IV. FOOD AND DRUG ADMINISTRATION

Legal citation	Type of authority	Legislative text
A. General Authority Applicable to all FDA Bureaus		
a) Federal Food, Drug and Cosmetic Act • P.L. 75-517$705 (1938) as amended • 21 Usc $375	Implied	(b) "The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department. "
B. Bureau of Biologics		
a) Public Health Service Act • P.L. 78-410$351 (1944) • 42 USC $262	Implied	(d) "Licenses for the maintenance of establishments for the propagation ***or*** manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards . . ."
C. Bureau of Drugs		
a) Federal Food, Drug and Cosmetic Act • P.L. 75-717$505 (1938) and amended • 21 Usc $355	Specific	(b) "Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.
	General	(i) The Secretary shall 'promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regula-

C. Bureau of Drugs—continued

Legal citation	Type of authority	Legislative text
		tions may, within the discretion of the Secretary . . . provide for conditioning such exemption upon— (1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing; (2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigators or to clinics, for administration to human beings; and (3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b) of this section. (j)(l) In the case of my Lr~g*fm which **an** approval of an application filed pursuant to this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may . . . prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine . . . whether there is or may be grounds for invoking subsection (e) of this section . . .“
b) Federal Food, Drug and Cosmetic Act ● P.L. 75-717$507, as added by Act of July 6,1945,$3, and amended ● 21 Usc ~357	General	(d) “The Secretary shall promulgate regulations exempting from any requirement of this section and of section 352(]) of this title, (1) drugs which are to be stored, processed, labeled, or repacked at establishments other than those where manufactured . . .; (2) drugs which conform to applicable standards of identity, strength, quality, and purity prescribed by these regulations and are intended for use in manufacturing other drugs; and (3) drugs which are intended solely for investigational use by experts qualified by

C. Bureau of Drugs—continued

Legal citation	Type of authority	Legislative text
		scientific training and experience to investigate the safety and efficacy of drugs. Such regulations may, within the discretion of the Secretary . . . provide for conditioning the exemption under clause (3) of this subsection upon— (1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, or preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing; * * * (3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application for certification or release pursuant to subsection (a) of this section. * * * (g)(l) Every person engaged in manufacturing, compounding, or processing any drug within the purview of this section with respect to which a certificate or release has been issued pursuant to this section shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such person with respect ***to*** such drug, as the Secretary may by general regulation, or by order with respect to such certification or release, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to make, or to facilitate, a determination as to whether such certification or release should be rescinded or whether any regulation issued under this section should be, amended or repealed . . .“
c) Public Health Service Act • P.L. 78-410$302, (1944) • 42 USC $242	General	(a) “In carrying out the purposes of section 241 of . . . title [42] with respect to drugs, the use or misuse of which might result in drug abuse or dependency, the studies and investigations authorized therein shall include the use and misuse of narcotic drugs and other drugs. Such studies and investigations shall further include the quantities of crude opium, coca leaves, and their salts, derivatives and preparation, and other drugs subject to control under the Controlled Substances Act and Controlled Substances Import and Export Act, together with reserves thereof, necessary to

C. Bureau of Drugs—continued

Legal citation	Type of authority	Legislative text
		supply the normal and emergency medicinal and scientific requirements of the United States. The results of studies and investigations of the quantities of narcotic drugs or other drugs subject to control under such Acts, together with reserves of such drugs, that are necessary to supply the normal and emergency medicinal and scientific requirements of the United States shall be reported not later than the first day of April of each year to the Attorney General, to be used at his discretion in determining manufacturing quotas or importation requirements under such Acts". * [Jointly administered with the National Institute on Drug Abuse (ADAMHA), and the Drug Enforcement Administration.]
d) Public Health Service Act ● P.L. 78-910$303, as added by P.L. 79-487 §7(c) (1946) and amended ● 42 USC §242a	General	(a) "In carrying out the purposes of section 241 of . . . title [42] with respect to mental health, the Surgeon General is authorized—. . . (2) to make grants . . . for investigations, experiments, demonstrations, studies, and research projects with respect to the development of improved methods of diagnosing mental illness (such as research on the use and effect of alcohol and other psychoactive drugs), and of care, treatment, and rehabilitation of the mentally ill. . . ."* [Jointly administered with the National Institute on Drug Abuse, and the National Institute of Mental Health, (ADAMHA); FDA authority extends to regulations of protection of research subjects and confidentiality.]

D. Bureau of Foods

a) Federal Food, Drug and Cosmetic Act ● P.L. 75-717 §408 **as** added by Act of July 22,1954,$3 (1954) and amended ● 21 USC §346a	Specific	(d)(l) "Any person who has registered, or who has submitted an application for the registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act may file with the Administrator, a petition proposing the issuance of a regulation establishing a tolerance for a pesticide chemical which constitutes, or is an ingredient of, such pesticide, or exempting the pesticide chemical from the requirement of a tolerance. The petition shall contain data showing—

'Section **301** of the Public Health Service Act, **42 USC $241,** is the general data collection authority for the Secretary of HEW.

