Good Guidance Practices

SLIDE 1
This presentation will address guidance documents.

SLIDE 2
FDA issues guidance documents in an attempt to be helpful to people -- to give more information on how people might be able to comply with FDA requirements. Guidance documents are one way that people can comply with existing requirements, but other ways also may be acceptable. People are always encouraged to talk with FDA if they might not want to do something that is in a guidance document.

SLIDE 3
FDA regulations contain information on how FDA develops and issues guidance documents.

SLIDE 4
There are two levels of guidance documents: Level 1 and Level 2. Level 1 guidance documents are the more significant ones: for example, first interpretations of a regulation, or guidance addressing highly controversial issues.

Usually, for a Level 1 guidance document, FDA will issue a Notice of Availability in the Federal Register. FDA will look at all the comments.

SLIDE 5
There is an exception when FDA might not issue a level 1 guidance as a draft, and that would be when it finds that prior public participation is not feasible or appropriate. An example of that might be where there was a public health emergency, and FDA needed to get something out quickly. FDA would still take comments, consider them, and consider whether the guidance document needed revision.

SLIDE 6
Level 2 guidance documents set forth FDA's existing practices or minor changes in interpretation of policy. FDA does not do a Notice of Availability in the Federal Register, but does post these documents on the FDA website.

FDA has a LISTSERV that the public can sign up for. When new information is put on the website, it is then sent to those who have subscribed.

SLIDE 7
This slide contains additional information about Level 2 guidance documents.

SLIDE 8
Sometimes when doing a guidance document, FDA realizes the need for additional information. So, FDA may have additional discussions at workshops or advisory committee meetings, to get more information before issuing a draft or final guidance.

SLIDE 9
FDA is often asked: Where are you with the final guidance? And what will it say?

FDA is precluded from talking about the specific contents of the guidance being worked on, while it is being worked on, because it would create an unlevel playing field. That does not mean, however, that FDA cannot talk at all about issues that might be covered in a guidance document that is under development. That is one of the areas where there has been some confusion.

SLIDE 10
Once a draft guidance is issued, FDA can talk generally about issues, but cannot discuss what the final guidance would say.

Slide 11
This concludes the presentation, "Good Guidance Practices".

We would like to acknowledge those who contributed to its development. Thank you!