§ 321d. Market names for catfish and ginseng

(a) Catfish labeling

(1) In general

Notwithstanding any other provision of law, for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.),—

(A) the term “catfish” may only be considered to be a common or usual name (or part thereof) for fish classified within the family Ictaluridae; and

(B) only labeling or advertising for fish classified within that family may include the term “catfish”.

(2) Omitted

(b) Ginseng labeling

(1) In general

Notwithstanding any other provision of law, for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.),—

(A) the term “ginseng” may only be considered to be a common or usual name (or part thereof) for any herb or herbal ingredient derived from a plant classified within the genus Panax; and

(B) only labeling or advertising for herbs or herbal ingredients classified within that genus may include the term “ginseng”.

(2) Omitted


REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a)(1), (b)(1), is act June 25, 1906, ch. 675, 52 Stat. 1040, as amended, which is classified generally to this chapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

CODIFICATION


Section was enacted as part of the Farm Security and Rural Investment Act of 2002, and not as part of Federal Food, Drug, and Cosmetic Act which comprises this chapter.

SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

§ 331. Prohibited acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 350d, 355, or 360bbb–3 of this title.

(e) The refusal to permit access to or copying of any record as required by section 350a, 350c, 350(r), 350e, 350f, 350g, 355(i) or (k), 360(b(a)(4)(C), 360(b)(j), (l) or (m), 360(c–1)(i), 360(e)(f), 360i, 360bbb–3, 379a, 379aa–1, 387i, or 387t of this title or the refusal to permit access to or verification or copying of any such required record; or the violation of any record-keeping requirement under section 2223 of this title (except when such violation is committed by a farm).

(f) The refusal to permit entry or inspection as authorized by section 374 of this title.

(g) The manufacture within any Territory of any food, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The giving of a guaranty or undertaking referred to in section 333(c)(2) of this title, which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 333(c)(3) of this title, which guaranty or undertaking is false.

(1)(d) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 344 or 379e of this title.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The use of any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of section 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 360k, 360ccc, 360ccc–1, 360ccc–2, 374, 379, 379e, 379k, 387, 387t, 387y, 387h, 387i, or 387t(b) of this title concerning any method or process which as a trade secret is entitled to protection; or the violating of section 346a(2) of this title or any regulation issued under that section.

This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such

1 See References in Text note below.

2 So in original.
or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.


(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of subsections (b) or (c) of section 347 of this title.

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 374(a) of this title.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

(p) The failure to register in accordance with section 360 or 387 of this title, the failure to provide any information required by section 360(j), 360(k), 387(e), or 387(e)(j) of this title, or the failure to provide a notice required by section 360(j)(2) or 387(e)(j) of this title.

(q) (1) The failure or refusal—

(A) to comply with any requirement prescribed under section 360h, 360(g), 387(a), 387g, 387h, or 387o of this title;

(B) to furnish any notification or other material or information required by or under section 360h, 360(g), 387(d), 387i, or 387t of this title; or

(C) to comply with a requirement under section 360l or 387m of this title.

(2) With respect to any device or tobacco product, the submission of any report that is required by or under this chapter that is false or misleading in any material respect.

(r) The movement of a device, drug, or tobacco product in violation of an order under section 334(g) of this title or the removal or alteration of any mark or label required by the order to identify the device, drug, or tobacco product as detained.

(s) The failure to provide the notice required by section 350a(c) or 350a(e) of this title, the failure to make the reports required by section 350a(f)(1)(B) of this title, the failure to retain the records required by section 350a(b)(4) of this title, or the failure to meet the requirements prescribed under section 350a(f)(3) of this title.

(t) The importation of a drug in violation of section 381(d)(1) of this title, the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 333(c) of this title, the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 333(c)(2) of this title, the distribution of a drug sample in violation of section 333(d) of this title or the failure to otherwise comply with the requirements of section 333(d) of this title, the distribution of drugs in violation of section 333(e) of this title, failure to comply with the requirements under section 360ee-1 of this title, the failure to comply with the requirements under section 360ee-3 of this title, as applicable, or the failure to otherwise comply with the requirements of section 333(e) of this title.

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 360(a)(4)(A), 360(a)(4)(D), or 360(a)(5) of this title.

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 350b of this title.

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 381(d)(3) of this title; the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 381(e) or 382 of this title, or with section 362(b) of title 42; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under section 360ee(c) of this title or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

(y) In the case of a drug, device, or food—

(1) the submission of a report or recommendation by a person accredited under section 360m of this title that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 360m of this title of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 360m of this title of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this chapter.

(2) Omitted.

