

From: Matsuoka, Karen Y.

Sent: Monday, March 16, 2009 3:41 PM

To: 'Berbakos, Elizabeth G'

Subject: RE: Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices

Thanks, Liz. In the future, please ensure that the guidance documents are submitted through ICRAS/ROCIS (with the "associated with other documents" box checked to prevent public disclosure).

The guidance is dated "January 2009." Does this mean the paperwork requirements are already in effect?

Also, can you send me a list of comments that FDA received regarding this guidance document?

Thanks.

Karen

From: Berbakos, Elizabeth G

Sent: Monday, March 16, 2009 2:46 PM

To: Matsuoka, Karen Y.

Subject: RE: Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices

[Karen, here is the guidance....](#)

From: Matsuoka, Karen Y.

Sent: Friday, March 13, 2009 7:24 PM

To: Berbakos, Elizabeth G; Capezzuto, JonnaLynn; Presley, Denver

Subject: Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices

Hi everyone. I don't see the guidance that this ICR is associated with. Did you upload it into ICRAS/ROCIS? Can you email it to me? Thanks. – Karen