

Federal Food, Drug, and Cosmetic Act

CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

MISBRANDED DRUGS AND DEVICES

SEC. 502. [21 U.S.C. 352] A drug or device shall be deemed to be misbranded— **3**

(a) If its labeling is false or misleading in any particular. Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading under this paragraph if the healthcare economic information directly relates to an indication approved under section 505 or under section 351(a) of the Public Health Service Act for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a) or in section 351(a) of the Public Health Service Act shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph.

Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term “health care economic information” means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention.

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

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

[(d) Repealed by Pub. L. 105–115, November 21, 1997.]

(e)(1)(A) **4** If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;

(ii) the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if determined to be appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscyne, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to nonprescription drugs not intended for human use; and

(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, except that nothing in this subclause shall be deemed to require that any trade secret be divulged, and except that the requirements of this subclause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and that this subclause shall not apply to nonprescription drugs not intended for human use.

(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient, except that to the extent that compliance with the requirements of subclause (ii) or (iii) of clause (A) or this clause is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(2) If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name (as defined in subparagraph (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(3) As used in subparagraph (1), the term "established name", with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 508, or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient, except that where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homeopathic Pharmacopeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopeia shall apply.

(4) As used in subparagraph (2), the term "established name" with respect to a device means (A) the applicable official name of the device designated pursuant to section 508, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein. The method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States, it shall be subject to the requirements of the United States Pharmacopeia with respect to packaging, and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States, and not to those of the United States Pharmacopeia, except that in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

(h) If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the

appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i)(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage or manner; or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

[(k) Repealed by Pub. L. 105–115, November 21, 1997.]

[(l) Repealed by Pub. L. 105–115, November 21, 1997.]

(m) **5** If it is a color additive the intended use of which is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in regulations issued under section 721.

(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in section 502(e) **6**, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e) **6**, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701(e) of this Act, except that (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall, with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 12 through 17 of the Federal Trade Commission Act, as amended (15 U.S.C. 52–57). This paragraph (n) **7** shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m) of this Act. Nothing in the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, shall be construed to prevent drug price communications to consumers. **8**

(o) If it was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered under section 510, if it was not included in a list required by section 510(j), if a notice or other information respecting it was not provided as required by such section or section 510(k), or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 510(e) as the Secretary by regulation requires.

(p) If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

(q) In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 520(e).

(r) In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing. Except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement and no advertisement of a restricted device, published after the effective date of this paragraph shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52–55).

This paragraph shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m).

(s) If it is a device subject to a performance standard established under section 514, unless it bears such labeling as may be prescribed in such performance standard.

(t) If it is a device and there was a failure or refusal (1) to comply with any requirement prescribed under section 518 respecting the device, (2) to furnish any material or information required by or under section 519 respecting the device, or (3) to comply with a requirement under section 522.

(u) **9** If it is a device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, except that the Secretary may waive any requirement under this paragraph for the device if the Secretary determines that compliance with the requirement is not feasible for the device or would compromise the provision of reasonable assurance of the safety or effectiveness of the device.

(v) **10** If it is a reprocessed single-use device, unless all labeling of the device prominently and conspicuously bears the statement 'Reprocessed device for single use. Reprocessed by ____.' The name of the manufacturer of the reprocessed device shall be placed in the space identifying the person responsible for reprocessing.

(w) If it is a new animal drug—

(1) that is conditionally approved under section 571 and its labeling does not conform with the approved application or section 571(f), or that is not conditionally approved under section 571 and its label bears the statement set forth in section 571(f)(1)(A); or

(2) that is indexed under section 572 and its labeling does not conform with the index listing under section 572(e) or 572(h), or that has not been indexed under section 572 and its label bears the statement set forth in section 572(h).

CHAPTER VI - COSMETICS

ADULTERATED COSMETICS

SEC. 601. [361] A cosmetic shall be deemed to be adulterated -

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual, except that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution - This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health

(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 721(a).

MISBRANDED COSMETICS.

SEC. 602. [362] A cosmetic shall be deemed to be misbranded -

- (a) If its labeling is false or misleading in any particular.
- (b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.
- (c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- (d) If its container is so made, formed, or filled as to be misleading.
- (e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 721. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a)).
- (f) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

REGULATIONS MAKING EXEMPTIONS

SEC. 603. [363] The Secretary shall promulgate regulations exempting from any labeling requirement of this Act cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

CHAPTER VII—GENERAL AUTHORITY

SUBCHAPTER A--GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701. [21 U.S.C. 371] (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

(b) 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 801, 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) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

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

(e)(1) Any action for the issuance, amendment, or repeal of any regulation under section 403(j), 404(a), 406, 501(b), or 502 (d) or (h) of this Act, and any action for the amendment or repeal of any definition and standard of identity under section 401 of this Act 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) 1 shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested persons, 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)(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 Circuit Court of Appeals of the United States 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, United States Code.

