Improved Device Inspection Process

The FDA Reauthorization Act of 2017, FDARA, changes the device inspection process. Section 702 has three sets of requirements: standard inspection process, guidance documents for the process, and inspection refusal.

FDA is to review the processes for “other than for cause” and adopt uniform processes and standards for these inspections. The standards include:

- Appropriate exceptions
- Announcing the inspection a reasonable time before it start
- A notification of the type and nature of the inspection
- A reasonable estimate of the inspection’ timeframe
- Advance notice of some records that will be requested, to the extent feasible
- Regular communications about the inspection’s status, “which may be recorded by either party with advance notice and mutual consent”

FDA will prepare draft guidance documents by one year of the enactment date that:

- Specify how FDA will implement the inspection process
- Provide for standard communication methods
- Provide a standard timeframe for inspections
- Identifies practices to facilitate the continuity of inspections over consecutive days
- Identifies practices to facilitate the continuity of inspections

FDA will issues the final guidance documents within one year of the notice for public comments on the draft guidance documents.

A device is now considered adulterated, just as a drug, if the manufacturer refuses entry or an inspection.