FOOD AND DRUG LAW AND REGULATION

THIRD EDITION

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CHAPTER 1

INTRODUCTION

RICHARD M. COOPER

The Focus of the Law

Food and drug law is about certain types of physical things. Most of these things are put into or onto, or are used with, the bodies of humans or animals—foods, drugs, medical devices, cosmetics, and, since June 22, 2009, tobacco products. Food and drug law also concerns aspects of radiation-emitting products (e.g., microwave ovens, laser lights) that relate to safety. The principal requirements and prohibitions of the law are about things: they shall not be adulterated or misbranded; they shall be manufactured and tested in accordance with certain standards; on their labels and in their labeling, certain disclosures shall be made, and certain kinds of claims shall not be made; certain kinds of things shall not be introduced into interstate commerce until their distribution has been authorized by the regulatory agency; and so on.

During the first few decades of modern food and drug law, the law's characteristic form of enforcement action was an *in rem* seizure action against physical objects that were in violation of the law.[1] The purpose of this type of action was to protect patients or other consumers from things that might harm or deceive them. In recent decades, seizure actions have largely (though not completely) been replaced by recalls, which serve the same purpose without intervention by a court. To the extent food and drug law regulates people and what they do, it regulates them only in relation to the physical things that are within the jurisdiction of the law, through injunctive, criminal, debarment, civil-penalty or certain other types of proceedings.

Some products within the jurisdiction of the Food and Drug Administration (FDA)—e.g., drugs and medical devices—are discovered or invented after substantial research. Generally, such a product undergoes a developmental process that includes testing in a laboratory and then in animals and humans; creation and validation of processes for manufacturing

[1] Federal Food, Drug, and Cosmetic Act (FDCA) § 304, 21 U.S.C. § 334 (2012).

and quality control on a commercial scale; and development of labeling that sets forth conditions of use. It then goes through some form of review by FDA and is approved, cleared, or otherwise permitted to be distributed in interstate commerce. Next, the product is manufactured in packaged and labeled form, is advertised and promoted, and is shipped commercially. During its life on the market, the product is from time to time the subject of reports of adverse events experienced by consumers and of complaints by consumers, which are reviewed by the product's manufacturer and possibly by FDA. Medical devices may undergo engineering changes. The labeling of drugs and medical devices changes as information on how to use them most effectively and safely accumulates. Additional uses for such products may be discovered, tested, and included in product labeling. Food and drug law addresses most stages of this product life cycle.

This focus on physical things sets the framework for regulation by FDA. The agency's most labor-intensive activities include: 1) review of applications to test potential new medical products in human subjects; 2) review of applications for permission for commercial marketing of new products or ingredients for use in products, and for changes in already marketed products; 3) review of reports and other data bearing on the safety of marketed products; 4) inspections of factories and of goods offered for importation, and testing of samples obtained in such inspections; 5) review of advertising and marketing of products; 6) regulatory and enforcement actions that result from such inspections and reviews; and 7) development and publication of regulations and guidance documents relating to products and activities within its jurisdiction.

FDA regulates products that account for more than 20 percent of consumer spending in the United States.[2] Whereas other administrative agencies have gone through periods of deregulation, in recent years Congress has expanded FDA's jurisdiction and its regulatory authorities.

A Little History

Although there were antecedents in the 19th century in America and even earlier in England,[3] the modern history of food and drug regulation begins with the Pure Food and Drugs Act of 1906.[4] That legislation, which had long been championed by Dr. Harvey W. Wiley, Chief Chemist of the U.S. Department of Agriculture (USDA), finally resulted from the sensational disclosures by the muckrakers of corruption, fraud, and improper conditions in many areas

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2 Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, Remarks at Generic Pharmaceutical Association Annual Meeting (Feb. 18, 2010), *available at* http://www.fda.gov/NewsEvents/Speeches/ucm201833.htm. *See also* Sean Silverthorne, *The FDA: What Will the Next 100 Years Bring?*, Harvard Bus. Sch. Working Knowledge (Sept. 24, 2007), *available at* http://hbswk.hbs.edu/item/5753.html; Alastair J.J. Wood, M.D., *Playing "Kick the FDA"—Risk-free to Players But Hazardous to Public Health*, 358 N. Eng. J. Med. 1774, 1774-75 (Apr. 24, 2008), *available at* http://www.nejm.org/doi/full/10.1056/NEJMp0802227.

3 *See, e.g.*, Peter Barton Hutt, *The Basis and Purpose of Government Regulation of Adulteration and Misbranding of Food*, 33 Food Drug Cosm. L.J. 505, 506-09 (1978).

