-CITE-

21 USC Sec. 321 01/16/96

-EXPCITE-

TITLE 21 - FOOD AND DRUGS

CHAPTER 9 - FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER II - DEFINITIONS

-HEAD-

Sec. 321. Definitions; generally **[(s) Food Additive (t) Color Additive]**

-STATUTE-

For the purposes of this chapter -

(a)(1) The term "State", except as used in the last sentence of section 372(a) of this title, means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means Department of Health and Human Services.

(d) The term "Secretary" means the Secretary of Health and Human Services.

(e) The term "person" includes individual, partnership,

corporation, and association.

(f) 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.

(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 drugs" 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.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) 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 Pharmacopeia, 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 its primary 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 its primary intended purposes.

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

(j) The term "official compendium" means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to

any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising 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 article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a

germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(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.

(q) The term "pesticide chemical" means any substance which, alone, in chemical combination or in formulation with one or more other substances, is "a pesticide" within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) as now in force or as hereafter amended, and which is used

in the production, storage, or transportation of raw agricultural commodities.

(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case as a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include -

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this

chapter, the Poultry Products Inspection Act (21 U.S.C. 451 et seq.) or the Meat Inspection Act of March 4, 1907, as amended and extended (21 U.S.C. 601 et seq.);

(5) a new animal drug; or

(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

(t)(1) The term "color additive" means a material which -

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

(u) The term "safe" as used in paragraph (s) of this section

and in sections 348, 360b, and 379e of this title, has reference to the health of man or animal.

(v) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed, -

(1) 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 animal 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 animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug 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) 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.

(w) The term "animal feed", as used in paragraph (w) (FOOTNOTE 1) of this section, in section 360b of this title, and in provisions of this chapter referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(FOOTNOTE 1) So in original. Probably should be paragraph "(v)".

(x) The term "informal hearing" means a hearing which is not subject to section 554, 556, or 557 of title 5 and which provides for the following:

(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

(5) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all

written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.

(y) The term "saccharin" includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(z) The term "infant formula" means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

(aa) The term "abbreviated drug application" means an application submitted under section 355(j) or 357 of this title for the approval of a drug that relies on the approved application of another drug with the same active ingredient to establish safety and efficacy, and -

(1) in the case of section 335a of this title, includes a supplement to such an application for a different or additional use of the drug but does not include a supplement to such an application for other than a different or additional use of the drug, and

(2) in the case of sections 335b and 335c of this title, includes any supplement to such an application.

(bb) The term "knowingly" or "knew" means that a person, with respect to information -

(1) has actual knowledge of the information, or

(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

(cc) For purposes of section 335a of this title, the term "high managerial agent" -

(1) means -

(A) an officer or director of a corporation or an association,

(B) a partner of a partnership, or

(C) any employee or other agent of a corporation, association, or partnership,

having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and

(2) includes persons having management responsibility for -

(A) submissions to the Food and Drug Administration regarding the development or approval of any drug product,

(B) production, quality assurance, or quality control of any drug product, or

(C) research and development of any drug product.

(dd) For purposes of sections 335a and 335b of this title, the term "drug product" means a drug subject to regulation under section 355, 357, 360b, or 382 of this title or under section 262 of title 42.

(ee) The term "Commissioner" means the Commissioner of Food and Drugs.

(ff) The term "dietary supplement" -

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following

dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that -

(A)(i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or

(ii) complies with section 350(c)(1)(B)(ii) of this title;

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and

(3) does -

(A) include an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342(f) of this title; and

(B) not include -

(i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42, or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

Except for purposes of paragraph (g), a dietary supplement shall be deemed to be a food within the meaning of this chapter.