(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, United States Code.

(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) 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 of this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

(h)(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) 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.

(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.

EXAMINATIONS AND INVESTIGATIONS

SEC. 702. [21 U.S.C. 372] (a) (1) The Secretary is authorized to conduct examinations and investigations for the purposes of this Act 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.

(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 Act 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 another 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 Act, 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) Where a sample of a food, drug, or cosmetic is collected for analysis under this Act 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 Act.

(c) For purposes of enforcement of this Act, 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) 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.

(e) Any officer or employee of the Department designated by the Secretary to conduct examinations, investigations, or inspections under this Act relating to counterfeit drugs may, when so authorized by the Secretary—

(1) carry firearms;

(2) execute and serve search warrants and arrest warrants;

(3) execute seizure by process issued pursuant to libel under section 304;

(4) make arrests without warrant for offenses under this Act with respect to such drugs if the offense is committed in his presence or, in the case of a felony, if he has probable cause to believe that the person so arrested has committed, or is committing, such offense; and

(5) make, prior to the institution of libel proceedings under section 304(a)(2), seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or he has reasonable grounds to believe that they are, subject to seizure and condemnation under such section

304(a)(2). In the event of seizure pursuant to this paragraph (5) [2](#) , libel proceedings under section 304(a)(2) shall be instituted promptly and the property seized be placed under the jurisdiction of the court.

RECORDS OF INTERSTATE SHIPMENT

SEC. 703. [21 U.S.C. 373] For the purpose of enforcing the provisions of this Act, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates, except that evidence obtained under this section, or any evidence which is directly or indirectly derived from such evidence, shall not be used in a criminal prosecution of the person from whom obtained, and except that carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers.

FACTORY INSPECTION

SEC. 704. [21 U.S.C. 374] (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle, being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414 when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k) [3](#) section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

(2) The provisions of the third sentence of paragraph (1) shall not apply to—

(A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients

under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice;

(C) persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale;

(D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records—

(A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or

(B) required to be maintained under section 412.

(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

(c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

(d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records.

(f)(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

(2) Within 15 days after the receipt of a written request from the Secretary an accredited person described in paragraph (3) for copies of records described in paragraph (1), the person shall produce the copies of the records at the place designated by the Secretary.

(3) For purposes of paragraphs (1) and (2), an accredited person described in this paragraph is a person who—

(A) is accredited under subsection (g); or

(B) is accredited under section 523.

(g)(1) Not later than one year after the date of the enactment of this subsection [4](#), the Secretary shall, subject to the provisions of this subsection, accredit persons for the purpose of conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices,

which inspections are required under section 510(h) or are inspections of such establishments required to register pursuant to section 510(i).

(2) Not later than 180 days after the date of enactment of this subsection, the Secretary shall publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in paragraph (1). Thereafter, the Secretary shall inform those requesting accreditation, within 60 days after the receipt of such request, whether the request for accreditation is adequate for review, and the Secretary shall promptly act on the request for accreditation. Any resulting accreditation shall state that such person is accredited to conduct inspections at device establishments identified in paragraph (1). The accreditation of such person shall specify the particular activities under this subsection for which such person is accredited. In the first year following the publication in the Federal Register of criteria to accredit or deny accreditation to persons who request to perform the duties specified in paragraph (1), the Secretary shall accredit no more than 15 persons who request to perform duties specified in paragraph (1).

(3) An accredited person shall, at a minimum, meet the following requirements:

(A) Such person may not be an employee of the Federal Government.

(B) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of articles regulated under this Act and which has no organizational, material, or financial affiliation (including a consultative affiliation) with such a manufacturer, supplier, or vendor.

(C) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

(D) Such person shall not engage in the design, manufacture, promotion, or sale of articles regulated under this Act.