(aa) The importation of a prescription drug in violation of section 384 of this title, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

(bb) The transfer of an article of food in violation of an order under section 333(h) of this title,
or the removal or alteration of any mark or label required by the order to identify the article as detained.

(cc) The importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of, a person debarred under section 355a(b)(3) of this title.

(dd) The failure to register in accordance with section 3504 of this title.

(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 381(m) of this title.

(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 381(o) of this title.

(gg) The knowing failure to comply with paragraph (7)(E) of section 374(g) of this title; the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

(hh) The failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by the Secretary under section 350e of this title.

(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 379aa or 379aa-1 of this title) or the falsification of a serious adverse event report (as defined under section 379aa or 379aa-1 of this title) submitted to the Secretary.

(jj)(1) The failure to submit the certification required by section 282(j)(5)(B) of title 42, or knowingly submitting a false certification under such section.

(2) The failure to submit clinical trial information required under subsection (j) of section 282 of title 42.

(3) The submission of clinical trial information under subsection (j) of section 282 of title 42 that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).

(kk) The dissemination of a television advertisement without complying with section 353c-1 of this title.

(ll) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 355 of this title, a biological product licensed under section 262 of title 42, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless—

(1) such drug or such biological product was marketed in food before any approval of the drug under section 355 of this title, before licensure of the biological product under such section 262 of title 42, or before any substantial clinical investigations involving the drug or the biological product have been instituted;

(2) the Secretary, in the Secretary’s discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

(3) the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with—

(A) a regulation issued under section 348 of this title prescribing conditions of safe use in food;

(B) a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier’s determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

(D) a food contact substance notification that is effective under section 348(h) of this title; or

(E) such drug or biological product had been marketed for smoking cessation prior to September 27, 2007; or

(4) the drug is a new animal drug whose use is not unsafe under section 360b of this title.

(mm) The failure to submit a report or provide a notification required under section 350f(d) of this title.

(nn) The falsification of a report or notification required under section 350f(d) of this title.

(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 333(f) of this title.

(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 367k of this title.

(qq)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(qq)(2) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

(rr) The charitable distribution of tobacco products.

(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.
(tt) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing that—

(1) the product is approved by the Food and Drug Administration;

(2) the Food and Drug Administration deems the product to be safe for use by consumers; or

(3) the product is endorsed by the Food and Drug Administration for use by consumers; or

(4) the product is safe or less harmful by virtue of—

(A) its regulation or inspection by the Food and Drug Administration; or

(B) its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under section 350 of this title.

(uu) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 350 of this title.

(vv) The failure to comply with the requirements under section 350f of this title.

(wv) The importation or offering for importation of a food if the importer (as defined in section 384a of this title) fails to notify the Secretary in accordance with subsection (b) of section 353b of this title.

(xx) The refusal or failure to follow an order under section 350f of this title.

(yy) The knowing and willful failure to comply with the notification requirement under section 350f(h) of this title.

(zz) The failure to register in accordance with subsection (b) of this section.

(aaa) The failure to notify the Secretary in violation of section 380b-7 of this title.

(ccc)(1) The resale of a compounded drug that is labeled “not for resale” in accordance with section 353b of this title.

(2) With respect to a drug to be compounded pursuant to section 353a or 353b of this title, the intentional falsification of a prescription, as applicable.

(3) The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 333b of this title.

(ddd)(1) The manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally-added plastic microbeads.

(2) In this paragraph—

(A) the term “plastic microbead” means any solid plastic particle that is less than five millimeters in size and is intended to be used to exfoliate or cleanse the human body or any part thereof; and

(B) the term “rinse-off cosmetic” includes toothpaste.

References in Text

Section 2223 of this title, referred to in par. (e), was in the original “section 294 of the FDA Food Safety Modernization Act”, meaning section 294 of Pub. L. 111–353, which enacted section 2223 of this title and amended this section and section 381 of this title.

Section 335c of this title, referred to in par. (kk), was in the original a reference to section 503b of act June 25, 1938, and was translated as if it referred to section 503c of that Act, to reflect the probable intent of Con-
gress and the renumbering of section 503B as 503c by Pub. L. 113–54, title I, §102(a)(1), Nov. 27, 2013, 127 Stat. 587, and its transfer to section 353c of this title. A new section 503B, which was enacted by section 102(a)(2) of Pub. L. 113–54, is classified to section 353b of this title and does not relate to television advertisements.