D. Bureau of Foods—continued

Legal citation	Type of authority	Legislative text
		(A) the name, chemical identity, and composition of the pesticide chemical; (B) the amount, frequency, and time of application of the pesticide chemical; (C) full reports of investigation made with respect to the safety of the pesticide chemical; (D) the results of tests on the amount of residue remaining, including a description of the analytical methods used; (E) practicable methods for removing residue which exceeds any proposed tolerance; (F) proposed tolerances for the pesticide chemical if tolerances are proposed; and (G) reasonable grounds in support of the petition. Samples of the pesticide chemical shall be furnished to the Administrator upon request. . . . Such notice shall include the analytical methods available for the determination of the residue of the pesticide chemical for which a tolerance or exemption is proposed, " [This authority was transferred to the Environmental Protection Agency (EPA) under Reorganization Plan No. 3, 1970. FDA enforces tolerances established by EPA through FDA's food inspection program.]
b) Federal Food, Drug and Cosmetic Act w P.L. 75-717$409, as added by P.L. 85-929 §4 (1958), and amended ● 21 USC §348	Specific	(b)(l) "Any person may, with respect to any intended use of a food additive, file with the Secretary **a** petition proposing the issuance of a regulation prescribing the conditions under which such additive **may** be **safely** used. (2) Such petition shall, in addition to any explanatory or supporting data, contain— (A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition; (B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling; (C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect; (D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and (E) full reports of investigations made with respect to the safety for use of such additive, including full information

0. Bureau of Foods—continued

Legal citation	Type of authority	Legislative text
		as to the methods and controls used in conducting such investigations. ”
c) Federal Food, Drug and Cosmetic Act ● P.L. 75-717 ~706, (1938), and amended ● 21 USC §376	Implied	(b)(S)(A) “In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors— (i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs or devices, or cosmetics because of the use of the additive; (ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet; (iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and (iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (11) such additive in or on any article of food, drug or device, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive . . .“

E. Bureau of Medical Devices

a) Federal Food, Drug and Cosmetic Act ● P.L. 75-717$513 as added by P.L. 94-295 §2 (1976) ● 21 USC §360c	Implied	(a)(3)(A) “Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 360d and 360e of this title, to be determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.”

E. Bureau of Medical Devices—continued

Legal citation	Type of authority	Legislative text
b) Federal Food, Drug and Cosmetic Act ● P.L. 75-717 §519, as added by P.L. 94-295 §2 (1976) 21 USC §360i	General	(a) "Every person who is a manufacturer, importer, or distributor of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. Regulations prescribed— . . . (3) which require submission of a report or information to the Secretary shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information;"
c) Federal Food, Drug and Cosmetic Act ● P.L. 75-717$520, as added by P.L. 94-295$2 (1976) ● 21 USC §360j	General	(g)(2)(A) "The Secretary shall, within the one hundred and twenty-day period beginning on May 28, 1976, by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 352, 360, 360d, 360e, 360f, 360i or 376 of this title or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety 'and effectiveness of such devices. (B) The conditions prescribed pursuant to subparagraph (A) shall include the following: (i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify. (ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device. (iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety. . . ."
	Implied	(h)(z) "The Secretary shall promulgate regulations under which each advisory committee established under section 360e (g)(2)(B) of this title shall make available to the public a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the advisory committee and which was the basis for its recom-

E. Bureau of Medical Devices—continued

Legal citation	Type of authority	Legislative text
		mendation to the Secretary made pursuant to Section 360e(g)(2)(A) of this title. A summary of information upon which such a recommendation is based shall be made available pursuant to this paragraph only after the issuance of the order with respect to which the recommendation was made and each summary shall include information respecting any adverse effect on health of the device subject to such order. (3) Any information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection (A) may not be used to establish the safety or effectiveness of another device for purposes of this chapter by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section. . . .“

F. Bureau of Radiological Health

a) Public Health Service Act ● P.L. 78-410 ¦354, as added by P.L. 90-602 §2(3) (1968) ● 42 USC §263b	Implied	“The Congress hereby declares that the public health and safety must be protected from the dangers of electronic product radiation. Thus, it is the purpose of this subpart to provide for the establishment by the Secretary of an electronic product radiation control program which shall include the development and administration of performance standards to control the emission of electronic product radiation from electronic products and the undertaking by public and private organizations of research and investigation into the effects and control of such radiation emissions. ”
b) Public Health Service Act ● P.L. 78-410 §356, as added by P.L. 90-602 §2(3) (1968) ● 42 USC §263d	General	(a) “The Secretary shall establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation. As a part of such program, he shall—. . . (2) plan, conduct, coordinate, and support research . . . to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation; . . . (4) study and evaluate emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields; . . . (b) In carrying out the purposes of subsection (a) of this section, the Secretary is authorized to— (1)(A) collect and make available, through publications and other appropriate means, the results of, and other in-