4 Pub. L. No. 59-384, 34 Stat. 768 (1906). Congress previously had enacted legislation to regulate products of biological origin. Pub. L. No. 57-244, 32 Stat. 728 (1902).

of economic activity, including food processing and the manufacture and marketing of patent medicines.[5]

The law specified conditions under which foods and drugs would be considered adulterated or misbranded (and therefore barred from interstate commerce), and authorized USDA's Bureau of Chemistry to recommend enforcement actions to the U.S. Department of Justice (DOJ). The law did not provide for governmental review of products prior to their marketing, and was limited in other ways.

Many of the recognized defects in the 1906 act were remedied by the FDCA of 1938, FDA's organic statute and the principal authority for its regulatory activities.[6] This statute greatly expanded FDA's authority by providing for premarket review of drugs under a requirement of safety, for standards of identity and quality for food, for regulation of medical devices and cosmetics, and for inspections by FDA employees of factories, warehouses, and other places where regulated products are made, tested, or held. This statute remains the basic food and drug law; and it has been amended many, many times, in most instances in ways that expand and strengthen the regulatory scheme. The principal amendments (some of which have been subsequently amended) have included the following:

- A series of amendments providing for regulation of insulin and various antibiotics;[7]
- Miller Act, which added to the FDCA section 301(k) (adulterating or misbranding a regulated product after it has been shipped in interstate commerce) and correspondingly amended section 304(a) (relating to seizure);[8]
- Durham-Humphrey Amendment (providing a statutory basis for a prescription requirement);[9]
- Pub. L. No. 83-217 (strengthening FDA's inspectional authority);[10]
- Food Additives Amendment of 1958;[11]
- Color Additive Amendments of 1960;[12]

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5 *See generally* Richard M. Cooper, *The Struggle for the 1906 Act, in* FDA: A Century of Consumer Protection 25-69 (Wayne Pines ed., FDLI 2006). The phenomenon of enacting food and drug legislation in response to harm, or a perceived threat of harm, to the public health (perceived as resulting from a lack of adequate regulation) was repeated, e.g., in 1938, when the modern food and drug statute was enacted; in 1962, when major amendments to the drug law were enacted; in 1976, when major amendments to the medical device law were enacted; in 2007, when further major amendments to the drug law and other parts of the Federal Food, Drug, and Cosmetic Act were enacted; and in 2013, when further amendments as to drugs were enacted.

6 Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-399f (2012)). Section 408 of the FDCA, 21 U.S.C. § 346a, relating to tolerances and exemptions for pesticide chemical residues, is administered by the Environmental Protection Agency.

7 Pub. L. No. 77-366, 55 Stat. 851 (1941) (insulin); Pub. L. No. 79-139, 59 Stat. 463 (1945) (penicillin); Pub. L. No. 80-16, 61 Stat. 11 (1947) (streptomycin); Pub. L. No. 81-164, 63 Stat. 409 (1949) (aureomycin, chloramphenicol, bacitracin); Pub. L. No. 83-201, 67 Stat. 389 (1953) (chlortetracycline).

8 Pub. L. No. 80-749, 62 Stat. 582 (1948).

9 Pub. L. No. 82-215, 65 Stat. 648 (1951).

10 67 Stat. 476 (1953).

11 Pub. L. No. 85-929, 72 Stat. 1784 (1958).

12 Pub. L. No. 86-618, 74 Stat. 397 (1960).

- Drug Amendments of 1962;[13]
- Animal Drug Amendments of 1968;[14]
- Drug Listing Act of 1972;[15]
- Medical Device Amendments of 1976;[16]
- Vitamins and Minerals Amendments;[17]
- Infant Formula Act of 1980;[18]
- Orphan Drug Act;[19]
- Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act);[20]
- Drug Export Amendments Act of 1986;[21]
- Prescription Drug Marketing Act of 1987;[22]
- Food and Drug Administration Act of 1988 (statutory establishment of FDA);[23]
- Generic Animal Drug and Patent Term Restoration Act;[24]
- Nutrition Labeling and Education Act of 1990;[25]
- Safe Medical Devices Act of 1990;[26]
- Food and Drug Administration Revitalization Act;[27]
- Generic Drug Enforcement Act of 1992;[28]
- Prescription Drug Amendments of 1992;[29]
- Medical Device Amendments of 1992;[30]
- Prescription Drug User Fee Act of 1992;[31]
- Animal Medicinal Drug Use Clarification Act of 1994;[32]
- Dietary Supplement Health and Education Act of 1994;[33]