CONSTITUTIONALITY


AMENDMENTS


Par. (t). Pub. L. 113–54, §206(a), struck out “or” after “the requirements of section 353(d) of this title,” and inserted “failure to comply with the requirements under section 360ee–1 of this title, the failure to comply with the requirements under section 360ee–3 of this title, as applicable,” after “in violation of section 333(e) of this title”.


Prior to amendment, text read as follows: “The knowing failure of a person accredited under paragraph (2) of section 374(g) of this title to comply with paragraph (7)(A) of such section; the knowing inclusion by such a person of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.”


Prior to amendment, text read as follows: “The knowing failure of a person accredited under paragraph (2) of section 374(g) of this title to comply with paragraph (7)(A) of such section; the knowing inclusion by such a person of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.”


Prior to amendment, text read as follows: “The knowing failure of a person accredited under paragraph (2) of section 374(g) of this title to comply with paragraph (7)(A) of such section; the knowing inclusion by such a person of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.”


Par. (g). Pub. L. 105–111, §103(b)(12), inserted “or tobacco product” after “device,” in two places.


Pars. (mm), (nn). Pub. L. 110–85, §1005(d)(2), added paras. (mm) and (nn).
Par. (l). Pub. L. 105–115, §421, struck out par. (l) which read as follows: “The using for introduction into interstate commerce of any drug or device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect under section 355, 360e, or 360(g) of this title, as the case may be, or that such drug or device complies with the provisions of such section.”
1996—Par. (e). Pub. L. 104–250 inserted “, 354,” before “or 373 of this title” and “, 355(i)” or “(k)”.
Par. (t). Pub. L. 104–170 inserted before period at end of first sentence “or the violating of section 348(a)(2) of this title or any regulation issued under that section.”
Par. (u) to (w). Pub. L. 104–134 redesignated par. (u) relating to introduction into interstate commerce of unsafe dietary supplement as (v) and added par. (w).
1994—Par. (e). Pub. L. 103–366, §2(b)(1)(A), substituted “357(d) or (g)” for “357(d) or (g)(2)”.
Par. (u). Pub. L. 103–417 added par. (u) relating to introduction into interstate commerce of unsafe dietary supplement.
Pub. L. 103–366, §2(b)(1)(B), added par. (u) relating to failure to comply with regulations or orders of Secretary.
1993—Par. (j). Pub. L. 103–80, §3(c)(1), substituted “379, or 379m for “350a(d)”.
1990—Par. (e). Pub. L. 101–502 substituted “or (k)” for “or (j)”.
Par. (j). Pub. L. 101–508 inserted at end “This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of master within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.”
1986—Par. (s). Pub. L. 99–570 amended par. (s) generally. Prior to amendment, par. (s) read as follows: “The failure to provide the notice required by section 356a(d) of this title, or to establish or maintain any record, or access to, or verification or copying of, any such record.
1970—Par. (q). Pub. L. 91–513 struck out par. (q) which set out penalties for illegal manufacture, sale, disposition, possession and other traffic in stimulant and depressant drugs. See section 801 et seq. of this title.
1968—Par. (e). Pub. L. 90–399, §103(l), struck out “or” before “357(d) or (g)” and inserted “, or 360(g) of this title, or the refusal to permit access to, or verification or copying of, any such record.
Par. (q). Pub. L. 90–638 divided cl. (s), which referred simply to possession in violation of section 368ac of this title, into subcls. (A) and (B) which refer, respectively, to possession in violation of section 360ac(c) of this title and possession in violation of section 360ac(c)(2) of this title.
1965—Par. (l). Pub. L. 89–74, §9(c), designated existing provisions as subpar. (1) and added subpars. (2) and (3).
1962—Par. (e). Pub. L. 87–781, §§106(c), 106(c), prohibited the failure to establish or maintain any record, or make any report, required under sections 355(i) or (j) and 357(d) or (g) of this title, or the refusal to permit access to, or verification or copying of, any such required record.
Par. (l). Pub. L. 87–781, §106(e)(1), inserted “approval of” before “an application”, and substituted “in effect” for “effective”.
1948—Par. (k). Act June 24, 1948, inserted “whether or not the first sale” so as to make it clear that this subsection is not limited to the case where the act occurs while the article is held for the first sale after interstate shipment, and extended coverage of subsection to acts which result in adulteration.

Effective Date of 2015 Amendment
“(1) In general.—The amendment made by subsection (a) [amending this section] applies—
“(A) with respect to manufacturing, beginning on July 1, 2017, and with respect to introduction or delivery for introduction into interstate commerce, beginning on July 1, 2018; and
“(B) notwithstanding subparagraph (A), in the case of a rinse-off cosmetic that is a nonprescription drug, with respect to manufacturing, beginning on July 1, 2018, and with respect to the introduction or delivery for introduction into interstate commerce, beginning on July 1, 2019.
“(2) NONPRESCRIPTION DRUG.—For purposes of this subsection, the term ‘nonprescription drug’ means a drug not subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).”

