1) The PRA requires agencies to solicit comment on, among other things, "ways to enhance the quality, utility, and clarity of the information to be collected."

A -- Wyeth specifically requested clarification on reporting option IV.C. (see page 5).

B -- Wyeth also suggested that the utility of the information collection could be improved—and burden reduced—if FDA were more clear about why FDA decided to adopt any particular standard. I quote: "We believe that recognition of a standard by publishing in the FR does not appropriately communicate revisions or updates to the standard and places an undue burden on the application holder to identify and assess each change. Communication of this information is necessary for the application holder to make a timely and accurate assessment of the label, determine if a labeling update is needed, provide justification for not making a label change, or justification to accept an alternate standard."

"Determine if a labeling update is needed" is burden associated with option IV.C. "Provide justification for not making a label change" is IV.C.

2) The PRA requires agencies to solicit comment on the "accuracy of FDA's estimated burden..."

Hospira indirectly commented on the burden associated with assessing which reporting option (including the option of not changing the labeling at all). Hospira does not cite IV.C., but it is clearly implied. The comment reads as follows:

"The process for the evaluation of the published standards would first include an assessment of the changes to determine whether the published standards should be accepted (approach IV.B.1) or whether the applicant chooses to maintain the current standard used in their application or another standard not recognized by the Agency (Approach IV.B.2). Either scenario would most likely exceed the 60 days suggested by the Agency...."

Again, Hospira does note cite IV.C. but the "or whether the applicant chooses to maintain the current standard used in their application" is option IV.C. Therefore, it is relevant to this collection.

3) The PRA requires agencies to solicit comment on "ways to minimize the burden of the collection of information on respondents..."

Almost every commenter said that it is burdensome to have to keep searching the FR to see if FDA published updated standards. Since learning about the FR notice is the trigger for any of the 3 reporting options—including IV.C—this is a relevant comment. In fact, Merck specifically identifies this comment as pertaining to option IV.C: "The Draft Guidance seems to suggest that marketing application holders will learn about and react to recognized standard when published in the FR. A described in the Draft Guidance, we believe that is a reversal of the process. It would be a significant burden to mobilize internal resource to put together and submit a labeling supplement to meet the 60 [calendar] day deadline form publication of a recognized standard. We believe a more direct process would be for the agency to first notify appropriate antibacterial application holders with sufficient time to respond prior to FR publication."

These commenters suggested a specific alternative. FDA should address the alternative.

4) Comments regarding the information collection requirements but covered under different ICRs

These comments should be acknowledged and the response should be something to the effect that they are covered under different OMB control numbers. To the extent that the comments suggest that the burden estimates for those ICRs are not accurate or the utility of those ICRs could be improved, FDA should state that FDA will revise the estimates or improve the utility of those ICRs when they next come up for renewal.