



U.S. Food and Drug Administration

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Importation of Active Pharmaceutical Ingredients (APIs) Requirements
FD&C Act 201(g) & (p) [21 USC 321(g) & (p)] Definitions; generally (Tab B)

For the purposes of this chapter —

(g)

(1) The term “drug” means

- (A)** 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
- (B)** articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
- (C)** articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
- (D)** articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343 (r)(1)(B) and 343 (r)(3) of this title or sections 343 (r)(1)(B) and 343 (r)(5)(D) of this title, is made in accordance with the requirements of section 343 (r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343 (r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(2) The term “counterfeit drug” means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(p) The term “new drug” means—

- (1)** Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a “new drug” if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or
- (2)** Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.