Effective Date of 2011 Amendment
Amendment by section 103(e) of Pub. L. 111–353 effective 18 months after Jan. 4, 2011, and applicable to a small business (as defined in the regulations promulgated under section 350(g)(n) of this title) beginning on the date that is 6 months after the effective date of such regulations and to a very small business (as de-

Amendment by section 401(b) of Pub. L. 105–115 effective 1 year after Nov. 21, 1997, or upon Secretary’s issuance of final regulations pursuant to section 401(c) of Pub. L. 105–115, whichever is sooner, and ceases to be effective Sept. 30, 2006, see section 401(d), (e) of Pub. L. 105–115, set out as an Effective and Termination Dates note under former section 360aa of this title.

Effective Date of 1994 Amendment

Amendment by Pub. L. 103–396 effective upon adoption of final regulations under section 2(c) of Pub. L. 103–396, set out as a Regulations note under section 360b of this title, section 2(d) of Pub. L. 103–396, set out as a note under section 360b of this title.

Effective Date of 1990 Amendment


Effective Date of 1988 Amendment

Amendment by Pub. L. 100–293 effective upon expiration of 90 days after Apr. 22, 1988, see section 8(a) of Pub. L. 100–293, set out as a note under section 333 of this title.

Effective Date of 1972 Amendment


Effective Date of 1970 Amendment


Effective Date of 1968 Amendments

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 360b of this title.

Amendment by Pub. L. 90–639 applicable only with respect to violations of this chapter committed after Oct. 24, 1968, see section 6 of Pub. L. 90–639, set out as an Effective Date of 1968 Amendments; Transitional Provisions note under section 321 of this title.
February 1, 1966, see section 11 of Pub. L. 89–74, set out as a note under section 321 of this title.

**Effective Date of 1962 Amendment**


Pub. L. 87–781, title I, §144(b), Oct. 10, 1962, 76 Stat. 791, provided that: "This section [amending this section] shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted (October 1962)."

**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 6(a) of Pub. L. 86–618, set out as a note under section 370c 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 1950 Amendment**

Amendment by Pub. L. 73–548, which cancels any regulations to implement this title [enacting subpart 9 of part C of subchapter VIII of this chapter and sections 535a–1 and 535a–2 of this title, amending this section and sections 252, 533a, 535a, 535a–2, and 333c of this title, and enacting provisions set out as notes under section 301 of this title (and the amendments made by this title)], the Secretary of Health and Human Services shall—

"(1) issue a notice of proposed rulemaking that includes the proposed regulation;

"(2) provide a period of not less than 60 calendar days for comments on the proposed regulation; and

"(3) publish the final regulation not more than 18 months following publication of the proposed rule and not less than 30 calendar days before the effective date of such final regulation.""

Secretary of Health and Human Services to promulgate regulations to implement amendments made by section 401 of Pub. L. 105–115 not later than 1 year after Nov. 21, 1997, see section 401(c) of Pub. L. 105–115, set out as a note under section 360aaa of this title.

**Savings Provisions**

Pub. L. 113–54, title II, §208, Nov. 27, 2013, 127 Stat. 640, provided that: "Except as provided in the amendments made by paragraphs (1), (2), and (3) of section 209(a) [amending section 305 of this title], and by section 209(a) [amending this section], nothing in this title [enacting part H of subchapter V of this chapter, amending this section and sections 333, 335, 333a, and 360aa and modifying existing limitations on State government authority over tribal restricted fee or trust lands.] shall be construed as altering any authority of the Secretary of Health and Human Services with respect to a drug subject to section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) under any other provision of such Act [21 U.S.C. 301 et seq.] or the Public Health Service Act (42 U.S.C. 201 et seq.) except as provided by Pub. L. 91–513 not to affect or abate any proceedings for violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91–513, set out as a note under section 321 of this title.

**Construction of 2015 Amendment**

Pub. L. 114–114, §2(d), Dec. 28, 2015, 129 Stat. 3130, provided that: "Nothing in this Act [amending this section and enacting provisions set out as notes under this section and section 301 of this title] or the amendments made by this Act shall be construed to apply with respect to drugs that are not also cosmetics (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321))."

**Construction of 2011 Amendment**

Nothing in amendments by sections 105(e), 106(c), 106(d), 208(j)(1), 211(b), (c), and 301(b) of Pub. L. 111–353 to be construed to apply to certain alcohol-related facilities, see section 2206 of this title.

