

to in subsecs. (b) and (c), means the amendments made by subtitle E (§§ 3501–3508) of title III of div. FF of Pub. L. 117–328, which enacted this section and sections 364 to 364i of this title and amended sections 331, 361, 362, 374, and 381 of this title.

The time of enactment of the Modernization of Cosmetics Regulation Act of 2022, referred to in subsec. (b), probably means the date of enactment of subtitle E (§§ 3501–3508) of title III of div. FF of Pub. L. 117–328, which was approved Dec. 29, 2022.

Statutory Notes and Related Subsidiaries

CONSTRUCTION; CONFIDENTIALITY

Nothing in section 3502 of Pub. L. 117–328, which enacted this section, to be construed to authorize the disclosure of information that is prohibited from disclosure under section 331(j) of this title or section 1905 of title 18 or that is subject to withholding under section 552(b)(4) of title 5, see section 3503(c)(2) of Pub. L. 117–328, set out as a note under section 364 of this title.

SUBCHAPTER VII—GENERAL AUTHORITY

PART A—GENERAL ADMINISTRATIVE PROVISIONS

§ 371. Regulations and hearings

(a) Authority to promulgate regulations

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

(b) Regulations for imports and exports

The Secretary of the Treasury and the Secretary of Health and Human Services shall jointly prescribe regulations for the efficient enforcement of the provisions of section 381 of this title, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health and Human Services shall determine.

(c) Conduct of hearings

Hearings authorized or required by this chapter shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) Effectiveness of definitions and standards of identity

The definitions and standards of identity promulgated in accordance with the provisions of this chapter shall be effective for the purposes of the enforcement of this chapter, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e) Procedure for establishment

(1) Any action for the issuance, amendment, or repeal of any regulation under section 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title, and any action for the amendment or repeal of any definition and standard of identity under section 341 of this title for any dairy product (including products regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all

interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f) Review of order

(1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were

reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) Copies of records of hearings

A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this chapter, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

(h) Guidance documents

(1)(A) The Secretary shall develop guidance documents with public participation and ensure that information identifying the existence of such documents and the documents themselves are made available to the public both in written form and, as feasible, through electronic means. Such documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration.

(B) Although guidance documents shall not be binding on the Secretary, the Secretary shall ensure that employees of the Food and Drug Administration do not deviate from such guidances without appropriate justification and supervisory concurrence. The Secretary shall provide training to employees in how to develop and use guidance documents and shall monitor the development and issuance of such documents.

(C)(i) For guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, the Secretary shall ensure public participation prior to implementation of guidance documents, unless the Secretary determines that such prior public participation is not feasible or appropriate. In such cases, the Secretary shall provide for public comment upon implementation and take such comment into account.

(ii) With respect to devices, if a notice to industry guidance letter, a notice to industry advisory letter, or any similar notice sets forth initial interpretations of a regulation or policy or sets forth changes in interpretation or policy, such notice shall be treated as a guidance document for purposes of this subparagraph.

(D) For guidance documents that set forth existing practices or minor changes in policy, the Secretary shall provide for public comment upon implementation.

(2) In developing guidance documents, the Secretary shall ensure uniform nomenclature for such documents and uniform internal procedures for approval of such documents. The Secretary shall ensure that guidance documents and revisions of such documents are properly dated and indicate the nonbinding nature of the documents. The Secretary shall periodically review all guidance documents and, where appropriate, revise such documents.

(3) The Secretary, acting through the Commissioner, shall maintain electronically and update and publish periodically in the Federal Register a list of guidance documents. All such documents shall be made available to the public.

(4) The Secretary shall ensure that an effective appeals mechanism is in place to address complaints that the Food and Drug Administration is not developing and using guidance documents in accordance with this subsection.

(5) Not later than July 1, 2000, the Secretary after evaluating the effectiveness of the Good Guidance Practices document, published in the Federal Register at 62 Fed. Reg. 8961, shall promulgate a regulation consistent with this subsection specifying the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents.

(June 25, 1938, ch. 675, § 701, 52 Stat. 1055; June 25, 1948, ch. 646, § 32, 62 Stat. 991; Apr. 15, 1954, ch. 143, § 2, 68 Stat. 55; Aug. 1, 1956, ch. 861, § 2, 70 Stat. 919; Pub. L. 85-791, § 21, Aug. 28, 1958, 72 Stat. 948; Pub. L. 86-618, title I, § 103(a)(4), July 12, 1960, 74 Stat. 398; Pub. L. 101-535, § 8, Nov. 8, 1990, 104 Stat. 2365; Pub. L. 102-300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 103-80, §§ 3(y), (dd)(1), 4(c), Aug. 13, 1993, 107 Stat. 778, 779; Pub. L. 103-396, § 3(b), Oct. 22, 1994, 108 Stat. 4155; Pub. L. 105-115, title IV, § 405, Nov. 21, 1997, 111 Stat. 2368; Pub. L. 112-144, title VI, § 619, July 9, 2012, 126 Stat. 1063.)

