

Commission, see Reorg. Plan No. 8 of 1950, §1, eff. May 24, 1950, 15 F.R. 3175, 64 Stat. 1264, set out under section 41 of this title.

§ 55. Additional definitions

For the purposes of sections 52 to 54 of this title—

(a) False advertisement

(1) The term “false advertisement” means an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual. No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug.

(2) In the case of oleomargarine or margarine an advertisement shall be deemed misleading in a material respect if in such advertisement representations are made or suggested by statement, word, grade designation, design, device, symbol, sound, or any combination thereof, that such oleomargarine or margarine is a dairy product, except that nothing contained herein shall prevent a truthful, accurate, and full statement in any such advertisement of all the ingredients contained in such oleomargarine or margarine.

(b) Food

The term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(c) Drug

The term “drug” means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

(d) Device

The term “device” (except when used in subsection (a) of this section) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(e) Cosmetic

The term “cosmetic” means (1) articles to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof intended for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such article; except that such term shall not include soap.

(f) Oleomargarine or margarine

For the purposes of this section and section 347 of title 21, the term “oleomargarine” or “margarine” includes—

(1) all substances, mixtures, and compounds known as oleomargarine or margarine;

(2) all substances, mixtures, and compounds which have a consistence similar to that of butter and which contain any edible oils or fats other than milk fat if made in imitation or semblance of butter.

(Sept. 26, 1914, ch. 311, §15, as added Mar. 21, 1938, ch. 49, §4, 52 Stat. 114; amended Mar. 16, 1950, ch. 61, §4(a), (b), 64 Stat. 21; Pub. L. 94-295, §3(a)(1)(B), May 28, 1976, 90 Stat. 575.)

AMENDMENTS

1976—Subsec. (d). Pub. L. 94-295 expanded definition of “device” to include implements, machines, implants, in vitro reagents, and other similar or related articles, added recognition in the National Formulary or the United States Pharmacopoeia, or any supplement to the Formulary or Pharmacopoeia, to the enumeration of conditions under which a device may qualify for inclusion under this chapter, and inserted requirements that a device be one which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

1950—Subsec. (a). Act Mar. 16, 1950, §4(a), designated existing provisions as par. (1) and added par. (2) relating to oleomargarine.

Subsec. (f). Act Mar. 16, 1950, §4(b), added subsec. (f).

EFFECTIVE DATE OF 1950 AMENDMENT

Amendment by act Mar. 16, 1950, effective July 1, 1950, see note set out under section 347 of Title 21, Food and Drugs.

§ 56. Commencement, defense, intervention and supervision of litigation and appeal by Commission or Attorney General

(a) Procedure for exercise of authority to litigate or appeal

(1) Except as otherwise provided in paragraph (2) or (3), if—