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§21–217.

(a) For purposes of this subtitle, a drug or device is misbranded if the standards in this section or in § 21-218 or § 21-220(d) or (e) of this subtitle apply.

(b) A drug or device is misbranded if:

(1) Its labeling is false or misleading in any way;

(2) Its labeling or packaging does not conform with any provision of § 21-248 of this subtitle;

(3) It is in package form and it does not bear a label that contains the name and place of business of the manufacturer, packer, or distributor;

(4) Any word, statement, or other information required under this subtitle to appear on its labeling is not placed prominently on the labeling in a manner that is:

(i) Conspicuous as compared with other words, statements, designs, or symbols on the labeling; and

(ii) In terms likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(5) Its labeling does not include, in whatever manner and form that may be necessary to protect the user of the drug or device:

(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) (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.

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