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13 Pub. L. No. 87-781, 76 Stat. 780 (1962).
14 Pub. L. No. 90-399, 82 Stat. 342 (1968).
15 Pub. L. No. 92-387, 86 Stat. 559 (1972).
16 Pub. L. No. 94-295, 90 Stat. 539 (1976).
17 Pub. L. No. 94-278, 90 Stat. 410 (1976).
18 Pub. L. No. 96-359, 94 Stat. 1190 (1980).
19 Pub. L. No. 97-414, 96 Stat. 2049 (1983).
20 Pub. L. No. 98-417, 98 Stat. 1585 (1984).
21 Pub. L. No. 99-660, 100 Stat. 3743 (1986).
22 Pub. L. No. 100-293, 102 Stat. 95 (1988).
23 Health Omnibus Programs Extension of 1988, Pub. L. No. 100-607, tit. V, 102 Stat. 3048, 3120-22 (1988).
24 Pub. L. No. 100-670, 102 Stat. 3971 (1988).
25 Pub. L. No. 101-535, 104 Stat. 2353 (1990).
26 Pub. L. No. 101-629, 104 Stat. 4511 (1990).
27 Pub. L. No. 101-635, 104 Stat. 4583 (1990).
28 Pub. L. No. 102-282, 106 Stat. 149 (1992).
29 Pub. L. No. 102-353, 106 Stat. 941 (1992).
30 Pub. L. No. 102-300, 106 Stat. 238 (1992).
31 Pub. L. No. 102-571, 106 Stat. 4491 (1992).
32 Pub. L. No. 103-396, 108 Stat. 4153 (1994).
33 Pub. L. No. 103-417, 108 Stat. 4325 (1994).

- FDA Export Reform and Enhancement Act of 1996;[34]
- Food Quality Protection Act of 1996;[35]
- Animal Drug Availability Act of 1996;[36]
- Food and Drug Administration Modernization Act of 1997;[37]
- Best Pharmaceuticals for Children Act;[38]
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002;[39]
- Medical Device User Fee and Modernization Act of 2002;[40]
- Animal Drug User Fee Act of 2003;[41]
- Pediatric Research Equity Act of 2003;[42]
- Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (relating to generic drugs);[43]
- Minor Use and Minor Species Animal Health Act of 2004;[44]
- Food Allergen Labeling and Consumer Protection Act of 2004;[45]
- Dietary Supplement and Nonprescription Drug Consumer Protection Act;[46]
- Food and Drug Administration Amendments Act of 2007;[47]
- QI Program Supplemental Funding Act of 2008 (section relating to certain antibiotic drugs);[48]
- Family Smoking Prevention and Tobacco Control Act;[49]
- Patient Protection and Affordable Care Act of 2010 (section relating to nutrition labeling of standard menu items at chain restaurants);[50]
- FDA Food Safety Modernization Act[51];
- Food and Drug Administration Safety and Innovation Act;[52] and
- Drug Quality and Security Act.[53]

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34 Pub. L. No. 104-134, tit. II, ch. 1A, 110 Stat. 1321-313 through 1321-320 (1996).
35 Pub. L. No. 104-170, 110 Stat. 1489 (1996).
36 Pub. L. No. 104-250, 110 Stat. 3151 (1996).
37 Pub. L. No. 105-115, 111 Stat. 2296 (1997).
38 Pub. L. No. 107-109, 115 Stat. 1408 (2002).
39 Pub. L. No. 107-188, 116 Stat. 594 (2002).
40 Pub. L. No. 107-250, 116 Stat. 1588 (2002).
41 Pub. L. No. 108-130, 117 Stat. 1361 (2003).
42 Pub. L. No. 108-155, 117 Stat. 1936 (2003).
43 Pub. L. No. 108-173, 117 Stat. 2066, 2448 (2003).
44 Pub. L. No. 108-282, tit. I, 118 Stat. 891, 891-905 (2004).
45 Pub. L. No. 108-282, tit. II, 118 Stat. 905, 905-11 (2004).
46 Pub. L. No. 109-462, 120 Stat. 3469 (2006).
47 Pub. L. No. 110-85, 121 Stat. 823 (2007).
48 Pub. L. No. 110-379, § 4, 122 Stat. 4075, 4076 (2008).
49 Pub. L. No. 111-31, 123 Stat. 1776 (2009).
50 Pub. L. No. 111-148, § 4205, 124 Stat. 119, 573 (2010).
51 Pub. L. No. 111-353, 124 Stat. 3885 (2011).
52 Pub. L. No. 112-144, 126 Stat. 993 (2012).
53 Pub. L. No. 113-54, 127 Stat. 587 (2013).

Although FDA is the agency principally responsible for regulation of foods, drugs, medical devices, cosmetics, and tobacco products, certain regulatory functions relating to some of those products are also performed by USDA, the Drug Enforcement Administration in DOJ, the Federal Trade Commission, and the states. In addition, the system for federal reimbursement for therapeutic products is administered by the Centers for Medicare & Medicaid Services in the Department of Health and Human Services (DHHS).

FDA's Place in the Executive Branch

FDA is, and always has been, an agency in the executive branch of the federal government.[54] Therefore, its budget, legislative proposals, congressional testimony, and major regulatory proposals are subject to approval by the Office of Management and Budget (OMB) on behalf of the President.

