§ 1702.13 Labeling and packaging samples.

Each petition for an exemption under this part shall include a sample of the label and complete packaging for each size in which each form of the product for which an exemption is sought is packaged. This shall include the immediate container labeling, any package inserts, and other carton or wrapping labeling in which the product is offered to the consumer. In the case of drugs, each petition shall be accompanied by labeling on the outer carton or wrapping in which the product is offered to the retailer, as well as samples of the promotional and advertising information for the product.

§ 1702.14 Marketing history.

Each petition for an exemption under this part shall include a statement of the marketing history of the substance for which an exemption is requested. The marketing history dates from the year in which each form of the product was introduced onto the market. The marketing history shall include the total number of units of each form or strength and package size of the product distributed since the product was introduced onto the market. In the case of prescription drugs, the average prescription size for the product should also be indicated, if known.

§ 1702.15 Petitions alleging the incompatiability of child resistant packaging with the particular substance petitioned for exemption.

(a) Where the petition for an exemption is based upon an allegation that the applicable special packaging standard is incompatible with the particular substance or would seriously and adversely compromise the utility or stability of a substance, the petitioner shall submit adequate evidence to support the allegation.

(b) If the allegation of incompatibility is based upon the fact that package choice is limited by a new drug application filed with the FDA, the petition shall state the limitation of package choice and a description of a time schedule to revise the NDA in order to allow additional package choice.

(c) If the allegation of incompatibility is based upon the fact that the shelf life of the product limits package choice, the petition shall outline the particular limitation and shall include a description of a time schedule to reestablish shelf-life data.

§ 1702.16 Petitions requesting an exemption for a drug or a new drug.

(a) Where the petition requests an exemption for a drug, as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1), the petitioner shall include those reports required to be filed under the Food and Drug Administration's Adverse Reaction Reporting Program.

(b) [Reserved]

[45 FR 13064, Feb. 28, 1980, as amended at 66 FR 40115, Aug. 2, 2001]

§ 1702.17 Granting petitions.

Where the Commission determines that reasonable grounds for an exemption are presented by the petition, the Commission shall publish, in the FEDERAL REGISTER, a proposed amendment to the listing of substances requiring special packaging under §1700.14(a). ''Reasonable grounds'' for publishing a proposed exemption are information and data sufficient to support the conclusion that:

(a) The degree or nature of the hazard to children in the availability of the substance, by reason of its packaging, is such that special packaging is not required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting the substance, or

(b) Special packaging is not technically feasible, practicable, or appropriate for the subject substance, or

(c) Special packaging is incompatible with the particular substance.

§ 1702.18 Denying petitions.

Where the Commission determines that reasonable grounds for an exemption are not presented by the petition, the petition shall be denied, and the petitioner notified in writing of the denial, including a brief statement of the reasons therefor.

§ 1702.19 Effect of filing petition.

The filing of a petition for exemption under this part 1702 shall not have the effect of staying the regulation from