§ 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, 350f (j), 350e, 354, 360bbb–3, 373, 374 (a), 379aa, or 379aa–1 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 350c (b), 350f, 350e, 354, 355 (i) or (k), 360b (a)(4)(C), 360b (j), (l) or (m), 360ccc–1 (i), 360e (f), 360i, 360bbb–3, 379aa, 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 recordkeeping requirement under section 2223 1 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, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(h) 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)(2) of this title, which guaranty or undertaking is false.

(i) (1) 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 using by 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, 360ccc, 360ccc–1, 360ccc–2, 374, 379, 379e, 387d, 387e, 387f, 387g, 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 (i)(2) of this title or any regulation issued under that section. 2 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 committee or any joint committee of Congress 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 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 387e of this title, the failure to provide any information required by section 360 (j), 360 (k), 387e (i), or 387e (j) of this title, or the failure to provide a notice required by section 360 (j)(2) or 387e (i)(3) of this title.

(q) (1) The failure or refusal—
(A) to comply with any requirement prescribed under section 360h, 360j (g), 387c (b), 387g, 387h, or 387o of this title;
(B) to furnish any notification or other material or information required by or under section 360i, 360j (g), 387d, 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 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 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 353 (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 353 (c)(2) of this title, the distribution of a drug sample in violation of section 353 (d) of this title or the failure to otherwise comply with the requirements of section 353 (d) of this title, or the distribution of drugs in violation of section 353 (e) of this title or the failure to otherwise comply with the requirements of section 353 (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 360b (a)(4)(A), 360b (a)(4)(D), or 360b (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 262 (h) 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 360d (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.

(z) 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 334 (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 335a (b)(3) of this title.

(dd) The failure to register in accordance with section 350d 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 353b 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, and 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 387k 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.

(3) 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;
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 387c 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 350g of this title.

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

(ww) The failure to comply with section 350i of this title.

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

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

(zz) The importation or offering for importation of a food if the importer (as defined in section 384a of this title) does not have in place a foreign supplier verification program in compliance with such section 384a of this title.

Footnotes

1 See References in Text note below.
2 So in original.

References in Text

Section 2223 of this title, referred to in par. (e), was in the original “section 204 of the FDA Food Safety Modernization Act”, meaning section 204 of Pub. L. 111–353, which enacted section 2223 of this title and amended this section and section 381 of this title.

Amendments


Par. (e). Pub. L. 111–353, §§ 204(j)(1), 211 (c), substituted “350f(j)” for “350f(g)” and inserted before period at end “; or the violation of any recordkeeping requirement under section 2223 of this title (except when such violation is committed by a farm)”.


Par. (vv). Pub. L. 111–353, § 105(c), added par. (vv).


2009—Pars. (a) to (c). Pub. L. 111–31, § 103(b)(1)–(3), inserted “tobacco product,” after “device.”.

Par. (e). Pub. L. 111–31, § 103(b)(4)(B), which directed substitution of “379aa–1, 387i, or 387t of this title or the refusal to permit access to” for “or 379aa–1 of this title or the refusal to permit access to”, was executed by making the substitution for “or 379aa–1 of this title, or the refusal to permit access to”, to reflect the probable intent of Congress.

Pub. L. 111–31, § 103(b)(4)(A), struck out period after “360ccc–1(i)”.

Pars. (g), (h). Pub. L. 111–31, § 103(b)(5), (6), inserted “tobacco product,” after “device.”.

Par. (j). Pub. L. 111–31, § 103(b)(7), struck out period after “360ccc–2” and substituted “379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387t(b)” for “379, or 379e”.

Par. (k). Pub. L. 111–31, § 103(b)(8), inserted “tobacco product,” after “device.”.

Par. (p). Pub. L. 111–31, § 103(b)(9), added par. (p) and struck out former par. (p) which read as follows: “The failure to register in accordance with section 360 of this title, the failure to provide any information required by section 360 (j) or 360 (k) of this title, or the failure to provide a notice required by section 360 (j)(2) of this title.”

Par. (q)(1). Pub. L. 111–31, § 103(b)(10), added subpar. (1) and struck out former subpar. (1) which read as follows: “The failure or refusal to (A) comply with any requirement prescribed under section 360h or 360j (g) of this title, (B) furnish any notification or other material or information required by or under section 360i or 360j (g) of this title, or (C) comply with a requirement under section 360l of this title.”

Par. (q)(2). Pub. L. 111–31, § 103(b)(11), substituted “device or tobacco product,” for “device.”.

Par. (r). Pub. L. 111–31, § 103(b)(12), inserted “or tobacco product” after “device” in two places.

Pars. (oo) to (tt). Pub. L. 111–31, § 103(b)(13), added pars. (oo) to (tt).

