Regulations Pertaining to Tamper-Resistant Packaging

Tamper Resistant Packaging

A tamper-resistant package is one having an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. The barrier is distinctive by design having identifying characteristics. The design may not be duplicated. This tamper-resistant feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution and retail display.

Products covered
1. All non-prescription drug products
   a. oral
   b. nasal
   c. otic
   d. ophthalmic
   e. rectal
   f. vaginal
   g. Excludes: dermatologicals, dentifrices, insulin and lozenges
2. Cosmetic liquid oral hygiene products such as mouthwashes, gargles and breath fresheners.
3. Cosmetic vaginal products
4. Contact lens solutions and tablets

Statement and labeling
A statement to appear on each product "to alert consumers to the specific tamper-resistant feature of the package." The statement must be placed so it is unaffected if the tamper-resistant feature is breached or missing. If the tamper-resistant feature has an identifying characteristic then the statement must designate what that is. (e.g., "for your protection, this bottle has an imprinted seal around the neck")

Exemptions from the Statement requirement
1. Ammonia inhalant in crushable glass ampules
2. Aerosol products
3. Compressed medical oxygen

Exemptions to the tamper-resistant regulations
Products are exempted if they are distributed in a manner that does not afford the public access to them while they are held for sale.

Examples of exemptions:
1. OTC drug products sold directly to a hospital, an institution, a medical or first aid unit or to a practitioner or pharmacy.
2. OTC drug products sold directly to a health professional or dispensing directly to patients.
3. First aid kits sold directly to organizations and that are not accessible to the general public.
4. Products sold in vending machines.
5. Products sold through the mail directly from a firm representative to an individual user.
6. Products sold in the same manner as #5, but from door to door.

(18 USC §1365, 21 CFR §211.132) 1/98 kdf
Federal Anti-Tampering Act
U.S.C. TITLE 18 - CRIMES AND CRIMINAL PROCEDURE
PART I - CRIMES
CHAPTER 65 - MALICIOUS MISCHIEF
§ 1365. Tampering with consumer products

(a) Whoever, with reckless disregard for the risk that another person will be placed in danger of death or bodily injury and under circumstances manifesting extreme indifference to such risk, tampers with any consumer product that affects interstate or foreign commerce, or the labeling of, or container for, any such product, or attempts to do so, shall -

- (1) in the case of an attempt, be fined under this title or imprisoned not more than ten years, or both;
- (2) if death of an individual results, be fined under this title or imprisoned for any term of years or for life, or both;
- (3) if serious bodily injury to any individual results, be fined under this title or imprisoned not more than twenty years, or both; and
- (4) in any other case, be fined under this title or imprisoned not more than ten years, or both.

(b) Whoever, with intent to cause serious injury to the business of any person, taints any consumer product or renders materially false or misleading the labeling of, or container for, a consumer product, if such consumer product affects interstate or foreign commerce, shall be fined under this title or imprisoned not more than three years, or both.

(c) (1) Whoever knowingly communicates false information that a consumer product has been tainted, if such product or the results of such communication affect interstate or foreign commerce, and if such tainting, had it occurred, would create a risk of death or bodily injury to another person, shall be fined under this title or imprisoned not more than five years, or both.

- (2) As used in paragraph (1) of this subsection, the term "communicates false information" means communicates information that is false and that the communicator knows is false, under circumstances in which the information may reasonably be expected to be believed.

(d) Whoever knowingly threatens, under circumstances in which the threat may reasonably be expected to be believed, that conduct that, if it occurred, would violate subsection (a) of this section will occur, shall be fined under this title or imprisoned not more than five years, or both.

(e) Whoever is a party to a conspiracy of two or more persons to commit an offense under subsection (a) of this section, if any of the parties intentionally engages in any conduct in furtherance of such offense, shall be fined under this title or imprisoned not more than ten years, or both.

(f) In addition to any other agency which has authority to investigate violations of this section, the Food and Drug Administration and the Department of Agriculture, respectively, have authority to investigate violations of this section involving a consumer product that is regulated by a provision of law such Administration or Department, as the case may be, administers.

(g) As used in this section -

- (1) the term "consumer product" means -
  - (A) any "food", "drug", "device", or "cosmetic", as those terms are respectively defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); or
  - (B) any article, product, or commodity which is customarily produced or distributed for consumption by individuals, or use by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household, and which is designed to be consumed or expended in the course of such consumption or use;

- (2) the term "labeling" has the meaning given such term in section 201(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(m));

- (3) the term "serious bodily injury" means bodily injury which involves -
  - (A) a substantial risk of death;
  - (B) extreme physical pain;
  - (C) protracted and obvious disfigurement; or
  - (D) protracted loss or impairment of the function of a bodily member, organ, or mental faculty; and

- (4) the term "bodily injury" means -
  - (A) a cut, abrasion, bruise, burn, or disfigurement;
  - (B) physical pain;
  - (C) illness;
  - (D) impairment of the function of a bodily member, organ, or mental faculty; or
  - (E) any other injury to the body, no matter how temporary.