Medical Gas Regulation – Public Workshop I – December 15, 2017

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).

1. In your view, what are the minimum regulations required to ensure quality manufacturing of medical gases? For example, if FDA were to issue a new section of regulations specific to medical gas current good manufacturing practice (CGMP), what provisions should be included?

2. In your view, should medical gas regulations be specific to the type of manufacturer (e.g., air separation unit vs. transfiller vs. chemical synthesizer), or general to all medical gas manufacturers?

3. In your view, what aspects of medical gas labeling that are not already covered in the current regulations should be covered to ensure appropriate labeling? What aspects that are currently covered should not be covered or should be addressed differently?

4. For questions 1-3, above, please elaborate. Why are particular regulations needed? Why it is your view that identified issues need to be addressed in regulation rather than by non-rulemaking measures, such as clarification in guidance to industry?

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

6. What additional issues have you observed with respect to medical gases that, in your view, should be addressed by regulation?