-SOURCE-

(June 25, 1938, ch. 675, Sec. 201, 52 Stat. 1040; July 22, 1954, ch. 559, Sec. 1, 68 Stat. 511; Sept. 6, 1958, Pub. L. 85-929, Sec. 2, 72 Stat. 1784; July 12, 1960, Pub. L. 86-618, title I, Sec. 101, 74 Stat. 397; Oct. 10, 1962, Pub. L. 87-781, title I, Sec. 102(a), title III, Sec. 307(a), 76 Stat. 781, 796; July 15, 1965, Pub. L. 89-74, Sec. 3(a), 9(b), 79 Stat. 227, 234; July 13, 1968, Pub. L. 90-399, Sec. 102, 82 Stat. 351; Oct. 24, 1968, Pub. L. 90-639, Sec. 1, 4(a), 82 Stat. 1361, 1362; Oct. 27, 1970, Pub. L. 91-513, title II, Sec. 701(a), (g), 84 Stat. 1281, 1282; Oct. 21, 1972, Pub. L. 92-516, Sec. 3(3), 86 Stat. 998; Apr. 22, 1976, Pub. L. 94-278, title V, Sec. 502(a)(2)(A), 90 Stat. 411; May 28, 1976, Pub. L.

94-295, Sec. 3(a)(1)(A), (2), 90 Stat. 575; Nov. 23, 1977, Pub. L. 95-203, Sec. 4(b)(3), 91 Stat. 1453; Sept. 26, 1980, Pub. L. 96-359, Sec. 3, 94 Stat. 1193; Nov. 16, 1988, Pub. L. 100-670, title I, Sec. 107(a)(1), 102 Stat. 3984; Nov. 8, 1990, Pub. L. 101-535, Sec. 5(b), 104 Stat. 2362; Nov. 28, 1990, Pub. L. 101-629, Sec. 16(b), 104 Stat. 4526; May 13, 1992, Pub. L. 102-282, Sec. 6, 106 Stat. 161; June 16, 1992, Pub. L. 102-300, Sec. 6(a), (b), 106 Stat. 240; Oct. 29, 1992, Pub. L. 102-571, title I, Sec. 107(1), 106 Stat. 4499; Aug. 13, 1993, Pub. L. 103-80, Sec. 3(b), (dd)(1), 4(b), 107 Stat. 775, 779; Oct. 25, 1994, Pub. L. 103-417, Sec. 3(a), (b), 10(a), 108 Stat. 4327, 4332.)

-REFTEXT-

REFERENCES IN TEXT

The Food and Drugs Act of June 30, 1906, as amended, referred to in par. (p)(1), and the Food and Drug Act of June 30, 1906, as amended, referred to in par. (v)(1), is act June 30, 1906, ch. 3915, 34 Stat. 768, as amended, which was classified to subchapter I (Sec. 1 et seq.) of chapter 1 of this title, was repealed (except for section 14a which was transferred to section 372a of this title) by act June 25, 1938, ch. 675, Sec. 902(a), 52 Stat. 1059, and is covered by this chapter.

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in par. (q), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92-516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (Sec. 136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

The Poultry Products Inspection Act, referred to in par. (s)(4), is Pub. L. 85-172, Aug. 28, 1957, 71 Stat. 441, as amended, which is classified generally to chapter 10 (Sec. 451 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 451 of this title and Tables.

The Meat Inspection Act of March 4, 1907, as amended and extended, referred to in par. (s)(4), is act Mar. 4, 1907, ch. 2907, titles I to IV, as added Dec. 15, 1967, Pub. L. 90-201, 81 Stat. 584, which are classified generally to subchapters I to IV (Sec. 601 et seq.) of chapter 12 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 601 of this title and Tables.

-MISC2-

AMENDMENTS

1994 - Par. (g)(1). Pub. L. 103-417, Sec. 10(a), amended last sentence generally. Prior to amendment, last sentence read as follows: "A food 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 under clause (B) solely because the label or labeling contains such a claim."

Par. (s)(6). Pub. L. 103-417, Sec. 3(b), added subpar. (6).

Par. (ff). Pub. L. 103-417, Sec. 3(a), added par. (ff).

1993 - Pars. (c), (d). Pub. L. 103-80, Sec. 3(dd)(1), substituted "Health and Human Services" for "Agriculture".

Par. (h). Pub. L. 103-80, Sec. 4(b), amended directory language

of Pub. L. 102-300, Sec. 6(a)(1). See 1992 amendment note below.