Editorial Notes

AMENDMENTS

2012—Subsec. (h)(1)(C). Pub. L. 112-144 designated existing provisions as cl. (i) and added cl. (ii).

1997—Subsec. (h). Pub. L. 105-115 added subsec. (h).

1994—Subsec. (e)(1). Pub. L. 103-396 which directed the amendment of par. (1) by striking out “or maple syrup (regulated under section 168.140 of title 21, Code of Federal Regulations).”, was executed by striking out “or maple sirup (regulated under section 168.140 of title 21, Code of Federal Regulations)” before “shall be begun by a proposal”, to reflect the probable intent of Congress.

1993—Subsec. (b). Pub. L. 103-80, §3(dd)(1), substituted “Health and Human Services” for “Agriculture” in two places.

Subsec. (e)(1). Pub. L. 103-80, §4(c), made technical correction to directory language of Pub. L. 101-535, §8. See 1990 Amendment note below.

Pub. L. 103-80, §3(y)(1), struck out period after second reference to “Regulations”.

Subsec. (f)(4). Pub. L. 103-80, §3(y)(2), substituted reference to section 1254 of title 28 for “sections 239 and 240 of the Judicial Code, as amended”.

1992—Subsec. (b). Pub. L. 102-300, which directed the substitution of “Health and Human Services” for “Health, Education, and Welfare”, could not be executed because such words did not appear in the original statutory text. See 1993 Amendment note above and Transfer of Functions note below.

1990—Subsec. (e)(1). Pub. L. 101-535, §8, as amended by Pub. L. 103-80, §4(c), substituted “Any action for the issuance, amendment, or repeal of any regulation under section 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title, and any action for the amendment or repeal of any definition and standard of identity under section 341 of this title for any dairy product (including products regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) or maple sirup (regulated under section 168.140 of title 21, Code of Federal Regulations)” for “Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title”.

1960—Subsec. (e). Pub. L. 86-618 substituted “section 341, 343(j), 344(a), 346, 351(b), or 352(d) or (h), of this title” for “section 341, 343(j), 344(a), 346(a) or (b), 351(b), 352(d) or (h), 354 or 364 of this title”.

1958—Subsec. (f)(1). Pub. L. 85-791, §21(a), substituted provisions requiring transmission of a copy of the petition by clerk to Secretary, and filing of the record by Secretary, for provisions which permitted service of summons and petition any place in United States and required Secretary to certify and file transcript of the proceedings and record upon service.

Subsec. (f)(3). Pub. L. 85-791, §21(b), inserted “Upon the filing of the petition referred to in paragraph (1) of this subsection”.

1956—Subsec. (e). Act Aug. 1, 1956, simplified procedures governing prescribing of regulations under certain provisions of this chapter.

1954—Subsec. (e). Act Apr. 15, 1954, struck out reference to section 341 of this title, before “343(j)”, such section 341 now containing its own provisions with respect to hearings regarding the establishment of food standards.

Statutory Notes and Related Subsidiaries

CHANGE OF NAME

Circuit Court of Appeals of the United States changed to United States court of appeals by act June 25, 1948, eff. Sept. 1, 1948.

EFFECTIVE DATE OF 1997 AMENDMENT

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 a note under section 321 of this title.

EFFECTIVE DATE OF 1960 AMENDMENT

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

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101-535

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

SAVINGS PROVISION

Savings clause of act Aug. 1, 1956, see note set out under section 341 of this title.

TRANSFER OF FUNCTIONS

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

NOTIFICATION OF FDA INTENT TO REGULATE LABORATORY-DEVELOPED TESTS

Pub. L. 112-144, title XI, §1143, July 9, 2012, 126 Stat. 1130, provided that the Food and Drug Administration could not issue any draft or final guidance on the regulation of laboratory-developed tests under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) without, at least 60 days prior to such issuance, notifying the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate of the Administration's intent to take such action and including in such notification the anticipated details of such action, and that such provision ceased to have force or effect on the date that was 5 years after the date of enactment of Pub. L. 112-144, which was approved July 9, 2012.