Like other executive branch agencies, FDA is subject to a wide variety of executive orders issued by the President. It is also subject to general statutes that bear on its regulatory activities.[55]

Also like other agencies in the executive branch, FDA has no authority to represent itself in court, but is represented by DOJ.[56] All litigation—civil and criminal—involving the agency, and including litigation brought against the agency, is supervised on behalf of the agency by the Consumer Protection Branch (CPB) (formerly known as the Office of Consumer Litigation) in the Civil Division of DOJ. In practice, responsibility for the actual conduct of litigation on behalf of the agency is divided between the CPB and the Offices of the United States Attorneys throughout the country. In general, DOJ permits lawyers in FDA's Office of the Chief Counsel to assist in the representation of the agency in litigation.

FDA originated as the Bureau of Chemistry in USDA before the enactment of the Pure Food and Drugs Act of 1906.[57] The agency remained part of USDA (under various names) until 1940, when it was transferred to the Federal Security Agency, which later became the

[54] By contrast, the Federal Trade Commission and the Consumer Product Safety Commission, for example, are independent agencies.

[55] *E.g.*, Administrative Procedure Act, Pub. L. No. 79-404, 60 Stat. 237 (1946) (codified as amended at 5 U.S.C. §§ 551, 553-559, 701-706 (2012)); Freedom of Information Act, Pub. L. No. 89-554, 80 Stat. 383 (1966) (codified as amended at 5 U.S.C. § 552 (2012)); Federal Advisory Committee Act, Pub. L. No. 92-463, 86 Stat. 770 (1972) (codified as amended at 5 U.S.C. app. 2 (2012)); National Environmental Policy Act of 1969, Pub. L. No. 91-190, 83 Stat. 852 (1970) (codified as amended at 42 U.S.C. §§ 4321, 4331-4335 (2012)); Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified as amended at 5 U.S.C. §§ 601-612 (2012)); Government Performance and Results Act of 1993, Pub. L. No. 103-62, 107 Stat. 285 (1993); Unfunded Mandates Reform Act of 1995, Pub. L. No. 104-4, 109 Stat. 48 (1995) (codified as amended at 2 U.S.C. §§ 1501-1504, 1511-1616, 1531-1538, 1551-1556, 1571 (2012)); Paperwork Reduction Act of 1995, Pub. L. No. 104-13, 109 Stat. 163 (1995) (codified at 44 U.S.C. §§ 3501-3520 (2012)). These statutes have been amended from time to time.

[56] *See* 28 U.S.C. §§ 516, 519 (2012). The agency is also bound by opinions of the Attorney General.

[57] The Bureau of Chemistry began in 1862 with President Lincoln's appointment of a chemist in the USDA. U.S. Department of Health and Human Services, Historical Highlights, *available at* http://www.hhs.gov/about/hhshist.html (last reviewed June 6, 2014). The name "Food and Drug Administration" first officially appeared in the Agricultural Appropriation Act of 1931, Pub. L. No. 71-272, 46 Stat. 392 (1930).

Department of Health, Education and Welfare, and then DHHS.[58] The agency was formally established by law in 1988.[59]

As part of DHHS, FDA is subject to oversight by the department on the same matters as to which it is subject to oversight by OMB. FDA is subject to review by DHHS of other important actions, including certain types of regulatory actions,[60] internal reorganizations, and important personnel actions. Issues of integrity or efficiency with respect to FDA are investigated by DHHS's Office of Inspector General.

Although not legally independent, FDA is culturally independent of DHHS. FDA's principal offices are located on a campus in White Oak, Maryland—a substantial distance from DHHS's headquarters which are near the U.S. Capitol in Washington, D.C. The agency perceives its statutory and regulatory systems as complex and highly technical, and its expertise in administering them as unmatched by any group outside the agency. FDA has a long history of deferring to superior legal authority only to the extent necessary, and of acting as independently as circumstances permit.

FDA and Congress

Despite the movement of FDA from USDA to DHHS, FDA's annual appropriation is still part of the agricultural appropriations process, and is reviewed and determined by the Subcommittees on Agriculture of the House of Representatives and Senate Appropriations Committees. FDA's authorizing committees are the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce. Within the latter, the Subcommittee on Oversight and Investigations and the Subcommittee on Health historically have taken a strong interest in the agency. The House Committee on Oversight and Government Reform also has responsibilities with respect to FDA. From time to time, other committees also have conducted investigations and hearings relating to FDA.

FDA frequently has been the subject of reports issued by congressional committees and by the Government Accountability Office (formerly known as the General Accounting Office).[61]

FDA's Internal Organization and Budget

FDA's internal organization is set forth in Part 5 of Title 21 of the *Code of Federal Regulations*. The head of the agency is a single Commissioner,[62] who, under a statute enacted in 1988,

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58 *See generally* Michael Brannon, *Organizing and Reorganizing FDA*, *in* Food and Drug Law 113-63 (Richard M. Cooper ed., FDLI 1991).

59 *See supra* note 23.