Pars. (v) to (ff). Pub. L. 103-80, Sec. 3(b), redesignated pars. (w) to (ff) as (v) to (ee), respectively.

1992 - Pars. (c), (d). Pub. L. 102-300, Sec. 6(b)(1), which directed the substitution of "Health and Human Services" for "Health, Education, and Welfare", could not be executed because such words did not appear in the original statutory text. See 1993 Amendment note above and Transfer of Functions notes below.

Par. (h). Pub. L. 102-300, Sec. 6(a)(1), as amended by Pub. L. 103-80, Sec. 4(b), substituted "its primary" for "any of its principal" in two places in concluding provisions.

Par. (u). Pub. L. 102-571 substituted "379e" for "376".

Par. (y)(1). Pub. L. 102-300, Sec. 6(b)(2), struck out "of Health, Education, and Welfare" after "employees of the Department".

Pars. (bb) to (ee). Pub. L. 102-282 added pars. (bb) to (ee).

Par. (ff). Pub. L. 102-300, Sec. 6(a)(2), added par. (ff).

1990 - Par. (g)(1). Pub. L. 101-629, Sec. 16(b)(1), struck out "; but does not include devices or their components, parts, or accessories" after "clause (A), (B), or (C)".

Pub. L. 101-535 inserted at end "A food 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 under clause (B) solely because the label or labeling contains such a claim."

Par. (h)(3). Pub. L. 101-629, Sec. 16(b)(2), which directed the amendment of subpar. (3) by substituting "its primary" for "any

of its principal", could not be executed because "any of its principal" did not appear in subpar. (3).

1988 - Par. (w)(3). Pub. L. 100-670 struck out subpar. (3) which read as follows: "which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, except when there is in effect a published order of the Secretary declaring such drug not to be a new animal drug on the grounds that (A) the requirement of certification of batches of such drug, as provided for in section 360b(n) of this title, is not necessary to insure that the objectives specified in paragraph (3) thereof are achieved and (B) that neither subparagraph (1) nor (2) of this paragraph (w) applies to such drug."

1980 - Par. (aa). Pub. L. 96-359 added par. (aa).

1977 - Par. (z). Pub. L. 95-203 added par. (z).

1976 - Par. (h). Pub. L. 94-295, Sec. 3(a)(1)(A), 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 Pharmacopeia, or any supplement to the Formulary or Pharmacopeia, 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.

Par. (n). Pub. L. 94-278 inserted "or advertising" after "labeling" wherever appearing.

Par. (y). Pub. L. 94-295, Sec. 3(a)(2), added par. (y).

1972 - Par. (q). Pub. L. 92-516 substituted reference to pesticide for reference to economic poison.

1970 - Par. (a)(2). Pub. L. 91-513, Sec. 701(g), struck out reference to sections 321, 331(i), 331(p), 331(q), 332, 333, 334, 337, 360, 360a, 372, 373, 374, and 375 of this title as they apply to depressant or stimulant drugs.

Par. (v). Pub. L. 91-513, Sec. 701(a), struck out par. (v) which defined "depressant or stimulant drug".

1968 - Par. (a)(2). Pub. L. 90-639, Sec. 4(a), extended provisions to cover depressant and stimulant drugs, the containers thereof, and equipment used in manufacturing, compounding, or processing such drugs, to the Canal Zone.

Par. (p). Pub. L. 90-399, Sec. 102(a), (b), inserted "(except a new animal drug or an animal feed bearing or containing a new animal drug)" after "Any drug" in subpars. (1) and (2), respectively.

Par. (s)(5). Pub. L. 90-399, Sec. 102(c), added subpar. (5).

Par. (u). Pub. L. 90-399, Sec. 102(d), inserted reference to section 360b of this title.

Par. (v)(3). Pub. L. 90-639, Sec. 1, inserted reference to lysergic acid diethylamide.

Pars. (w), (x). Pub. L. 90-399, Sec. 102(e), added pars. (w) and (x).

1965 - Par. (g). Pub. L. 89-74, Sec. 9(b), designated existing provisions as subpar. (1), redesignated cls. (1) to (4) thereof as (A) to (D), substituted "(A), (B), or (C)" for "(1), (2), or (3)" and added subpar. (2).

