VI. SUMMARY

Black box warnings include statements that the drug should be administered by a physician experienced with that particular drug. Black box warnings can identify specific populations especially susceptible to toxicity, such as children or patients with cardiac disease. The warnings may refer to animal studies, such as animal toxicity studies showing that the drug results in death to embryo. Moreover, black box warnings can mandate that the patient be closely monitored or observed. Drug–drug interactions and food–drug interactions take into account adverse reactions that can interfere with the safety or efficacy of the drug that is marketed with the package insert. The package insert can also include animal toxicity data, thereby improving vigilance for adverse effects that may present in the patient.

VII. BRAND NAMES, CHEMICAL NAMES, PACKAGING

a. Introduction to Brand Names

This concerns the proprietary name (brand name) and accompanying chemical name (non-proprietary name, established name) of drugs.

The CFR establishes that the brand name or proprietary name be unique. Title 21 of the CFR warns that labeling of a drug is misleading where, "[d]esignation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient" (21 CFR §201.10).

FDA's Guidance for Industry requires using a brand name that prevents confusion with other drugs. The Sponsor must submit, and FDA reviews, proposed proprietary names as part of its NDA or BLA. Many drug manufacturers prefer to have the FDA evaluate a proposed brand name even earlier in the drug development process. FDA permits the Sponsor to seek FDA's evaluation of the name when the product is in the IND stage, that is, in a timeframe before the Sponsor is able to submit an NDA or BLA (70). Brand names find a basis in the CFR. For example, 21 CFR §201.10 requires that the brand name should be written next to the established name, "the established name shall be placed in direct conjunction with the proprietary name ... and the established name shall be made clear by use of ... brackets surrounding the established name."

FDA requires "pharmaceutical companies to test proposed drug names to identify and remedy potential sound-alike and look-alike confusion with existing drug names" (71). To further prevent medication errors, FDA recommends using different packaging, capsule color, and so on, where the same product is marketed in different strengths. FDA's Guidance for Industry states that (72):

> [i]f multiple strengths are being developed, they should look different from each other, especially to reduce the chances of use errors that can result in harm if an overdose occurs due to administration of an incorrect strength ... error has been attributed to inadequate differentiation among dosage strengths with respect to tablet/capsule color, size, and shape.

[70]U.S. Department of Health and Human Services. Food and Drug Administration. Guidance for industry. Contents of a complete submission for the evaluation of proprietary names; February 2010 (19 pp.).

[71]U.S. Department of Health and Human Services. Food and Drug Administration. Guidance for industry. Safety considerations for product design to minimize medication errors; December 2012 (15 pp.).

[72]U.S. Department of Health and Human Services. Food and Drug Administration. Guidance for industry. Safety considerations for product design to minimize medication errors; December 2012 (15 pp.).