60 *See infra* notes 85-86 and accompanying text.

61 *See* Peter Barton Hutt, *Investigations and Reports on the Food and Drug Administration, in* Food and Drug Law 41-60 (Richard M. Cooper ed., FDLI 1991).

62 There is no corresponding commission.

is appointed by the President with the advice and consent of the Senate.[63] Under the Commissioner, FDA units with agency-wide responsibilities are:

- Office of the Commissioner (including Chief of Staff)
  - Office of the Chief Counsel[64]
  - Office of the Executive Secretariat
  - Office of the Counselor to the Commissioner
    - Office of Legislation
    - Office of External Affairs
    - Office of Policy and Planning
  - Office of the Chief Scientist
    - National Center for Toxicological Research
    - Office of Women's Health
    - Office of Minority Health
- Office of Operations
  - Office of Equal Employment Opportunity
  - Office of Finance, Budget and Acquisitions
  - Office of Facilities Engineering & Mission Support Services
  - Office of Information Management and Technology
  - Office of Human Resources
  - Office of Security Operations
- Office of Food and Veterinary Medicine
  - Office of Resource Planning and Strategic Management
  - Office of Coordinated Outbreak Response and Evaluation Network
  - Center for Veterinary Medicine
  - Center for Food Safety and Applied Nutrition
- Office of Medical Products and Tobacco
    - Office of Special Medical Programs
    - Center for Devices and Radiological Health
    - Center for Biologics Evaluation and Research

63 FDCA § 1003, 21 U.S.C. § 393(d); *see supra* note 23. Previously, the Commissioner had been appointed by the Secretary without Senate confirmation.

64 FDA's Office of the Chief Counsel is, technically, part of the Office of the General Counsel of DHHS, which, in turn, is part of the Office of the Secretary. The FDA Chief Counsel is officially an Associate General Counsel of DHHS, and as such reports to the General Counsel of DHHS. *See* DHHS, Office of the General Counsel, Key Personnel, Food and Drug Division, *available at* http://www.hhs.gov/ogc/personnel/index.html#FoodandDrugDivisionStaffContactInformation (last updated Apr. 23, 2014). For a description of the Office of the Chief Counsel, *see* Office of the Chief Counsel, http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeoftheChiefCounsel/default.htm (last updated Feb. 24, 2010).

  - Center for Drug Evaluation and Research
  - Center for Tobacco Products
- Office of Global Regulatory Operations and Policy
  - Office of International Programs
  - Office of Regulatory Affairs.[65]

FDA also has an agency-wide ombudsman and ombudsmen in the Centers for Drugs, Devices, Biologics, Tobacco, and Veterinary Medicine.[66]

The organization of the Office of the Commissioner changes from time to time to suit the preferences of particular Commissioners.

FDA's principal regulatory programs are administered by six Centers:

- Center for Biologics Evaluation and Research;
- Center for Devices and Radiological Health;
- Center for Drug Evaluation and Research;
- Center for Food Safety and Applied Nutrition;
- Center for Tobacco Products; and
- Center for Veterinary Medicine.

As of January 2015, FDA had numerous advisory committees, principally for drugs, biological products, and devices.[67]

FDA's total appropriated program funding in fiscal 2014 (ending September 30, 2014) was $4.4 billion, which included $2.561 billion in appropriated budget authority and $1.826 billion in user fees.[68] For fiscal 2015, the President requested a total of $4.7 billion in program funding, of which $2.584 billion is budget authority and $2.161 billion is user fees.[69]

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65 Information about these offices is available at www.fda.gov/AboutFDA/CentersOffices/ (last visited Jan. 18, 2015).

66 *See generally* the description of the Office of the Ombudsman, *available at* http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofScientificandMedicalPrograms/ucm197508.htm (last updated Dec. 4, 2014); FDA's Office of the Ombudsman, Consultation[,] Dispute Resolution[,] Mediation (undated), http://www.fda.gov/downloads/aboutfda/contactfda/resolveadispute/ucm164330.pdf (last visited Jan. 18, 2015).

67 *See* http://www.fda.gov/AdvisoryCommittees/default.htm (last updated Feb. 25, 2015) (for lists of committees, click on individual subject matter areas).

68 FY 2015 FDA Justification of Estimates for Appropriations Committees, Overview of the Budget Request, *available at* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM394601.pdf (last visited Jan. 18, 2015).

