

Poison Prevention Packaging Act

PPPA Petitions for Exemption

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Examples of Exempted Products

- Powdered unflavored aspirin
- Effervescent aspirin
- Sublingual nitroglycerin
- Oral contraceptives
- Hormone replacement therapy
- Powdered iron preparations
- Effervescent acetaminophen
- Hydrocarbon-containing products where the liquid cannot flow freely.

Petitions for Exemption

- **16 CFR part 1702**
- **Requirements**
 - **Procedural – 16 CFR § 1702.2**
 - **Substantive – 16 CFR § 1702.3**

Petitions for Exemption (Cont.)

- **Justification – 16 CFR § 1702.7**
 - **Lack of toxicity**
 - **CR packaging not technically feasible, practicable, or appropriate**
 - **CR package is incompatible with substance**

Petitions for Exemption (Cont.)

- **Information and Data Submission**
 - **Human experience**
 - Child
 - Adult
 - **Experimental data**
 - **Packaging and labeling**
 - Samples

Examples of Exempted Products from Petitions

- Erythromycin ethylsuccinate tablets in packages containing no more than the equivalent of 16 grams of erythromycin.
- Medroxyprogesterone acetate tablets.
- Sacrosidase in a solution of glycerol and water.