F. Bureau of Radiological Health—continued

Legal citation	Type of authority	Legislative text
		formation concerning, research and studies relating to the nature and extent of the hazards and control of electronic product radiation . . . (c)(l) each recipient of assistance under this subpart . . . shall keep such records as the Secretary shall prescribe . . ."
c) Public Health Service Act ● P.L. 78-410$357 as added by P.L. 90-602 §2(3), (1968) ● 42 USC §263e	Specific	(a) "The Secretary shall conduct the foIlowing studies, and shall make a report or reports of the results of such studies to Congress on or before January 1, 1970, and from time to time thereafter as he may find necessary, together with such recommendations for legislation as he may deem appropriate: (1) A study of present State and Federal control of health hazards from electronic product radiation and other types of ionizing radiation, which study shall include, but not be limited to— (A) control of health hazards from radioactive materials other than material regulated under the Atomic Energy Act of 1954; (B) any gaps and inconsistencies in present controls; **(C) the** need for controlling the sale of certain used electronic products, particularly antiquated X-ray equipment, without upgrading such products to meet the standards for new products or separate standards for used products; (D) measures to assure consistent and effective control of the aforementioned health hazards; (E) measures to strengthen radiological health programs of State governments; and (F) the feasibility of authorizing the Secretary to enter into arrangements with individual States or groups of States to define their respective functions and responsibilities for the control of electronic product radiation and other ionizing radiation; (2) A study to determine the necessity for the development of standards for the use of nonmedical electronic products for commercial and industrial purposes; and (3) A study of the development of practicable procedures for the detection and measurement of electronic product radiation which may be emitted from the electronic products manufactured or imported prior to the effective date of any applicable standards established pursuant to this subpart. . . . (c) The Secretary or his designee shall organize the studies and the participation of the invited participants as he deems best. Any dissent from the findings and recommendations of

F. Bureau of Radiological Health—continued

Legal citation	Type of authority	Legislative text
		the Secretary shall be included in the report if so requested by the dissenter. "
d) Public Health Service Act • P.L. 78-410 §360A, as added by P.L. 90-602 §2(3) (1968) • 42 USC §263i	General	(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to this subpart. (c) Every manufacturer of electronic products shall provide to the Secretary such performance data and other technical data related to safety as may be required to carry out the purposes of this subpart. The Secretary is authorized to require the manufacturer to give such notification of such performance and technical data at the time of original purchase to the ultimate purchaser of the electronic product, as he determines necessary to carry out the purposes of this subpart after consulting with the affected industry. . . . (f) The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 263g of this title, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information. . . . If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. . . . "
e) Public Health Service Act • P.L. 78-410 §60D, as added by P.L. 90-602 62(3) (1968) • 42 USC §2631	Specific	(a) "The Secretary shall prepare and submit to the President for transmittal to the Congress on or before April 1 of each year a comprehensive report on the administration of this subpart for the preceding calendar year. Such report shall include— (1) a thorough appraisal (including statistical analyses, estimates, and long-term projections) of the incidence of biological injury, and effects, including genetic effects, to the population resulting from exposure to electronic product

F. Bureau of Radiological Health—continued

Legal citation	Type of authority	Legislative text

radiation, with a breakdown, insofar as practicable, among the various sources of such radiation;

(2) a list of Federal electronic product radiation control standards prescribed or in effect in such year, with identification of standards newly prescribed during such year;

(3) an evaluation of the degree of observance of applicable standards, including a list of enforcement actions, court decisions, and compromises of alleged violations by location and company name;

(4) a summary of outstanding problems confronting the administration of this subpart in order of priority;

(5) an analysis and evaluation of research activities completed as a result of Government and private sponsorship, and technological progress for safety achieved during such year;

(6) a list, with a brief statement of the issues, of completed or pending judicial actions under this subpart;

(7) the extent to which technical information was disseminated to the scientific, commercial, and labor community and consumer oriented information was made available to the public; and

(8) the extent of cooperation between Government officials and representatives of industry and other interested parties in the implementation of this subpart including a log or summary of meetings held between Government officials and representatives of industry and other interested parties.

(b) The report required by subsection (a) of this section shall contain such recommendations for additional legislation as the Secretary deems necessary to promote cooperation among the several States in the improvement of electronic product radiation control and to strengthen the national electronic product radiation control program. ”

NOTE: Under 42 USC 263, FDA authority extends to electronic product radiation control. Environmental aspects were transferred to EPA under Reorganization Plan No. 3, 1970.

G. Bureau of *Veterinary Medicine*

Legal citation	Type of authority	Legislative text

G. Bureau of Veterinary Medicine

a) Federal Food, Drug and Cosmetic Act • P.L. 75-717 §512, as added by P.L. 90-399 §Iol(b) **(1968)** and amended • 21 USC ~360b	General	(1)(1) "In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) of this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to deiermine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m) (4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary. (m)(5) In case of an animal feed for which an approval of an application filed pursuant to this subsection is in effect— (A) the applicant shall establish and maintain such records, and make such reports to the Secretary, or (at the option of the Secretary) to the appropriate person or persons holding an approved application filed under subsection (b) of this section, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary . . . to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section or paragraph (4) of this subsection. . . ."