FDA Questions to the Panel

General Hospital and Personal Use Devices Panel

Medical Device Supply Chain Resiliency and Shortages & 506J Device List

February 6, 2024

1. Do the device types (by product code) on the proposed 506J Device List meet the requirements for a critical device as outlined in section 506J of the FD&C Act?
    a. Are there device types (by product code) on the proposed 506J Device List that are not critical to public health during a public health emergency and should be removed from the list?
    b. Are there device types (by product code) that are not on the proposed 506J Device List that are critical to public health during a public health emergency and should be added to the list?
    c. What additional devices would be needed for national emergency preparedness?

2. How should supply chain resilience and vulnerabilities be considered when determining device types (by product code) for inclusion or exclusion on the 506J Device List?

3. How should the following device types be addressed with regard to the proposed 506J Device List?
    a. Single-use disposable vs. multi-patient reusable devices
    b. Convenience kits
    c. Capital equipment (e.g., imaging devices)