

(I) ADEQUATE DIRECTIONS FOR THE USE OF THE DRUG OR DEVICE; AND

(II) ADEQUATE WARNINGS AGAINST:

1. THE USE OF THE DRUG OR DEVICE BY ANYONE SUFFERING FROM A PATHOLOGICAL CONDITION THAT MAY CAUSE ITS USE TO BE DANGEROUS TO HEALTH;

2. THE USE OF THE DRUG OR DEVICE BY A CHILD IF ITS USE BY A CHILD MAY BE DANGEROUS; AND

3. UNSAFE DOSAGES, METHODS OF ADMINISTRATION, OR DURATION OF ADMINISTRATION OF THE DRUG OR DEVICE;

(6) IT IS DANGEROUS TO HEALTH WHEN USED IN THE DOSAGE, WITH THE FREQUENCY, OR FOR THE DURATION SPECIFIED, RECOMMENDED, OR SUGGESTED IN THE LABELING OF THE DRUG OR DEVICE; OR

(7) THE TRADEMARK, TRADE NAME, IMPRINT, SYMBOL, OR OTHER IDENTIFYING MARK OF ANOTHER DRUG OR ANY LIKENESS OF ANY OF THESE MARKINGS OF ANOTHER DRUG OR DEVICE IS PLACED ON THE DRUG OR DEVICE OR ITS CONTAINER WITH THE INTENT TO DEFRAUD.

(C) EXEMPTIONS FROM LABELING REQUIREMENTS.

(1) SUBSECTION (B)(5)(I) OF THIS SECTION, WHICH CONCERNS THE PROVISION OF DIRECTIONS FOR THE USE OF A DRUG OR DEVICE, DOES NOT APPLY TO A DRUG OR DEVICE THAT IS EXEMPTED BY:

(I) A RULE OR REGULATION ADOPTED UNDER THE FEDERAL ACT; OR

(II) A RULE OR REGULATION ADOPTED BY THE SECRETARY UNDER THIS SUBSECTION.

(2) IF THE SECRETARY FINDS THAT, AS APPLIED TO A PARTICULAR DRUG OR DEVICE, ANY REQUIREMENT OF SUBSECTION (B)(5)(I) OF THIS SECTION IS NOT NECESSARY FOR THE PROTECTION OF THE PUBLIC HEALTH, THE SECRETARY SHALL ADOPT A RULE OR REGULATION TO EXEMPT THE DRUG OR DEVICE FROM THAT REQUIREMENT.

REVISOR'S NOTE: This section is new language derived without substantive change from former Article 43, § 189B(1), (2), (3), (7), (11), and (16).

As to the reference to the Federal Act in subsection (c)(1) of this section, see 21 U.S.C. 352(f).