ALERTS AND UPDATES

FDA: Processing and Reprocessing Medical Devices in Healthcare Settings

May 4, 2011

On May 2, 2011, the U.S. Food and Drug Administration (FDA) issued a Draft Guidance for Industry and FDA Staff on "Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" ("Draft Guidance"). To ensure FDA's consideration prior to final drafting, comments should be submitted by August 1, 2011.

In light of increasing technological and scientific advances in reprocessing reusable medical devices, the Draft Guidance details the FDA's current view on the content of and review procedures for premarket notification submissions under section 510(k) of the federal Food, Drug, and Cosmetic Act (FD&C Act); premarket approval applications; humanitarian device exemption applications; and investigational device exemption applications concerning the labeling instructions for reprocessing reusable medical devices. The recommendations generally apply to three device-reprocessing situations:

1. Reusable medical devices supplied as sterile to the end-user and requiring the end-user to process the devices after initial use and prior to subsequent use;
2. Reusable medical devices supplied as non-sterile to the end-user and requiring the end-user to disinfect or sterilize prior to initial use and to reprocess after initial use; and
3. Single-use medical devices supplied as non-sterile and requiring the end-user to sterilize prior to use.

The Draft Guidance sets forth the FDA's process for the review of labels containing reprocessing instructions. The FDA will review the label during the premarket submission process and will require that all validations for cleaning, disinfecting and sterilization procedures occur prior to submission of the premarket application. Reprocessing instructions should include the seven items identified in the Draft Guidance:

1. The device's intended use;
2. Notice that users should thoroughly clean the device;
3. The appropriate microbicidal process;
4. Technically feasible reprocessing recommendations;
5. Only devices and accessories that are legally marketed;
6. Comprehensive instructions; and
7. Understandable instructions.

Additionally, the Draft Guidance identifies the FDA's recommendations on validating the processes for cleaning reusable medical devices. Pursuant to these recommendations, cleaning methods should be established through a two-step process: (1) developing the cleaning process, instructions and disassembly; and then (2) conducting validation studies to confirm the efficacy of the process and labeling instructions. The recommendations also appear to suggest that the validation studies should include "worst-case" scenarios and be based on comprehensive validation protocols using soils that are clinically relevant to the device.

In premarket submissions, the premarket application and humanitarian device exemption applications should submit a complete report of the validation studies in the manufacturing and design section, and the 510(k) notification submission should include validated labeling instructions for reprocessing. However, investigational device exemption applications need only include a summary of the validation of the reprocessing instructions.

The FDA is also hosting a public workshop on "Reprocessing of Reusable Medical Devices," to be held on June 8–9, 2011. Additional information on the public workshop and registration may be found at www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm252205.htm.

For Further Information

If you have any questions about this *Alert*, please contact Frederick R. Ball, any member of the Pharmaceutical, Pharmacy & Food industry group or the attorney in the firm with whom you are regularly in contact.