2007—Par. (e). Pub. L. 110–85, § 1005(d)(1), substituted “350c, 350f(g),” for “350c,” and “350c(b), 350f” for “350c(b)”. 


Par. (mm), (nn). Pub. L. 110–85, § 1005(d)(2), added pars. (mm) and (nn).

2006—Par. (e). Pub. L. 109–462, § 3(b), substituted “374(a), 379aa, or 379aa–1” for “374(a), or 379aa” and “360bbb–3, 379aa, or 379aa–1” for “360bbb–3, or 379aa”.

Par. (ll). Pub. L. 109–462, § 2(c), substituted “374(a), or 379aa” for “, or 374(a)” and “, 360bbb–3, or 379aa” for “, or 360bbb–3”.


Par. (jj). Pub. L. 109–462, § 102(b)(5)(C), which directed the substitution of “360b(a)(4)(C), 360b (j), (l) or (m), 360ccc–1(i).” for “360b(a)(4)(C), 360b(j), (l) or (m)” was executed by making the substitution for “360b(a)(4)(C), 360b(j), (l), or (m),” to reflect the probable intent of Congress.


Par. (gg). Pub. L. 108–214 amended par. (gg) generally. 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)(E) 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. (ee). Pub. L. 108–282, § 306(c)(2), inserted “350c,” after “354c,” and substituted “360i, or 360bbb–3” for “or 360i”.


Par. (gg). Pub. L. 107–188, § 306(c)(1), substituted “by section 350a, 350c, 354, 373, or 374 (a) of this title” for “by section 350a, 350c, 354, or 373 or 374 of this title” and “under section 350a, 350c (b)” for “under section 350a”.


Par. (kk). Pub. L. 105–115, § 125(b)(2)(B), struck out “357(d) or (g),” after “355(i) or (k),”.


Par. (ll). Pub. L. 105–115, § 421, struck out par. (l) which read as follows: “The using, on the labeling of any drug or device or in any advertising relating to such 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 360j (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 “354,” before “355(i) or (k)”.
Par. (j). Pub. L. 104–170 inserted before period at end of first sentence “; or the violating of section 346a (i)(2) of this title or any regulation issued under that section.”

Pars. (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. 103–396, § 2(b)(1)(A), substituted “357(d) or (g), 360b(a)(4)(C),” for “357(d) or (g),”.
Par. (u). Pub. L. 103–417 added par. (u) relating to introduction into interstate commerce of unsafe dietary supplement.
Pub. L. 103–396, § 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 379e” for “379e, or 379”.
Par. (s). Pub. L. 103–80, § 3(c)(2), substituted “350a(e)” 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 matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.”

Par. (q). 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 350a (b) or 350a (c), the failure to make the reports required by section 350a (d)(1)(B), or the failure to meet the requirements prescribed under section 350a (d)(2).”

Par. (s). Pub. L. 96–359, § 5(a), added par. (s).

1976—Par. (e). Pub. L. 94–295, § 3(b)(2), inserted references to sections 360e (f) and 360i of this title.
Par. (j). Pub. L. 94–295, § 3(b)(3), inserted references to sections 360, 360c, 360d, 360e, 360f, 360h, 360i, 360j, and 379 of this title.
Par. (l). Pub. L. 94–295, § 3(b)(4), substituted “drug or device” for “drug” wherever appearing, and inserted references to sections 360e and 360j (g) of this title.
Par. (p). Pub. L. 94–295, § 4(b)(1), substituted “section 360 (j) or 360 (k) of this title,” for “section 360 (j) of this title.”
1972—Par. (p). Pub. L. 92–387 added failure to provide information required by section 360 (j) of this title, and failure to provide notice required by section 360 (j)(2) of this title as prohibited acts.

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(1), struck out “or” before “357(d) or (g)” and inserted “, or 360b(j), (l), or (m)” after “357(d) or (g)”. Amendment striking out “or” was executed as described, notwithstanding directory language that “or” before “357,” be stricken out, to reflect the probable intent of Congress.
Par. (q). Pub. L. 90–639 divided cl. (3), which referred simply to possession in violation of section 360a (c) of this title, into subcls. (A) and (B) which refer, respectively, to possession in violation of section 360a (c)(1) of this title and possession in violation of section 360a (c)(2) of this title.
1965—Par. (i). 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, §§ 103(c), 106 (c), prohibited the failure to establish or maintain any record, or make any report, required under sections 355 (i) or (j) and 507 (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, § 104(e)(1), inserted “approval of” before “an application”, and substituted “in effect” for “effective”.


1960—Par. (i). Pub. L. 86–618, § 105(a), struck out references to sections 346 (b), 354, and 364 of this title and inserted reference to section 376 of this title.


