *Federal Register* notice announcing the medical gas public workshops, *Medical Gas Regulation; Announcement of Public Workshops* (82 FR 54353, Nov. 17, 2017; available at https://www.gpo.gov/fdsys/pkg/FR-2017-11-17/pdf/2017-24918.pdf).

Post-Market Reporting of Adverse Drug Experiences Related to Medical Gases

1. a) In your view, what information should FDA require to be reported regarding adverse drug experiences, including adverse reactions and medication errors, related to medical gases? See, e.g., 21 CFR 314.80, 21 CFR 514.80, and 21 CFR 310.305.

   b) In your view, what information on adverse drug experiences would provide the most value to FDA as an indicator of a potential safety issue related to medical gases?

   c) In your view, who should be responsible for reporting this information?

   d) What is your view regarding how soon (e.g., number of days) non-expedited individual case safety reports (ICSRs) should be submitted and how often periodic adverse drug experience safety reports (PADERS) should be submitted?

2. In your experience, what challenges do the medical gas industry, patients, and health care providers face with regard to reporting information about adverse drug experiences related to medical gases? What regulation changes and/or other actions (e.g., guidance to industry) do you believe could address these issues?

3. a) If FDA becomes aware of adverse drug experiences regarding a particular medical gas and, after review, determines that there is a safety issue that should be addressed, what do you think would be the most effective and efficient way to communicate that information to (1) manufacturers, and (2) other stakeholders, such as healthcare providers and patients (e.g., a letter to healthcare providers; a drug safety communication or other public announcement; an FDA webpage dedicated to medical gas information that could be referenced by providers and/or the public)?

   b) If FDA were to determine that a medical gas safety issue warranted a labeling change, how could those changes be implemented (e.g., adding an informational sticker to the existing labeling on each container; requiring a new permanent label; other)?

Other Post-Market Reporting

4. Regarding periodic reporting required for approved drug products (see, e.g., 21 CFR 314.81 annual report requirements), what information should FDA require to be reported regarding medical gases? What is your view regarding how soon and how often FDA should require this information to be reported? Who should be responsible for reporting this information?

Certification, Registration, and Listing

5. In your view, are there any issues with or additional clarifications needed for the current certification process for designated medical gases?

   A copy of the current revised draft guidance for industry, *Certification Process for Designated Medical Gases*, is available at https://www.fda.gov/downloads/drugs/guidances/ucm332136.pdf .

6. In your view, are there any issues with or clarifications needed for the current registration and listing process for medical gases?

Use of Medical Gases in Animals

7. What issues, if any, have you observed with respect to the use of medical gases in animals that you would like FDA to consider?

Other Issues

8. What additional issues, if any, have you observed with respect to medical gases that, in your view, should be addressed by regulation and/or clarified in future guidance? Please explain.