

## **FDA Questions to the Panel**

1. Do you believe that General Controls are sufficient to provide a reasonable assurance of safety and effectiveness of the rapid influenza detection devices?
2. If you believe that General Controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device, do you believe there is sufficient information to establish Special Controls to provide reasonable assurance of the safety and effectiveness of the devices?
3. Do you agree that the proposed Special Controls are sufficient to mitigate the risks associated with rapid influenza detection devices?
4. Do you recommend that rapid influenza detection test systems currently regulated as Class I devices should be reclassified into Class II?
5. Do you agree that the Special Controls for the Respiratory Viral Panel regulation (21 CFR 866.3980) should be amended to add an annual monitoring requirement for any influenza device in a multiplex format?