(E) The operations of such person shall be in accordance with generally accepted professional and ethical business practices, and such person shall agree in writing that at a minimum the person will--

(i) certify that reported information accurately reflects data reviewed, inspection observations made, other matters that relate to or may influence compliance with this Act, and recommendations made during an inspection or at an inspection's closing meeting;

(ii) limit work to that for which competence and capacity are available;

(iii) treat information received, records, reports, and recommendations as confidential commercial or financial information or trade secret information, except such information may be made available to the Secretary;

(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

(v) protect against the use, in carrying out paragraph (1), of any officer or employee of the accredited person who has a financial conflict of interest regarding any product regulated under this Act, and annually make available to the public disclosures of the extent to which the accredited person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

(4) The Secretary shall publish on the Internet site of the Food and Drug Administration a list of persons who are accredited under paragraph (2). Such list shall be updated to ensure that the identity of each accredited person, and the particular activities for which the person is accredited, is known to the public. The updating of such list shall be no later than one month after the accreditation of a person under this subsection or the suspension or withdrawal of accreditation, or the modification of the particular activities for which the person is accredited.

(5)(A) To ensure that persons accredited under this subsection continue to meet the standards of accreditation, the Secretary shall (i) audit the performance of such persons on a periodic basis through the review of inspection reports and inspections by persons designated by the Secretary to evaluate the compliance status of a device establishment and the performance of accredited persons, and (ii) take such additional measures as the Secretary determines to be appropriate.

(B) The Secretary may withdraw accreditation of any person accredited under paragraph (2), after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the standards of accreditation, poses a threat to public health, fails to act in a manner that is consistent with the purposes of this subsection, or where the Secretary determines that there is a financial conflict of interest in the relationship between the accredited person and the owner or operator of a device establishment that the accredited person has inspected under this subsection. The Secretary

may suspend the accreditation of such person during the pendency of the process under the preceding sentence.

(6)(A) Subject to subparagraphs (B) and (C), a device establishment is eligible for inspections by persons accredited under paragraph (2) if the following conditions are met:

(i) The Secretary classified the results of the most recent inspection described in paragraph (1) as "no action indicated" or "voluntary action indicated".

(ii) With respect to inspections to be conducted by an accredited person--

(I) the owner or operator of the establishment submits to the Secretary a notice requesting clearance to use an accredited person to conduct the inspection, and the Secretary provides such clearance; and
(II) such notice identifies the accredited person whom the establishment has selected to conduct the inspection, and the Secretary agrees to the selected accredited person.

(iii) With respect to the devices that are manufactured, prepared, propagated, compounded, or processed by the establishment, at least one of such devices is marketed in the United States, and 1 or both of the following additional conditions are met:

(I) At least one of such devices is marketed, or is intended to be marketed, or is intended to be marketed, in one or more foreign countries, one of which countries certifies, accredits, or otherwise recognizes the person (accredited under paragraph (2) and identified under clause (ii)(I)) as a person authorized to conduct such inspections of device establishments.

(II) The owner or operator of the establishment submits to the Secretary a statement that the law of a country in which such a device is marketed, or is intended to be marketed, recognizes an inspection of the establishment by the Secretary or by a person accredited under paragraph (2), and not later than 30 days after receiving such statement, the Secretary informs the owner or operator of the establishment that the owner or operator may submit a notice requesting clearance under clause (ii).

(iv)(I) In the case of an inspection to be conducted pursuant to section 510(h), persons accredited under paragraph (2) did not conduct inspections of the establishment during the previous 4 years, except that the establishment may petition the Secretary for a waiver of such condition. Such a waiver may be granted only if the petition states a commercial reason for the waiver; the Secretary determines that the public health would be served by granting the waiver; and the Secretary has conducted an inspection of the establishment during the four-year period preceding the date on which the notice under clause (ii) is submitted to the Secretary. Such a waiver is deemed to be granted only if the Secretary has not determined that the public health would not be served by granting the waiver; and the owner or operator of the device establishment has requested in writing, not later than 18 months following the most recent inspection of such establishment by a person accredited under paragraph (2), that the Secretary inspect the establishment and the Secretary has not conducted an inspection within 30 months after the most recent inspection. With respect to such a waiver that is granted or deemed to be granted, no additional such waiver may be granted or deemed to be granted until after the Secretary has conducted an inspection of the establishment.

(II) In the case of an inspection to be conducted of a device establishment required to register pursuant to section 510(i), the Secretary periodically conducts inspections of the establishment.

(B)(i) The Secretary shall respond to a notice under subparagraph (A) from a device establishment not later than 30 days after the Secretary receives the notice. Through such response, the Secretary shall (I) provide clearance under such subparagraph, and agree to the selection of an accredited person, or (II) make a request under clause (ii). If the Secretary fails to respond to the notice within such 30-day period, the establishment is deemed to have such clearance, and to have the agreement of the Secretary for such selection.