Nothing in amendments by Pub. L. 111–353 to be construed to alter jurisdiction and authorities established under certain other Acts or in a manner inconsistent with international agreements to which the United States is a party, see sections 2251 and 2252 of this title.

**Construction of 2009 Amendments**

Pub. L. 111–31, div. A, title I, §103(p), June 22, 2009, 123 Stat. 1638, provided that: "Nothing in this section [amending this section and sections 333, 334, 335, 360m, 372 to 374, 375, 379a, 381, 393, 399, and 679 of this title and enacting provisions set out as notes under sections 333 and 337 of this title] is intended or shall be construed to expand, contract, or otherwise modify or amend the existing limitations on State government authority over tribal restricted fee or trust lands."

**Construction of 2002 Amendments**

Pub. L. 107–188, title III, §315, June 12, 2002, 116 Stat. 675, provided that: "Nothing in this title [enacting sections 335c, 350d, 396, 399, and 679 of this title, sections 333a, 352, and 360m of this title, and section 247b–20 of Title 42, The Public Health and Welfare, amending this section, sections 334, 335a, 342, 343, 360, 372, 374, and 381 of this title, and section 43 of Title 18, Crimes and Criminal Procedure, and enacting provisions set out as notes under this section and sections 341, 350c, 350d, and 381 of this title] or an amendment made by this title, shall be construed to alter the jurisdiction between the Secretary of Agriculture and the Secretary of Health and Human Services, under applicable statutes and regulations."

**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.

**Preemption of State Laws**

Pub. L. 114–114, §2(c), Dec. 28, 2015, 129 Stat. 3129, provided that: "No State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect restrictions with respect to the manufacture or introduction or delivery for introduction into interstate commerce of rinse-off cosmetics containing plastic microbeads (as defined in section 301(dd) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) that are not identical to the restrictions under such section 301(dd) that have begun to apply under subsection (b) [set out as a note above])."
§ 332. Injunction proceedings
(a) Jurisdiction of courts
The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown\(^1\) to restrain violations of section 331 of this title, except paragraphs (h), (i), and (j).

(b) Violation of injunction
In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by the court, or, upon demand of the accused, by a jury.


AMENDMENTS
1993—Subsec. (a). Pub. L. 103–80, § 3(d)(1), struck out "(1)" and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled "An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes", approved Oct. 15, 1914, as amended (U.S.C., 1934 ed., title 29, sec. 381)," after "for cause shown".

Subsec. (b). Pub. L. 103–80, § 3(d)(2), struck out at end "Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended (U.S.C., 1934 ed., title 29, sec. 367)."

1962—Subsec. (a). Pub. L. 87–781, § 103(d), struck out "(e)," after "paragraphs".

Pub. L. 87–781, § 201(c), struck out "(f)," after "paragraphs".

EFFECTIVE DATE OF 1962 AMENDMENT
Amendment by section 103(c) of Pub. L. 87–781 effective on first day of seventh calendar month following October 10, 1962, see section 107 of Pub. L. 87–781, set out as a note under section 321 of this title.

Pub. L. 87–781, title II, § 203, Oct. 10, 1962, 76 Stat. 793, provided that: "The amendments made by this title (amending this section and section 374 of this title and enacting provisions set out as notes under sections 321 and 374 of this title) shall take effect on the date of enactment of this Act (Oct. 10, 1962)."

§ 333. Penalties
(a) Violation of section 331 of this title; second violation; intent to defraud or mislead
(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section,\(^2\) if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

(b) Prescription drug marketing violations
(1) Notwithstanding subsection (a), any person who violates section 351(t) of this title by—

\(^1\) So in original. Probably should be followed by a comma.

\(^2\) So in original. Words `of this section` probably should not appear.

(A) knowingly importing a drug in violation of section 381(d)(1) of this title,

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 353(c)(1) of this title,

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 353(e)(1) of this title, or

(D) knowingly distributing drugs in violation of section 353(e)(1) of this title, shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative’s employment or association with that manufacturer or distributor, violated section 331(t) of this title because of a violation of section 353(c)(1) of this title or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 353(b) of this title or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than $50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

(B) A civil penalty of not more than $1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

(3) Any manufacturer or distributor who violates section 331(t) of this title because of a failure to make a report required by section 353(d)(3)(E) of this title shall be subject to a civil penalty of not more than $100,000.

(4)(A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section 331(t) of this title because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 353(c)(1) of this title or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence—

(i) that the manufacturer or distributor conducted, before the institution of a criminal