69 *Id.*

In fiscal 2014, FDA's estimated staffing of full-time-equivalent positions was as follows:

Center for Food Safety and Applied Nutrition	948
Center for Drug Evaluation and Research	4,245
Center for Biologics Evaluation and Research	1,138
Center for Veterinary Medicine	521
Center for Devices and Radiological Health	1,666
National Center for Toxicological Research	281
Office of Regulatory Affairs	4,970
Headquarters and Office of the Commissioner	1,307
Export Certification	22
Color Certification	37
Family Smoking Prevention and Tobacco Control Act	570
TOTAL	15,705[70]

Although FDA has received budget increases in recent years, there is reason to believe that the resources provided by Congress to FDA chronically have been, and remain, inadequate to enable the agency to fulfill its statutory responsibilities.[71]

FDA's Statutory Authorities

All authority exercised by FDA is derived from congressional delegations to the Secretary of Health and Human Services (the Secretary), and redelegations by the Secretary to the Commissioner of Food and Drugs.[72] FDA has no independent regulatory authority delegated directly to it by Congress.[73]

FDA administers the FDCA, and certain other statutes, including the Mammography Quality Standards Act of 1992,[74] certain provisions of the Public Health Service Act,[75]

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70 *Id.*, Detail of Full-Time Equivalent (FTE) Employment, *available at* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM394944.pdf (last visited Jan. 18, 2015).

71 *See, e.g.*, FDA Science and Mission at Risk, Report of the Subcommittee on Science and Technology (Nov. 2007), *available at* http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf.

72 The delegations are set forth in FDA Staff Manual Guides Volume II – Delegations of Authority, Regulatory, Delegations of Authority to the Commissioner Food and Drugs § 1410.10 (2014), *available at* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM273771.pdf. *See also* Removal of Delegations of Authority and Conforming Changes to Regulations, 69 Fed. Reg. 17,285 (Apr. 2, 2004) (removing list of delegated authorities from the *Code of Federal Regulations*).

73 The Commissioner is directly authorized by FDCA § 1004, 21 U.S.C. § 394, to establish technical and scientific review groups and to appoint and pay their members.

74 Pub. L. No. 102-539, 106 Stat. 3547 (1992).

75 *See* FDA Staff Manual Guides Volume II – Delegations of Authority, Regulatory, Delegations of Authority to the Commissioner Food and Drugs § 1410.10, ¶ 1, *supra* note 72.

the Filled Milk Act,[76] the Federal Import Milk Act,[77] the Saccharin Study and Labeling Act,[78] and certain provisions of laws relating to controlled substances and drug abuse,[79] and has important functions under the Federal Caustic Poison Act,[80] the Lead-Based Paint Poisoning Prevention Act,[81] and the Fair Packaging and Labeling Act.[82] The agency also has certain functions under statutes administered principally by USDA.[83] The functions that FDA performs under statutes other than the FDCA are ancillary to its functions under the FDCA.[84]

Moreover, despite the broad delegations by the Secretary to the Commissioner, the Secretary in 1982[85] reserved, and continues to reserve, authority to approve regulations promulgated by FDA that:

(1) Establish procedural rules applicable to a general class of foods, drugs, cosmetics, medical devices, or other subjects of regulation; or

(2) Present highly significant public issues involving the quality, availability, marketability, or cost of one or more foods, drugs, cosmetics, medical devices, or other subjects of regulation.[86]

This reservation of authority was not intended to create any private right or benefit,[87] although, as a practical matter, it does invite lobbying at the department with respect to regulations to which it applies.

FDA's internal redelegations of authority are available at http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm136380.htm (last updated Oct. 22, 2014).

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76 21 U.S.C. §§ 61-64.

77 *Id.* §§ 141-149.

78 Pub. L. No. 95-203, 91 Stat. 1451 (1977). This statute subsequently has been amended.

79 Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, tit. I, § 4, 84 Stat. 1236, 1241 (1970); Controlled Substances Act, Pub. L. No. 91-513, tit. II, § 303(f), 84 Stat. 1242, 1253, 1255 (1970) (codified as amended at 21 U.S.C. § 823(f) (2012)).

80 Pub. L. No. 69-783, 44 Stat. 1406 (1927).

81 Pub. L. No. 91-695, tit. IV, § 401, 84 Stat. 2078, 2079 (1971), *as amended by* Pub. L. No. 94-317, tit. II, 90 Stat. 695, 705 (1976) (codified as amended at 42 U.S.C. § 4831(a) (2012)).

82 15 U.S.C. §§ 1451-1461 (2012).

83 Federal Meat Inspection Act § 409(b) (codified as amended at 21 U.S.C. § 679(b) (2012)); Poultry Products Inspection Act § 24(b) (codified as amended at 21 U.S.C. § 467(b) (2012)); Egg Products Inspection Act (codified as amended at 21 U.S.C. § 1031-1056) (2012)).

84 For a list of other statutes FDA considers itself affected by, *see* http://www.fda.gov/RegulatoryInformation/Legislation/ucm153119.htm (last updated June 18, 2009).

85 Reservation of Rulemaking Authority of the Food and Drug Administration in Matters Involving Significant Public Policy; Revision, 47 Fed. Reg. 16,318 (Apr. 16, 1982).

86 *See* FDA Staff Manual Guides Volume II – Delegations of Authority, Regulatory, Delegations of Authority to the Commissioner Food and Drugs § 1410.10 at 10, § 2 (Reservation of Authority), *supra* note 72.