(ii) The request referred to in clause (i)(II) is—

(I) a request to the device establishment involved to submit to the Secretary compliance data in accordance with clause (iii); or

(II) a request to the establishment, or to the accredited person identified in the notice under subparagraph (A), for information concerning the relationship between the establishment and such accredited person, including information about the number of inspections of the establishment, or other establishments owned or operated by the owner or operator of the establishment, that have been conducted by the accredited person. The Secretary may make both such requests.

(iii) The compliance data to be submitted by a device establishment under clause (ii) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 501(h) and with other applicable

provisions of this Act. Such data shall include complete reports of inspectional findings regarding good manufacturing practice or other quality control audits that, during the preceding two-year period, were conducted at the establishment by persons other than the owner or operator of the establishment, together with all other relevant compliance data the Secretary deems necessary. Data under the preceding sentence shall demonstrate to the Secretary whether the establishment has facilitated consistent compliance by promptly correcting any compliance problems identified in such inspections.

(iv) (I) Not later than 60 days after receiving compliance data under clause (iii) from a device establishment, the Secretary shall provide or deny clearance under subparagraph (A). The Secretary may deny clearance if the Secretary determines that the establishment has failed to demonstrate consistent compliance for purposes of clause (iii). The Secretary shall provide to the establishment a statement of such reasons for such determination. If the Secretary fails to provide such statement to the establishment within such 60-day period, the establishment is deemed to have such clearance.

(II) If, during the two-year period following clearance under subparagraph (A), the Secretary determines that the device establishment is substantially not in compliance with this Act, the Secretary may, after notice and a written response, notify the establishment that the eligibility of the establishment for the inspections by accredited persons has been suspended.

(v) (I) A request to an accredited person under clause (ii) (II) may not seek any information that is not required to be maintained by such person in records under subsection (f)(1). Not later than 60 days after receiving the information sought by the request, the Secretary shall agree to, or reject, the selection of such person by the device establishment involved. The Secretary may reject the selection if the Secretary provides to the establishment a statement of the reasons for such rejection. Reasons for the rejection may include that the establishment or the accredited person, as the case may be, has failed to fully respond to the request, or that the Secretary has concerns regarding the relationship between the establishment and such accredited person. If within such 60-day period the Secretary fails to agree to or reject the selection in accordance with this subclause, the Secretary is deemed to have agreed to the selection.

(II) If the Secretary rejects the selection of an accredited person by a device establishment, the establishment may make an additional selection of an accredited person by submitting to the Secretary a notice that identifies the additional selection. Clauses (i) and (ii), and subclause (I) of this clause, apply to the selection of an accredited person through a notice under the preceding sentence in the same manner and to the same extent as such provisions apply to a selection of an accredited person through a notice under subparagraph (A).

(vi) In the case of a device establishment that under clause (iv) is denied clearance under subparagraph (A), or whose selection of an accredited person is rejected under clause (v), the Secretary shall designate a person to review the findings of the Secretary under such clause if, during the 30-day period beginning on the date on which the establishment receives the findings, the establishment requests the review. The review shall commence not later than 30 days after the establishment requests the review, unless the Secretary and the establishment otherwise agree.

(C) (i) In the case of a device establishment for which the Secretary classified the results of the most recent inspection of the establishment by a person accredited under paragraph (2) as 'official action indicated', the establishment, if otherwise eligible under subparagraph (A), is eligible for further inspections by persons accredited under such paragraph if (I) the Secretary issues a written statement to the owner or operator of the establishment that the violations leading to such classification have been resolved, and (II) the Secretary, either upon the Secretary's own initiative or a petition of the owner or operator of the establishment, notifies the establishment that it has clearance to use an accredited person for the inspections. The Secretary shall respond to such petition within 30 days after the receipt of the petition.

(ii) If the Secretary denies a petition under clause (i), the device establishment involved may, after the expiration of one year after such denial, again petition the Secretary for a determination of eligibility for inspection by persons accredited by the Secretary under paragraph (2). If the Secretary denies such petition, the Secretary shall provide the establishment with such reasons for such denial within 60 days after the denial. If, as of the expiration of 48 months after the receipt of the first petition, the establishment has not been inspected by the Secretary, the establishment is eligible for further inspections by accredited persons.

(7) (A) Persons accredited under paragraph (2) to conduct inspections shall record in writing their inspection observations and shall present the observations to the device establishment's designated

representative and describe each observation. Additionally, such accredited person shall prepare an inspection report (including for inspections classified as 'no action indicated') in a form and manner consistent with such reports prepared by employees and officials designated by the Secretary to conduct inspections.

