ALERTS AND UPDATES

FDA: Liquid OTC Drugs with Poorly Labeled Measuring Devices May Constitute Misbranding

May 10, 2011

The FDA issued its final guidance relating to over-the-counter liquid drug products that are sold with measuring devices, such as spoons, cups or droppers. The FDA's guidance was prompted by reports of accidental overdose, many of which were attributed partly to poorly labeled dosage delivery devices. Manufacturers of such products should be aware that failing to issue proper labeling on the dosage delivery device may constitute misbranding under section 502 of the Federal Food, Drug, and Cosmetic Act ("the FD&C Act").

Between 1991 and 2008, the FDA has made numerous efforts to ensure proper patient dosing of liquid OTC drugs: The FDA has encouraged patients to use the dosage delivery devices provided with the product and has encouraged drug companies to provide accurately labeled delivery devices. In order to further facilitate compliance, the FDA's guidance lists a number of nonbinding recommendations:

- A liquid formulation should include a dosage delivery device;
- The dosage delivery device should be calibrated with the same units as specified on any outside packaging or written instructions accompanying the product;
- The dosage delivery device should use the same abbreviations as used on any outside packaging or written instructions accompanying the product;
- Zeros after the decimal point (for example, 4.0) should not be used, while zeros before the decimal point (for example 0.4) should be used to avoid confusion;
- Dosage delivery devices should avoid extra markings, as these may confuse the consumer;
- Dosage delivery devices should not be much larger than the largest dose described in the written instructions and should still be able to deliver the smallest dose;
- Measurement marks must not be obscured once the liquid is added; and
- Usability studies of the dosage delivery device are highly recommended.

The FDA also recommends that all OTC liquid drug products include dosage devices. Failure to include these devices can lead to consumers' using household spoons, which are often inaccurate. Second, the dosage devices should be calibrated consistently with the written labeling. To the extent that any inconsistency exists, that inconsistency may render the product misbranded under section 502 and subject to an enforcement action.

For Further Information

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