Par. (v). Pub. L. 89-74, Sec. 3(a), added par. (v).

1962 - Par. (a). Pub. L. 87-781, Sec. 307(a), designated existing provisions as subpar. (2), inserted "Commonwealth of Puerto Rico and the", and added subpar. (1).

Par. (p)(1). Pub. L. 87-781, Sec. 102(a)(1), inserted "and effectiveness" after "to evaluate the safety", and "and effective" after "as safe".

Par. (p)(2). Pub. L. 87-781, Sec. 102(a)(2), inserted "and effectiveness" after "safety".

1960 - Par. (s). Pub. L. 86-618, Sec. 101(a), excluded color additives from definition of "food additive".

Par. (t). Pub. L. 86-618, Sec. 101(c), added par. (t). Former par. (t) redesignated (u).

Par. (u). Pub. L. 86-618, Sec. 101(b), redesignated par. (t) as (u) and inserted reference to section 376 of this title.

1958 - Pars. (s), (t). Pub. L. 85-929 added pars. (s) and (t).

1954 - Pars. (q), (r). Act July 22, 1954, added pars. (q) and (r).

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-535 effective six months after the date of the promulgation of final regulations to implement section 343(r) of this title, or if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations (Nov. 8, 1992), with exception for persons marketing food the brand name of which contains a term defined by the Secretary under section 343(r)(2)(A)(i) of this title, see section 10(a) of Pub. L. 101-535, set out as a note under section 343 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94-278 effective 180 days after Apr. 22, 1976, see section 502(c) of Pub. L. 94-278, set out as a note under section 334 of this title.

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92-516 effective at the close of Oct. 21, 1972, except if regulations are necessary for the implementation of any provision that becomes effective on Oct. 21, 1972, and continuation in effect of subchapter I of chapter 6 of Title 7, and regulations thereunder, relating to the control of economic poisons, as in existence prior to Oct. 21, 1972, until superseded by provisions of Pub. L. 92-516, and regulations thereunder, see section 4 of Pub. L. 92-516, set out as an Effective Date note under section 136 of Title 7, Agriculture.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91-513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91-513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENTS; TRANSITIONAL PROVISIONS

Section 6 of Pub. L. 90-639 provided that: "The amendments made by this Act (amending this section, sections 331, 333, 334, and 360a of this title, and provisions set out as a note under section 289a of Title 42, The Public Health and Welfare) shall apply only with respect to violations of the Federal Food, Drug, and Cosmetic Act (this chapter) committed after the date of the enactment of this Act (Oct. 24, 1968)."

Amendment by Pub. L. 90-399 effective on first day of thirteenth

calendar month after July 13, 1968, except that in the case of a drug (other than one subject to section 360b(n) of this title) intended for use in animals other than man which, on Oct. 9, 1962, was commercially used or sold in the United States, was not a new drug as defined in par. (p) of this section then in force, and was not covered by an effective application under section 355 of this title, the words "effectiveness" and "effective" contained in par. (w) of this section not applicable to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day, see section 108(a), (b)(3) of Pub. L. 90-399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Section 11 of Pub. L. 89-74 provided that: "The foregoing provisions of this Act (see Short Title of 1965 Amendment note set out under section 301 of this title) shall take effect on the first day of the seventh calendar month (Feb. 1, 1966) following the month in which this Act is enacted (July 15, 1965); except that (1) the Secretary shall permit persons, owning or operating any establishment engaged in manufacturing, preparing, propagating, compounding, processing, wholesaling, jobbing, or distributing any depressant or stimulant drug, as referred to in the amendments made by section 4 of this Act to section 510 of the Federal Food, Drug, and Cosmetic Act (section 360 of this title), to register their name, places of business, and establishments, and other information prescribed by such amendments, with the Secretary prior to such effective date, and (2) sections 201(v) and 511(g) of the Federal

Food, Drug, and Cosmetic Act, as added by this act (par. (v) of this section and par. (g) of section 360a of this title), and the provisions of sections 8 (amending section 372 of this title and section 1114 of Title 18, Crimes and Criminal Procedure) and 10 (set out as a note under this section) shall take effect upon the date of enactment of this Act (July 15, 1965)."

