Labeling Requirements for Specific Devices

(21 CFR 801.405 to 801.437)

Certain devices require specific labeling which may include not only package labeling, but informational literature, patient release forms, performance testing, and/or specific tolerances or prohibitions on certain ingredients. The following devices have additional labeling requirements:

- Denture repair or refitting kits 21 CFR 801.405
  (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=801.405) - Special labeling and directions are listed in this section.

- Impact resistant lenses in sunglasses and eyeglasses 21 CFR 801.410
  (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=801.410) - This section specifies that case hardening of glass lenses, statistical testing of plastic lenses, "drop ball" testing, and documentation of these activities are required.

- Ozone emission levels 21 CFR 801.415
  (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=801.415) - This section specifies that ozone emission is restricted to levels below 0.05 parts per million in certain devices, and not permitted at all for use in any medical conditions for which there is no proof of safety or efficacy.

- Chlorofluorocarbon propellants 21 CFR 801.417
  (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=801.417) - This section specifies the use is prohibited except for use in contraceptive foams and certain metered drug dosage forms as detailed under 21 CFR 2.125. Special labeling is required on devices using this propellant as listed under 801.425.

- Hearing aids 21 CFR 801.420
FR=801.421)

- Menstrual tampons 21 CFR 801.430
  (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=801.430) - This section contains those labeling requirements related to Toxic Shock Syndrome (TSS) information, warnings, and advisories.

- Chlorofluorocarbons or other ozone depleting substances 21 CFR 801.433
  (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=801.433) - This section contains specific warning statements for all prescription and restricted devices containing or manufactured with chlorofluorocarbons, halons, carbon tetrachloride, methyl chloride, or any other Class I substance designated by the U.S. EPA.

- Latex condoms 21 CFR 801.435
  (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=801.435) - This section contains specific requirements for user labeling including data related to natural integrity, expiration dating requirements, storage conditions and inclusion of spermicidal ingredients.

- Devices containing natural rubber 21 CFR 801.437
  (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=801.437) - This section contains information related to the definities of latex, natural rubber, and human contact and specific informational and caution requirements and restrictions related to the composition of the device.