a public health advisory described in para-

graph (1).


Stat. 3943.)

REFERENCES IN TEXT

Subsection (a), referred to in par. (1), means subsec.

(a) of section 206 of Pub. L. 111–353.

CONSTRUCTION

Section was enacted as part of the FDA Food Safety

Modernization Act, and not as part of the Federal

Food, Drug, and Cosmetic Act which comprises this

chapter.

SUBCHAPTER V—DRUGS AND DEVICES

PART A—DRUGS AND DEVICES

§ 351. Adulterated drugs and devices

A drug or device shall be deemed to be adulter-

ated—

(a) Poisonous, insanitary, etc., ingredients; ade-

quate controls in manufacture

(1) If it consists in whole or in part of any

filthy, putrid, or decomposed substance; or

(2)(A) If it has been prepared, packed, or held

under insanitary conditions whereby it may

have been contaminated with filth, or whereby

it may have been rendered injurious to health;

or (B) if it is a drug and the methods used in, or

the facilities or controls used for, its manufac-

ture, processing, packing, or holding do not con-

form to or are not operated or administered in

conformity with current good manufacturing

practice to assure that such drug meets the re-

quirements of this chapter as to safety and has

the identity and strength, and meets the quality

and purity characteristics, which it purports or

is represented to possess; or (C) if it is a com-

pounded positron emission tomography drug and

is represented to possess; or (3) if its container is composed, in

whole or in part, of any poisonous or deleterious

substance which may render the contents injuri-

ous to health; or (4) if (A) it bears or contains,

for purposes of coloring only, a color additive

which is unsafe within the meaning of section

379e(a) of this title, or (B) it is a color additive

the intended use of which in or on drugs or de-

vices is for purposes of coloring only and is un-

safe within the meaning of section 379e(a) of this

title; or (5) if it is a new animal drug which is

unsafe within the meaning of section 360b of this

title; or (6) if it is an animal feed bearing or con-

taining a new animal drug, and such animal feed

is unsafe within the meaning of section 360b of

this title.

(b) Strength, quality, or purity differing from of-

ficial compendium

If it purports to be or is represented as a drug

the name of which is recognized in an official

compendium, and its strength differs from, or

its quality or purity fails below, the standard

set forth in such compendium. Such determina-

tion as to strength, quality, or purity shall be

made in accordance with the tests or methods of

assay set forth in such compendium, except that

whenever tests or methods of assay have not

been prescribed in such compendium, or such

tests or methods of assay as are prescribed are,

in the judgment of the Secretary, insufficient

for the making of such determination, the Sec-

retary shall bring such fact to the attention of

the appropriate body charged with the revision

of such compendium, and if such body fails with-

in a reasonable time to prescribe tests or meth-

ods of assay which, in the judgment of the Sec-

retary, are sufficient for purposes of this para-

graph, then the Secretary shall promulgate reg-

ulations prescribing appropriate tests or meth-

ods of assay in accordance with which such de-

termination as to strength, quality, or purity

shall be made. No drug defined in an official

compendium shall be deemed to be adulterated

under this paragraph because it differs from the

standard of strength, quality, or purity therefor

set forth in such compendium, if its difference in

strength, quality, or purity from such standard

is plainly stated on its label. Whenever a drug is

recognized in both the United States Pharma-

copoeia and the Homoeopathic Pharmacopoeia

of the United States it shall be subject to the re-

quirements of the United States Pharmacopoeia

unless it is labeled and offered for sale as a

homeopathic drug, in which case it shall be

subject to the provisions of the Homoeopathic

Pharmacopoeia of the United States and not to

those of the United States Pharmacopoeia.

(c) Misrepresentation of strength, etc., where

drug is unrecognized in compendium

If it is not subject to the provisions of para-

graph (b) of this section and its strength differs

from, or its purity or quality falls below, that

which it purports or is represented to possess.

(d) Mixture with or substitution of another sub-

stance

If it is a drug and any substance has been (1)

mixed or packed therewith so as to reduce its

quality or strength or (2) substituted wholly or

in part therefor.

(e) Devices not in conformity with performance

standards

(1) If it is, or purports to be or is represented

as, a device which is subject to a performance

standard established under section 360d of this

title unless such device is in all respects in con-

formity with such standard.

(2) If it is declared to be, purports to be, or is

represented as, a device that is in conformity

with any standard recognized under section

360d(c) of this title unless such device is in all

respects in conformity with such standard.
(f) Certain class III devices

(1) If it is a class III device—

(A)(i) which is required by a regulation promulgated under subsection (b) of section 360e of this title to have an approval under such section of an application for premarket approval and which is not exempt from section 360e of this title under section 360j(g) of this title, and

(ii) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the Secretary within the ninety-day period beginning on the date of the promulgation of such regulation, or

(II) for which such an application was filed and approval of the application has been denied, suspended, or withdrawn, or such a notice was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

(B)(i) which was classified under section 360(f)(l) of this title into class III, which under section 360a of this title is required to have in effect an approved application for premarket approval, and which is not exempt from section 360e of this title under section 360j(g) of this title, and

(ii) which has an application which has been suspended or is otherwise not in effect; or

(C) which was classified under section 360j(i) of this title into class III, which under such section is required to have in effect an approved application under section 360e of this title, and which has an application which has been suspended or is otherwise not in effect.