EFFECTIVE DATE OF 1962 AMENDMENT

Section 107 of Pub. L. 87-781 provided that:

"(a) Except as otherwise provided in this section, the amendments made by the foregoing sections of this part A (amending this section and sections 331, 332, 348, 351 to 353, 355, 357, 379e of this title, and enacting provisions set out as a note under section 355 of this title) shall take effect on the date of enactment of this Act (Oct. 10, 1962).

"(b) The amendments made by sections 101, 103, 105, and 106 of this part A (amending sections 331, 332, 351, 352, 355, and 357 of this title) shall, with respect to any drug, take effect on the first day of the seventh calendar month following the month in which this Act is enacted (Oct. 1962).

"(c)(1) As used in this subsection, the term 'enactment date' means the date of enactment of this Act; and the term 'basic Act' means the Federal Food, Drug, and Cosmetic Act (this chapter).

"(2) An application filed pursuant to section 505(b) of the basic Act (section 355(b) of this title) which was 'effective' within the meaning of that Act on the day immediately preceding the enactment date shall be deemed as of the enactment date, to be an application 'approved' by the Secretary within the meaning of the basic Act as amended by this Act.

"(3) In the case of any drug with respect to which an application filed under section 505(b) of the basic Act is deemed to be an approved application on the enactment date by virtue of paragraph (2) of this subsection -

"(A) the amendments made by this Act to section 201(p), and to subsections (b) and (d) of section 505, of the basic Act (par. (p) of this section, and subsecs. (b) and (d) of section 355 of this title), insofar as such amendments relate to the effectiveness of drugs, shall not, so long as approval of such application is not withdrawn or suspended pursuant to section 505(e) of that Act (section 355(e) of this title), apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling covered by such approved application, but shall apply to any changed use, or conditions of use, prescribed, recommended, or suggested in its labeling, including such conditions of use as are the subject of an amendment or supplement to such application pending on, or filed after, the enactment date; and

"(B) clause (3) of the first sentence of section 505(e) of the basic Act, as amended by this Act (section 355(e) of this title), shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling covered by such approved application (except with respect to such use, or conditions of use, as are the subject of an amendment or supplement to such approved application, which amendment or supplement has been approved after the enactment date under section 505 of the basic Act as amended by this Act (section 355 of this title)) until whichever of the following first occurs:

(i) the expiration of the two-year period beginning with the enactment date; (ii) the effective date of an order under section 505(e) of the basic Act (section 355(e) of this title), other than clause (3) of the first sentence of such section 505(e) (section 355(e) of this title), withdrawing or suspending the approval of such application.

"(4) In the case of any drug which, on the day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force (par. (p) of this section), and (C) was not covered by an effective application under section 505 of that Act (section 355 of this title), the amendments to section 201(p) (par. (p) of this section) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day."

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective July 12, 1960, subject to provisions of section 203 of Pub. L. 86-618, see section 202 of Pub. L. 86-618, set out as a note under section 379e of this title.

EFFECTIVE DATE OF 1958 AMENDMENT

Amendment by Pub. L. 85-929 effective Sept. 6, 1958, see section 6(a) of Pub. L. 85-929, set out as a note under section 342 of this title.

EFFECTIVE DATE OF 1954 AMENDMENT

For effective date of amendment by act July 22, 1954, see section 5 of that act, set out as a note under section 342 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 102-282

Amendment by Pub. L. 102-282 not to preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by Pub. L. 102-282, see section 7 of Pub. L. 102-282, set out as a note under section 335a of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101-535

Amendments by Pub. L. 101-535 not to be construed to alter authority of Secretary of Health and Human Services and Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101-535, set out as a note under section 343 of this title.