87 *Id.* § 2.C.

An Overview of the Federal Food, Drug, and Cosmetic Act

The FDCA is organized into 10 chapters:

- Short Title;
- Definitions;
- Prohibited Acts and Penalties;
- Food;
- Drugs and Devices;[88]
- Cosmetics;
- General Authority;
- Imports and Exports;
- Tobacco Products; and
- Miscellaneous.

The statute is codified in Title 21 of the *United States Code*. The critical terms of the statute are defined in section 201.[89] Among the terms defined are the jurisdictional terms ("food," "drug," "device" (the term "device" refers to a medical device), "cosmetic," and "tobacco product"), and other terms critical to the operation of the statute (e.g., "interstate commerce," "label" and "labeling," "new drug," "food additive," and "color additive"). Section 201(u) specifies that, for purposes of food additives, new animal drugs, and color additives, the term "safe" refers to "the health of man or animal";[90] but the statute contains no general definition of "safe" or "safety," and consequently the definitions of those terms for particular regulatory purposes must be derived from other legal and regulatory materials.

The general strategy of the statute consists of three steps. First, the statute specifies circumstances in which an article (food, drug, device, cosmetic, or tobacco product) is "adulterated" or "misbranded,"[91] or lacks required permission to be marketed.[92] Second, the

[88] The provisions relating to electronic products, including definitions, substantive, administrative, and enforcement provisions, and a list of prohibited acts, appear in FDCA sections 531-542, 21 U.S.C. §§ 360hh-360ss. FDA originally regulated radiation-emitting electronic products under the Radiation Control for Health and Safety Act of 1968, Pub. L. No. 90-602, 82 Stat. 1173 (1968), which originally was codified as part of the Public Health Service Act. Responsibility for administration of this statute was transferred to FDA by Redelegation of Authority, 36 Fed. Reg. 12,803 (July 7, 1971); and the statute, itself, was recodified in the FDCA by Pub. L. No. 101-629, § 19(a)(3), (4), 104 Stat. 4511, 4529-4530 (1990).

[89] 21 U.S.C. § 321.

[90] 21 U.S.C. § 321(u).

[91] *See* FDCA §§ 402 (adulterated food), 403 (misbranded food), 501 (adulterated drugs and devices), 502 (misbranded drugs and devices), 601 (adulterated cosmetics), 602 (misbranded cosmetics), 902 (adulterated tobacco products) & 903 (misbranded tobacco products), 21 U.S.C. §§ 342, 343, 351, 352, 361, 362, 387b & 387c.

[92] *See id.* §§ 404 (emergency permit control for certain foods), 505 (new drugs for human use), 21 U.S.C. §§ 344, 355. Other requirements for authorization for distribution, including *id.* §§ 409 (food additives), 512 (new animal drugs), 515 (Class III devices), 721 (color additives), & 910 (tobacco products), 21 U.S.C. §§ 348, 360b, 360e, 379e, & 387j, operate through the adulteration provisions, *id.* §§ 402(a)(2)(C)(i) (food additives), 402(a)(2)(C)(ii) (foods containing a new animal drug), 501(a)(5)-(6) (new animal drugs), 351(f)

statute defines a set of prohibited acts with respect to such an article.[93] Third, the statute authorizes a set of enforcement actions in response to a prohibited act.[94]

With respect to food, drugs, devices, cosmetics, and tobacco products, the adulteration and misbranding provisions use terms elaborated on in other substantive provisions of the statute, located in Chapter IV (Food), Chapter V (Drugs and Devices), Chapter VI (Cosmetics), and Chapter IX (Tobacco Products). Under FDCA section 701(a),[95] FDA has exercised general authority to elaborate by regulation the statutory standards for adulteration and misbranding, and those for approvals and other authorizations for marketing of products.[96] Section 301 prohibits certain acts with respect to an article that is adulterated or misbranded.[97] For example, section 301(a) declares it a prohibited act to introduce such an article into interstate commerce.[98] Similarly, section 301(d)[99] directly (i.e., without reference to adulteration or misbranding) prohibits the introduction into interstate commerce of any new drug for which an approval required by section 505(a)[100] is lacking and of any food subject to section 404[101] for which a permit required under that section is lacking.

Under section 304, an article that was adulterated or misbranded when introduced into interstate commerce or while in interstate commerce or while held for sale after shipment in interstate commerce, or that lacks a required authorization for distribution, is subject to seizure.[102] Commission of acts prohibited by section 301 may be enjoined under section

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(Class III medical devices), 402(c) (food containing a color additive), 501(a)(4)(A) (drug or device containing a color additive), 501(a)(4)(B) (color additive for use on a drug or device), 601(e) (cosmetic containing a color additive), 902(6) (tobacco product), 21 U.S.C. §§ 342(a)(2)(C)(i), 342(a)(2)(C)(ii), 351(a)(5)-(6), 342(c), 351(a)(4)(A), 351(a)(4)(B), 361(e), 402(c), & 387b(6).