APPROVAL OF SUPPLEMENTAL APPLICATIONS FOR APPROVED PRODUCTS

Pub. L. 105-115, title IV, §403, Nov. 21, 1997, 111 Stat. 2367, provided that:

“(a) STANDARDS.—Not later than 180 days after the date of enactment of this Act [Nov. 21, 1997], the Secretary of Health and Human Services shall publish in the Federal Register standards for the prompt review of supplemental applications submitted for approved articles under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 351 of the Public Health Service Act (42 U.S.C. 262).

“(b) GUIDANCE TO INDUSTRY.—Not later than 180 days after the date of enactment of this Act [Nov. 21, 1997], the Secretary shall issue final guidances to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for the approved articles described in subsection (a). The guidances shall—

“(1) clarify circumstances in which published matter may be the basis for approval of a supplemental application;

“(2) specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

“(3) define supplemental applications that are eligible for priority review.

“(c) RESPONSIBILITIES OF CENTERS.—The Secretary shall designate an individual in each center within the Food and Drug Administration (except the Center for Food Safety and Applied Nutrition) to be responsible for—

“(1) encouraging the prompt review of supplemental applications for approved articles; and

“(2) working with sponsors to facilitate the development and submission of data to support supplemental applications.

“(d) COLLABORATION.—The Secretary shall implement programs and policies that will foster collaboration between the Food and Drug Administration, the National Institutes of Health, professional medical and scientific societies, and other persons, to identify published and unpublished studies that may support a supplemental application, and to encourage sponsors to make supplemental applications or conduct further research in support of a supplemental application based, in whole or in part, on such studies.”

HEARINGS PENDING ON APRIL 15, 1954, WITH RESPECT
TO FOOD STANDARDS

Provisions of this chapter in effect prior to Apr. 15, 1954, as applicable with respect to hearings begun prior to such date under subsection (e) of this section, regarding food standards, see Savings Provisions note set out under section 341 of this title.

Executive Documents

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.

§ 372. Examinations and investigations

(a) Authority to conduct

(1)(A) The Secretary is authorized to conduct examinations and investigations for the purposes of this chapter through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department.

(B)(i) For a tobacco product, to the extent feasible, the Secretary shall contract with the States in accordance with this paragraph to carry out inspections of retailers within that State in connection with the enforcement of this chapter.

(ii) The Secretary shall not enter into any contract under clause (i) with the government of any of the several States to exercise enforcement authority under this chapter on Indian country without the express written consent of the Indian tribe involved.

(2)(A) In addition to the authority established in paragraph (1), the Secretary, pursuant to a memorandum of understanding between the Secretary and the head of another Federal department or agency, is authorized to conduct examinations and investigations for the purposes of this chapter through the officers and employees of such other department or agency, subject to subparagraph (B). Such a memorandum shall include provisions to ensure adequate training of such officers and employees to conduct the examinations and investigations. The memorandum of understanding shall contain provisions regarding reimbursement. Such provisions may, at the sole discretion of the head of the other department or agency, require reimbursement, in whole or in part, from the Secretary for the examinations or investigations performed under this section by the officers or employees of the other department or agency.

(B) A memorandum of understanding under subparagraph (A) between the Secretary and an-

other Federal department or agency is effective only in the case of examinations or inspections at facilities or other locations that are jointly regulated by the Secretary and such department or agency.

(C) For any fiscal year in which the Secretary and the head of another Federal department or agency carries out one or more examinations or inspections under a memorandum of understanding under subparagraph (A), the Secretary and the head of such department or agency shall with respect to their respective departments or agencies submit to the committees of jurisdiction (authorizing and appropriating) in the House of Representatives and the Senate a report that provides, for such year—

(i) the number of officers or employees that carried out one or more programs, projects, or activities under such memorandum;

(ii) the number of additional articles that were inspected or examined as a result of such memorandum; and

(iii) the number of additional examinations or investigations that were carried out pursuant to such memorandum.

(3) In the case of food packed in the Commonwealth of Puerto Rico or a Territory the Secretary shall attempt to make inspection of such food at the first point of entry within the United States when, in his opinion and with due regard to the enforcement of all the provisions of this chapter, the facilities at his disposal will permit of such inspection.

(4) For the purposes of this subsection, the term “United States” means the States and the District of Columbia.

(b) Availability to owner of part of analysis samples

Where a sample of a food, drug, or cosmetic is collected for analysis under this chapter the Secretary shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this chapter.

(c) Records of other departments and agencies

For purposes of enforcement of this chapter, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Department duly authorized by the Secretary to make such inspection.

(d) Information on patents for drugs

The Secretary is authorized and directed, upon request from the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, to furnish full and complete information with respect to such questions relating to drugs as the Director may submit concerning any patent application. The Secretary is further authorized, upon receipt of any such request, to conduct or cause to be conducted, such research as may be required.