SAVINGS PROVISION

Section 702 of Pub. L. 91-513, as amended by Pub. L. 93-481, Sec. 2, Oct. 26, 1974, 88 Stat. 1455, provided that:

"(a) Prosecutions for any violation of law occurring prior to the effective date (see Effective Date of 1970 Amendment note above) of section 701 (repealing section 360a of this title, and amending sections 321, 331, 333, 334, 360, 372, and 381 of this title, sections 1114 and 1952 of Title 18, Crimes and Criminal Procedure, and section 242 of Title 42, The Public Health and Welfare) shall not be affected by the repeals or amendments made by such section, or abated by reason thereof.

"(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of section 701 shall not be

affected by the repeals or amendments made by such section, or abated by reason thereof.

"(c) All administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs (now the Drug Enforcement Administration) on the date of enactment of this Act (Oct. 27, 1970) shall be continued and brought to final determination in accord with laws and regulations in effect prior to such date of enactment. Where a drug is finally determined under such proceedings to be a depressant or stimulant drug, as defined in section 201(v) of the Federal Food, Drug, and Cosmetic Act (par. (v) of this section), such drug shall automatically be controlled under this title (subchapter I of chapter 13 of this title) by the Attorney General without further proceedings and listed in the appropriate schedule after he has obtained the recommendation of the Secretary. Any drug with respect to which such a final determination has been made prior to the date of enactment of this Act which is not listed in section 202 (section 812 of this title) within schedules I through V shall automatically be controlled under this title (subchapter I of chapter 13 of this title) by the Attorney General without further proceedings, and be listed in the appropriate schedule, after he has obtained the recommendations of the Secretary.

"(d) Notwithstanding subsection (a) of this section or section 1103 (of Pub. L. 91-513, set out as a note under sections 171 to 174 of this title), section 4202 of title 18, United States Code, shall apply to any individual convicted under any of the laws repealed by this title or title III (subchapter I or subchapter II of chapter 13 of this title) without regard to the terms of any

sentence imposed on such individual under such law."

-TRANS-

TRANSFER OF FUNCTIONS

Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by Pub. L. 96-88, title V, Sec. 509(b), Oct. 17, 1979, 93 Stat. 695, which is classified to section 3508(b) of Title 20, Education.

Functions of Secretary of Health, Education, and Welfare (now Health and Human Services) under Federal Food, Drug, and Cosmetic Act, to the extent such functions related to administration and enforcement of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), transferred to Consumer Product Safety Commission by section 2079 of Title 15, Commerce and Trade.

Functions of Secretary of Health, Education, and Welfare (now Health and Human Services) under Drug Abuse Control Amendments of 1965 (see Short Title of 1965 Amendment note set out under section 301 of this title) transferred to Attorney General except function of regulating counterfeiting of those drugs which are not "depressant or stimulant" drugs, see section 2 of Reorg. Plan No. 1 of 1968, set out in the Appendix to Title 5, Government Organization and Employees.

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare (now Health and Human Services), and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

-MISC5-

CONGRESSIONAL FINDINGS RELATING TO PUB. L. 103-417

Section 2 of Pub. L. 103-417 provided that: "Congress finds that

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"(1) improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government;

"(2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies;

"(3)(A) there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis; and

"(B) clinical research has shown that several chronic diseases can be prevented simply with a healthful diet, such as a diet that is low in fat, saturated fat, cholesterol, and sodium, with a high proportion of plant-based foods;

"(4) healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty;

"(5) preventive health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures;

"(6)(A) promotion of good health and healthy lifestyles improves and extends lives while reducing health care expenditures; and

"(B) reduction in health care expenditures is of paramount importance to the future of the country and the economic well-being of the country;

"(7) there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health;

"(8) consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements;

"(9) national surveys have revealed that almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition;

"(10) studies indicate that consumers are placing increased reliance on the use of nontraditional health care providers to avoid the excessive costs of traditional medical services and to obtain more holistic consideration of their needs;

"(11) the United States will spend over $1,000,000,000,000 on health care in 1994, which is about 12 percent of the Gross National Product of the United States, and this amount and percentage will continue to increase unless significant efforts are undertaken to reverse the increase;

"(12)(A) the nutritional supplement industry is an integral part of the economy of the United States;

"(B) the industry consistently projects a positive trade balance; and

"(C) the estimated 600 dietary supplement manufacturers in the United States produce approximately 4,000 products, with total annual sales of such products alone reaching at least $4,000,000,000;

"(13) although the Federal Government should take swift action

against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers;

"(14) dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and

"(15)(A) legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness; and

"(B) a rational Federal framework must be established to supersede the current ad hoc, patchwork regulatory policy on dietary supplements."

