Additional Regulations Pertaining to OTC Drug Labeling (21 C.F.R Part 201)

§ 201.1 - Drugs; name and place of business of manufacturer, packer, or distributor.

§ 201.2 - Drugs and devices; National Drug Code numbers.

§ 201.5 - Drugs; adequate directions for use.

§ 201.6 - Drugs; misleading statements.

§ 201.10 - Drugs; statement of ingredients.

§ 201.15 - Drugs; prominence of required label statements.

§ 201.16 - Drugs; Spanish-language version of certain required statements.

§ 201.17 - Drugs; location of expiration date.

§ 201.18 - Drugs; significance of control numbers.

§ 201.19 - Drugs; use of term "infant".

§ 201.20 - Declaration of presence of FD&C Yellow No. 5 and/or FD&C Yellow No. 6 in certain drugs for human use.

§ 201.21 - Declaration of presence of phenylalanine as a component of aspartame in over-the-counter and prescription drugs for human use.

§ 201.23 - Required pediatric studies.

§ 201.25 - Bar code label requirements.

§ 201.26 - Exceptions or alternatives to labeling requirements for human drug products held by the Strategic National Stockpile.

§ 201.60 - Principal display panel.

§ 201.61 - Statement of identity.

§ 201.62 - Declaration of net quantity of contents.

§ 201.63 - Pregnancy/breast-feeding warning.

§ 201.64 - Sodium labeling.

§ 201.70 - Calcium labeling.

§ 201.71 - Magnesium labeling.
§ 201.72 - Potassium labeling.

§ 201.302 - Notice to manufacturers, packers, and distributors of drugs for internal use which contain mineral oil.

§ 201.303 - Labeling of drug preparations containing significant proportions of wintergreen oil.

§ 201.305 - Isoproterenol inhalation preparations (pressurized aerosols, nebulizers, powders) for human use; warnings.

§ 201.306 - Potassium salt preparations intended for oral ingestion by man.

§ 201.307 - Sodium phosphates; package size limitation, warnings, and directions for over-the-counter sale.

§ 201.308 - Ipecac syrup; warnings and directions for use for over-the-counter sale.

§ 201.312 - Magnesium sulfate heptahydrate; label declaration on drug products.

§ 201.314 - Labeling of drug preparations containing salicylates.

§ 201.315 - Over-the-counter drugs for minor sore throats; suggested warning.

§ 201.319 - Water-soluble gums, hydrophilic gums, and hydrophilic muciloids (including, but not limited to agar, alginic acid, calcium polycarbophil, carboxymethylcellulose sodium, carrageenan, chondrus, glucomannan (B-1,4 linked) polymannose acetate), guar gum, karaya gum, kelp, methylcellulose, plantago seed (psyllium), polycarbophil tragacanth, and xanthan gum) as active ingredients; required warnings and directions.

§ 201.320 - Warning statements for drug products containing or manufactured with chlorofluorocarbons or other ozone-depleting substances.

§ 201.323 - Aluminum in large and small volume parenterals used in total parenteral nutrition.

§ 201.325 - Over-the-counter drugs for vaginal contraceptive and spermicide use containing nonoxynol 9 as the active ingredient; required warnings and labeling information.

§ 201.326 - Over-the-counter drug products containing internal analgesic/antipyretic active ingredients; required warnings and other labeling.

§ 369.21 - Drugs; warning and caution statements required by regulations.