

### § 1701.3

### 16 CFR Ch. II (1-1-05 Edition)

requirements contained in 16 CFR 1700.15.

(b) Manufacturers of prescription drugs may package such drugs for distribution to pharmacies in different types of packages, depending on whether the manufacturer intends that the package will be the one in which the drug is ultimately given to the consumer or whether it is intended that the pharmacist will repackage the drug before it is dispensed to the consumer. If the drug is supplied in a bulk package from which individual prescriptions are intended to be repackaged by the pharmacist, the manufacturer need not utilize special packaging. However, the Commission interprets the provision of the act as requiring that all prescription drugs subject to a special packaging standard that are distributed to pharmacies shall be in special packaging if the immediate package in which the drugs are distributed by the manufacturer is intended to be the package in which the drugs are dispensed to the consumer. Examples of such packages include mnemonic dispensing devices; dropper bottles; packages with "tear off" labels; packages which incorporate ancillary instructions for consumer handling, storage, or use on permanently affixed portions of their labels; and products intended to be reconstituted in their original containers. The Commission believes that this interpretation is necessary in order to insure that the pharmacist will actually dispense the drug in the proper package. If the pharmacist receives a request from the consumer or an order from the prescribing medical practitioner for conventional (noncomplying) packaging, section 4(b) of the act permits the pharmacist to convert the package to conventional packaging or repackage the drug in conventional packaging.

(c) Manufacturers should also note that section 4(a) of the act (which allows a product to be marketed in noncomplying packaging of a single size under certain circumstances) does not apply to prescription drugs subject to section 4(b) of the act. Thus, since the section 4(a) single-size exemption for over-the-counter drugs and other household substances does not apply to prescription drugs, every unit of a pre-

scription drug subject to a special packaging standard which is distributed to a pharmacy in a package intended by the manufacturer to be dispensed to a consumer shall be in special packaging.

(d) Nothing in this statement of policy and interpretation should be interpreted as relieving the pharmacist of the responsibility of insuring that all prescription drugs subject to a special packaging standard are dispensed to the consumer in special packaging unless otherwise ordered by the prescribing practitioner or otherwise requested by the consumer.

(Secs. 2-4, Pub. L. 91-601, 84 Stat. 1670, 1671 (15 U.S.C. 1471-1473); sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))

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#### § 1701.3 Applicability of special packaging requirements to hazardous substances in large size containers.

The special packaging requirements of the PPPA apply to "household substances" for which the Commission has determined there is a need for special packaging, as provided in section 3 of the act (15 U.S.C. 1472). At section 2(2) of the act (15 U.S.C. 1471) (restated at 16 CFR 1700.1(b)(2)), the term *household substance* is defined as "any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household \* \* \*." The Commission has issued requirements for special packaging for certain hazardous substances at 16 CFR 1700.14(a). Unless otherwise indicated in the requirements for specific hazardous substances, the Commission interprets the term "household substance" as only applying to these hazardous substances when packaged in containers with a capacity of less than 5 gallons. As a result, unless otherwise specified, the hazardous substances at 16 CFR 1700.14(a) are not required to be in special packaging when packaged in containers of 5 gallons or more.

(Secs. 2, 5, 7, 9, Pub. L. 91-601; 94 Stat. 1670-1674 (15 U.S.C. 1471, 1474, 1476, 1478); sec. 30(a), Pub. L. 92-573, 86 Stat. 1231 (15 U.S.C. 2079(a))

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