DISSEMINATION OF INFORMATION REGARDING THE DANGERS OF DRUG ABUSE

Section 5 of Pub. L. 90-639 provided that: "It is the sense of the Congress that, because of the inadequate knowledge on the part of the people of the United States of the substantial adverse effects of misuse of depressant and stimulant drugs, and of other drugs liable to abuse, on the individual, his family, and the community, the highest priority should be given to Federal programs to disseminate information which may be used to educate the public, particularly young persons, regarding the dangers of drug abuse."

CONGRESSIONAL FINDINGS AND DECLARATION OF POLICY

Section 2 of Pub. L. 89-74 provided that: "The Congress hereby finds and declares that there is a widespread illicit traffic in depressant and stimulant drugs moving in or otherwise affecting interstate commerce; that the use of such drugs, when not under the supervision of a licensed practitioner, often endangers safety on

the highways (without distinction of interstate and intrastate traffic thereon) and otherwise has become a threat to the public health and safety, making additional regulation of such drugs necessary regardless of the intrastate or interstate origin of such drugs; that in order to make regulation and protection of interstate commerce in such drugs effective, regulation of intrastate commerce is also necessary because, among other things, such drugs, when held for illicit sale, often do not bear labeling showing their place of origin and because in the form in which they are so held or in which they are consumed a determination of their place of origin is often extremely difficult or impossible; and that regulation of interstate commerce without the regulation of intrastate commerce in such drugs, as provided in this Act (see Short Title of 1965 Amendment note set out under section 301 of this title), would discriminate against and adversely affect interstate commerce in such drugs."

EFFECT OF DRUG ABUSE CONTROL AMENDMENTS OF 1965 ON STATE LAWS

Section 10 of Pub. L. 89-74 provided that:

"(a) Nothing in this Act (enacting section 360a of this title, amending sections 321, 331, 333, 334, 360, and 372 of this title and section 1114 of Title 18, Crimes and Criminal Procedure, and enacting provisions set out as notes under sections 321, 352, and 360a of this title) shall be construed as authorizing the manufacture, compounding, processing, possession, sale, delivery, or other disposal of any drug in any State in contravention of the laws of such State.

"(b) No provision of this Act nor any amendment made by it shall be construed as indicating an intent on the part of the Congress to

occupy the field in which such provision or amendment operates to the exclusion of any State law on the same subject matter, unless there is a direct and positive conflict between such provision or amendment and such State law so that the two cannot be reconciled or consistently stand together.

"(c) No amendment made by this Act shall be construed to prevent the enforcement in the courts of any State of any statute of such State prescribing any criminal penalty for any act made criminal by any such amendment."

EFFECT OF DRUG AMENDMENTS OF 1962 ON STATE LAWS

Section 202 of Pub. L. 87-781 provided that: "Nothing in the amendments made by this Act (enacting sections 358 to 360, amending sections 321, 331, 332, 348, 351 to 353, 355, 357, 372, 374, 379e, and 381 of this title, and enacting provisions set out as notes under sections 321, 331, 332, 352, 355, 360, and 374 of this title) to the Federal Food, Drug, and Cosmetic Act (this chapter) shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law."

-CROSS-

CROSS REFERENCES

Appropriations for purpose and administration of pars. (q) and (r) of this section, see section 346b of this title.

-SECREF-

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 343, 346b, 350, 352, 355, 360b, 379e, 802, 825 of this title; title 7 section 136; title 15

sections 1454, 1456, 1471, 2052, 2602; title 18 sections 842, 1365;

title 35 section 156; title 42 sections 274e, 287c-11, 289g-2,

300cc-12, 1396r-8; title 49 section 5702.