(2)(A) In the case of a device classified under section 360(f) of this title into class III and intended solely for investigational use, paragraph(1)(B) shall not apply with respect to such device during the period ending on the ninetieth day after the date of the promulgation of the regulations prescribing the procedures and conditions required by section 360j(g)(2) of this title.

(B) In the case of a device subject to a regulation promulgated under subsection (b) of section 360e of this title, paragraph(1) shall not apply with respect to such device during the period ending—

(i) on the last day of the thirtieth calendar month beginning after the month in which the classification of the device in class III became effective under section 360e of this title, or

(ii) on the ninetieth day after the date of the promulgation of such regulation, whichever occurs later.

(g) Banned devices

If it is a banned device.

(h) Manufacture, packing, storage, or installation of device not in conformity with applicable requirements or conditions

If it is a device and the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 360(f)(1) of this title or an applicable condition prescribed by an order under section 360(f)(2) of this title.

(i) Failure to comply with requirements under which device was exempted for investigational use

If it is a device for which an exemption has been granted under section 360(g) of this title for investigational use and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section.


AMENDMENTS

1997—Par. (a)(2)(C), Pub. L. 105–115, §121(b)(1), inserted “; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopeia to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess;” before “or (3)”.

Par. (e), Pub. L. 105–115, §204(c), designated existing provisions as subpar. (1) and added subpar. (2).

1992—Par. (a)(4), Pub. L. 102–571 substituted “379e(a)” for “376(a)” in cls. (A) and (B).

1990—Par. (f)(1), Pub. L. 101–629, §9(b), which directed the amendment of subpars. (A) to (C) of par. (f), was executed by making the amendments in cls. (A) to (C) of subpar. (1) of par. (f) as follows to reflect the probable intent of Congress: in cl. (A)(i)(II), substituted “suspended, or withdrawn” for “or withdrawn”; in cl. (B)(ii), substituted “which has an application which has been suspended or is otherwise not in effect” for “which does not have such an application in effect”; and in cl. (C), substituted “which has an application which has been suspended or is otherwise not in effect” for “which does not have such an application in effect”.

1976—Par. (a), Pub. L. 94–295, §9(b)(1), substituted “(3) if its” for “(3) if it is a drug and its” in cl. (3), substituted “(4) If (A) it bears or contains” for “(4) if (A)” in cl. (4) which is a drug and its’ contains” in cl. (4)(A), and substituted “drugs or devices” for “drugs” in cl. (4)(B).

1968—Par. (a), Pub. L. 90–399 added cls. (5) and (6).

1962—Par. (a), Pub. L. 87–781 designated existing provisions of cl. (2) as (A) and added (B).

1960—Par. (a), Pub. L. 86–438 substituted provisions in cl. (4) relating to unsafe color additives for provisions which related to a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 354 of this title.

Effective and Termination Dates of 1997 Amendment

Section 121(b)(2) of Pub. L. 105–115 provided that “Section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §351(a)(2)(C)) shall not apply 4 years after the date of enactment of this Act [Nov. 21,
1997 or 2 years after the date on which the Secretary of Health and Human Services establishes the requirements described in subsection (c)(1)(B) [section 352(b)(1)(B) of Pub. L. 105-115, set out as a note under section 355 of this title], whichever is later."

Amendment by Pub. L. 105-115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

**Effective Date of 1968 Amendment**
Amendment by Pub. L. 90-399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90-399, set out as an Effective Date and Transitional Provisions note under section 368b of this title.

**Effective Date of 1962 Amendment; Exceptions**
Amendment by Pub. L. 87-781 effective on first day of seventh calendar month following October 1962, see section 107 of Pub. L. 87-781, set out as a note under section 321 of this title.

**Effective Date of 1960 Amendment**

**Effective Date: Postponement**
Par. (a)(4) effective Jan. 1, 1940, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date; Postponement in Certain Cases note under section 301 of this title.

**Transfer of Functions**
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 notes set out under section 321 of this title.

§ 352. Misbranded drugs and devices
A drug or device shall be deemed to be misbranded—

(a) False or misleading label
If its labeling is false or misleading in any particular. Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading under this paragraph if the health care economic information directly relates to an indication approved under section 355 of this title or under section 262(a) of title 42 for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 355(a) of this title or in section 262(a) of title 42 shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term “health care economic information” means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention.

(b) Package form; contents of label
If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) Prominence of information on label
If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.


(e) Designation of drugs or devices by established names
(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—
(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;
(ii) the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if determined to be appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetaldehyde, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscynamine, arsenic, digitalis, digitals glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to nonprescription drugs not intended for human use; and
(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail packaging and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, except that nothing in this subclause shall be deemed to require that any trade secret be divulged and except that the requirements of this subclause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and that this subclause shall not apply to nonprescription drugs not intended for human use.

(B) For any prescription drug the established name of such drug or ingredient, as the case