

The KFDA is interested in using the Proposed Rule issued on April 26, 2004 as a reference for Korea.

- In particular, we think the sampling method can serve as a good reference for us in managing our own sampling regime.

Regarding the sampling services provision in part C. *Proposed Subpart C operations*, which describes only six general requirements, the KFDA is of the view that the provision is too general to give a full and detailed explanation on sampling operations.

- Therefore, please let us know if the proposed six general requirements are detailed enough for successful implementation of the proposed sampling method, or if the FDA will require a private laboratory to set more detailed rules on the sampling method, or if the FDA itself will make a detailed guideline for the sampling method.

We also request that the FDA let us know about various sampling methods that were explored in preparing the sampling methods of the Proposed Rule, and if possible, that the FDA send us a copy of the various sampling methods explored.

It is our understanding that the provision *D. Proposed Subpart D-Requirement for Private Laboratories* omits the laboratory accreditation requirement. Please let us know if private laboratories will be required to receive certification such as accreditation, by the FDA or whether the FDA will mandate private laboratories to register with the FDA.