Sec. 21a-115-21. Directions for use; exemptions

(a) Directions for use may be inadequate by reason, among other reasons, of omission, in whole or in part, or incorrect specification of (1) directions for use in all conditions for which such drug or device is prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or on behalf of its manufacturer or packer, or in such other conditions, if any, for which such drug or device is commonly and effectively used; (2) quantity of dose, including quantities for persons of different ages and different physical conditions; (3) frequency of administration or application; (4) duration of administration or application; (5) time of administration or application, in relation to time of meals, time of onset of symptoms or other time factor; (6) route or method of administration or application; or (7) preparation for use (shaking, dilution, adjustment of temperature or other manipulation or process).

(b) A shipment or other delivery of a drug or device shall be exempt from compliance with the requirements of section 21a-106 of the general statutes in the following cases: (1) A drug or device which because of its toxicity or because of the degree of skill required in its administration cannot be used with safety except by or under the supervision of a physician, dentist or veterinarian; provided the label of such drug or device shall bear the statement "Caution—to be used only by or on the prescription of a physician" (dentist or veterinarian as the case may be); (2) official drugs which are dispensed only after compounding with other substances in filling prescriptions of physicians, dentists or veterinarians; (3) inactive ingredients of drugs such as solvents, colorings and flavorings; (4) drugs and devices shipped to physicians, dentists or veterinarians, hospitals or clinics, for use in professional practice and under professional supervision; (5) a drug or device intended solely for use in the manufacture of other drugs and devices; provided the label of such drug or device bears the statement "for manufacturing purposes only." The term "manufacture" does not include compounding of a prescription issued by a physician, dentist or veterinarian, in his professional practice; (6) common household preparations, adequate directions for the use of which are known by the ordinary individual.

(See 1963 Supp. § 21a-106 (f).)

(Effective July 27, 1984)