(B) At a minimum, an inspection report under subparagraph (A) shall identify the persons responsible for good manufacturing practice compliance at the inspected device establishment, the dates of the inspection, the scope of the inspection, and shall describe in detail each observation identified by the accredited person, identify other matters that relate to or may influence compliance with this Act, and describe any recommendations during the inspection or at the inspection's closing meeting.

(C) An inspection report under subparagraph (A) shall be sent to the Secretary and to the designated representative of the inspected device establishment at the same time, but under no circumstances later than three weeks after the last day of the inspection. The report to the Secretary shall be accompanied by all written inspection observations previously provided to the designated representative of the establishment.

(D) Any statement or representation made by an employee or agent of a device establishment to a person accredited under paragraph (2) to conduct inspections shall be subject to section 1001 of title 18, United States Code.

(E) If at any time during an inspection by an accredited person the accredited person discovers a condition that could cause or contribute to an unreasonable risk to the public health, the accredited person shall immediately notify the Secretary of the identification of the device establishment subject to inspection and such condition.

(8) Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

(9) Nothing in this subsection affects the authority of the Secretary to inspect any device establishment pursuant to this Act.

(10)(A) For fiscal year 2005 and each subsequent fiscal year, no device establishment may be inspected during the fiscal year involved by a person accredited under paragraph (2) if—

(i) of the amounts appropriated for salaries and expenses of the Food and Drug Administration for the preceding fiscal year (referred to in this subparagraph as the 'first prior fiscal year'), the amount obligated by the Secretary for inspections of device establishments by the Secretary was less than the adjusted base amount applicable to such first prior fiscal year; and

(ii) of the amounts appropriated for salaries and expenses of the Food and Drug Administration for the fiscal year preceding the first prior fiscal year (referred to in this subparagraph as the 'second prior fiscal year'), the amount obligated by the Secretary for inspections of device establishments by the Secretary was less than the adjusted base amount applicable to such second prior fiscal year.

(B)(i) Subject to clause (ii), the Comptroller General of the United States shall determine the amount that was obligated by the Secretary for fiscal year 2002 for compliance activities of the Food and Drug Administration with respect to devices (referred to in this subparagraph as the 'compliance budget'), and of such amount, the amount that was obligated for inspections by the Secretary of device establishments (referred to in this subparagraph as the 'inspection budget').

(ii) For purposes of determinations under clause (i), the Comptroller General shall not include in the compliance budget or the inspection budget any amounts obligated for inspections of device establishments conducted as part of the process of reviewing applications under section 515.

(iii) Not later than March 31, 2003, the Comptroller General shall complete the determinations required in this subparagraph and submit to the Secretary and the Congress a report describing the findings made through such determinations.

(C) For purposes of this paragraph:

(i) The term 'base amount' means the inspection budget determined under subparagraph (B) for fiscal year 2002.

(ii) The term 'adjusted base amount', in the case of applicability to fiscal year 2003, means an amount equal to the base amount increased by 5 percent.

(iii) The term 'adjusted base amount', with respect to applicability to fiscal year 2004 or any subsequent fiscal year, means the adjusted based amount [5](#) applicable to the preceding year increased by 5 percent.

(11) The authority provided by this subsection terminates on October 1, 2012 .

(12) No later than four years after the enactment of this subsection the Comptroller General shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate—

(A) the number of inspections conducted by accredited persons pursuant to this subsection and the number of inspections conducted by Federal employees pursuant to section 510(h) and of device establishments required to register under section 510(i);

(B) the number of persons who sought accreditation under this subsection, as well as the number of persons who were accredited under this subsection;

(C) the reasons why persons who sought accreditation, but were denied accreditation, were denied;

(D) the number of audits conducted by the Secretary of accredited persons, the quality of inspections conducted by accredited persons, whether accredited persons are meeting their obligations under this Act, and whether the number of audits conducted is sufficient to permit these assessments;

(E) whether this subsection is achieving the goal of ensuring more information about device establishment compliance is being presented to the Secretary, and whether that information is of a quality consistent with information obtained by the Secretary pursuant to inspections conducted by Federal employees;

(F) whether this subsection is advancing efforts to allow device establishments to rely upon third-party inspections for purposes of compliance with the laws of foreign governments; and

(G) whether the Congress should continue, modify, or terminate the program under this subsection.

(13) The Secretary shall include in the annual report required under section 903(g) the names of all accredited persons and the particular activities under this subsection for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

(14) Notwithstanding any provision of this subsection, this subsection does not have any legal effect on any agreement described in section 803(b) between the Secretary and a foreign country.