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 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 350g (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 defined in such regulations) beginning on the date that is 18 months after the effective date of such regulations, see section 103(i) of Pub. L. 111–353, set out as an Effective Date note under section 350g of this title.

Pub. L. 111–353, title III, § 301(d), Jan. 4, 2011, 124 Stat. 3955, provided that: “The amendments made by this section (enacting section 384a of this title and amending this section and section 381 of this title) shall take effect 2 years after the date of enactment of this Act [Jan. 4, 2011].”

Effective Date of 2007 Amendment

Pub. L. 110–85, title IX, § 909, Sept. 27, 2007, 121 Stat. 950, provided that:

“(a) Effective Date.—This subtitle [subtitle A (§§ 901–909) of title IX of Pub. L. 110–85, enacting sections 353b and 355–1 of this title, amending this section, sections 333, 352, and 355 of this title, and section 262 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under sections 352, 355, and 355a of this title] takes effect 180 days after the date of the enactment of this Act [Sept. 27, 2007].”

“(b) Drugs Deemed to Have Risk Evaluation and Mitigation Strategies.—

“(1) In general.—A drug that was approved before the effective date of this Act [probably means “this subtitle”, see above] is, in accordance with paragraph (2), deemed to have in effect an approved risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355–1] (as added by section 901) (referred to in this section as the ‘Act’) if there are in effect on the effective date of this Act elements to assure safe use—

“(A) required under section 314.520 or section 601.42 of title 21, Code of Federal Regulations; or

“(B) otherwise agreed to by the applicant and the Secretary for such drug.

“(2) Elements of strategy; enforcement.—The approved risk evaluation and mitigation strategy in effect for a drug under paragraph (1)—

“(A) is deemed to consist of the timetable required under section 505–1 (d) and any additional elements under subsections (e) and (f) of such section in effect for such drug on the effective date of this Act; and

“(B) is subject to enforcement by the Secretary to the same extent as any other risk evaluation and mitigation strategy under section 505–1 of the Act, except that sections 303(f)(4) and 502(y) and (z) of the Act [21 U.S.C. 333 (f)(4), 352323]—
(y), (z)] (as added by section 902) shall not apply to such strategy before the Secretary has completed review of, and acted on, the first assessment of such strategy under such section 505–1.

“(3) Submission.—Not later than 180 days after the effective date of this Act, the holder of an approved application for which a risk evaluation and mitigation strategy is deemed to be in effect under paragraph (1) shall submit to the Secretary a proposed risk evaluation and mitigation strategy. Such proposed strategy is subject to section 505–1 of the Act as if included in such application at the time of submission of the application to the Secretary.”

Effective Date of 2006 Amendment
Amendment by section 2(c) of Pub. L. 109–462 effective 1 year after Dec. 22, 2006, see section 2(e)(1) of Pub. L. 109–462, set out as a note under section 352 of this title.

Amendment by section 3(b) of Pub. L. 109–462 effective 1 year after Dec. 22, 2006, see section 3(d)(1) of Pub. L. 109–462, set out as a note under section 343 of this title.


Effective Date of 2005 Amendment

Effective Date of 2002 Amendment
Pub. L. 107–188, title III, § 321(c), June 12, 2002, 116 Stat. 676, provided that: “The amendments made by this section [amending this section and sections 360 and 381 of this title] take effect upon the expiration of the 180-day period beginning on the date of the enactment of this Act [June 12, 2002].”

Pub. L. 107–188, title III, § 322(c), June 12, 2002, 116 Stat. 678, provided that: “The amendments made by this section [amending this section and section 381 of this title] take effect upon the expiration of the 90-day period beginning on the date of the enactment of this Act [June 12, 2002].”

Effective and Termination Dates of 1997 Amendment

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 360aaa 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, see 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 353 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.

Effective Date of 1965 Amendment

Effective Date of 1962 Amendment
Amendment by sections 103(c) and 106(c) of Pub. L. 87–781 effective on first day of seventh calendar month following Oct. 1962, and amendment by section 104(e)(1) of Pub. L. 87–781 effective Oct. 10, 1962, see section 107 of Pub. L. 87–781, set out as a note under section 321 of this title.
Section 114(b) of Pub. L. 87–781 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

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 act Mar. 16, 1950, effective July 1, 1950, see section 7 of that act, set out as an Effective Date note under section 347 of this title.

Regulations
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 Provision
Amendment by Pub. L. 91–513 not to affect or abate any prosecutions 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 2011 Amendment
Nothing in amendments by sections 103(e), 105(c), 106(d), 204(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. 1838, provided that: “Nothing in this section [amending this section and sections 333, 334, 355, 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 387c 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 350c, 350d, 398, 399, and 679c of this title, sections 3353, 3354, 8319, and 8320 of Title 7, Agriculture, 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 Secretaries of Agriculture and 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.