QUESTIONS FROM MEMBERS AND FDA'S ANSWERS

1. We would like to know if FDA will be taking any additional steps in 2016 to incentivize device companies to participate in the program. I received a quote from our notified body, and learned that switching to an MDSAP audit for our small company, adding only the FDA requirements to our current 13485, CMDCAS, and EC certification would double our audit days and increase costs by approximately $12,000/year.

Making the program more attractive to manufacturers (especially small manufacturers) without reducing its reliability has been the topic of quite a bit of discussion amongst the five participating regulatory authorities as well as the participating auditing organizations (currently limited to CMDCAS registrars).

For example, we are currently working with the participating auditing organizations on a project to reassess the specific audit tasks needed to conduct initial certification, surveillance (two per certification cycle), and re-certification audits. Our goal is to "tighten up" the currently defined audit process without jeopardizing the robustness of the process. The most likely time savings will occur within surveillance audits. If this exercise is successful, a reduction in on-site audit time should result in a reduction in overall audit costs.

2. When will the GUDID be made available to Class II labelers?

The GUDID will open to Class II labelers on February 1, 2016. Labelers of Class III or I/LS/LS devices who already have a GUDID account may submit their Class II data immediately.

We'll be presenting a UDI Industry Basics webcast on January 27, 2016. It's directed primarily towards Class II labelers, and we'll have a section on opening accounts. More information may be found here:

http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm480237.htm