Food and drug law uses varying terminology to refer to actions by FDA to permit the distribution of different kinds of products in interstate commerce. For example, FDA may "approve" a new drug application under FDCA § 505(c)(1)(A), 21 U.S.C. § 355(c)(1)(A); and it may "approve" a device premarket approval application under section 515(d)(1), 21 U.S.C. § 360e(d)(1). FDA may "clear" a device to enter the market by means of a notification under section 510(k), 21 U.S.C. § 360(k). *See*, *e.g.*, FDA, 510(k) Clearances, *available at* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm (last updated Jan. 13, 2015). Under section 404, 21 U.S.C. § 344, FDA issues "permits" for interstate distribution of certain foods. With respect to a new tobacco product reviewed under FDCA § 910, 21 U.S.C. § 387j, FDA may, under section 910(c)(1)(A)(i), 21 U.S.C. § 387j(c)(1)(A)(i), "issue an order that the new product may be introduced or delivered for introduction into interstate commerce . . . ." Most authorizations for marketing are by letter (which constitutes an "order" for purposes of the Administrative Procedure Act, 5 U.S.C. § 551(6)), but an authorization for the marketing and use of a food additive or color additive is in the form of a regulation, *see* FDCA § 409(c), 21 U.S.C. § 348(c) (food additives); FDCA § 721(b)(1), 21 U.S.C. § 379e(b)(1) (color additives).

93 FDCA § 301, 21 U.S.C. § 331.

94 FDCA §§ 302-310, 21 U.S.C. §§ 332-337. Certain additional, administrative enforcement actions are authorized in substantive provisions of the statute. For example, FDCA § 505(e), 21 U.S.C. § 355(e), authorizes withdrawal of approval of a new drug application on certain specified grounds.

95 21 U.S.C. § 371(a).

96 *See, e.g.*, 21 C.F.R. pts. 101 (food labeling), 110 (current good manufacturing practices for human food), 201 (drug labeling), 210-211 (good manufacturing practices for drugs), 314 (premarket approvals of new drugs), 801 (device labeling), 814 (premarket approvals of devices), and 820 (quality system regulation for devices).

97 21 U.S.C. § 331.

98 *Id.* § 331(a).

99 *Id.* § 331(d).

100 *Id.* § 355(a).

101 *Id.* § 344.

102 *Id.* § 334.

302,[103] and may be the basis for a criminal prosecution and/or, in certain circumstances, an action for civil penalties under section 303.[104] Other remedies for certain kinds of prohibited acts are available to FDA under other provisions of the statute.[105]

FDA's Mission

FDA's mission is stated in section 1003(b) of the FDCA:

The Administration shall—

> (1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;
>
> (2) with respect to such products, protect the public health by ensuring that—
>
> (A) foods are safe, wholesome, sanitary, and properly labeled;
>
> (B) human and veterinary drugs are safe and effective;
>
> (C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;
>
> (D) cosmetics are safe and properly labeled; and
>
> (E) public health and safety are protected from electronic product radiation;
>
> (3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and
>
> (4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.[106]

Here is FDA's statement of what it does:

> FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

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103 *Id.* § 332.
104 *Id.* § 333.
105 *See generally* Chapter 21, *infra*.
106 21 U.S.C. § 393(b).

> FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.
>
> FDA plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.[107]

FDA states that it strives to:

- Enforce FDA laws and regulations, using all appropriate legal means.
- Base regulatory decisions on a strong scientific and analytical base and the law; and understand, conduct, and apply excellent science and research.
- Be a positive force in making safe and effective products available to the consumer, and focus special attention on rare and life-threatening diseases.
- Provide clear standards of compliance to regulated industry, and advise industry on how to meet those standards.
- Identify and effectively address critical public health problems arising from use of FDA-regulated products.
- Increase FDA's effectiveness through collaboration and cooperation with state and local governments; domestic, foreign, and international agencies; industry; and academia.
- Assist the media, consumer groups, and health professionals in providing accurate, current information about regulated products to the public.
- Work consistently toward effective and efficient application of resources to our responsibilities.
- Provide superior public service by developing, maintaining, and supporting a high-quality, diverse workforce.
- Be honest, fair, and accountable in all of our actions and decisions.[108]

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107 Statement of FDA Mission, *available at* http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/budgetreports/ucm298331.pdf (last visited Jan. 18, 2015).

108 FDA Investigations Operations Manual, FDA Principles § 1.8.1, *available at* http://www.fda.gov/ICECI/Inspections/IOM/ucm122507.htm (last updated Dec. 18, 2014).

FDA's International Activities

Under Chapter VIII of the FDCA, FDA long has had responsibilities with respect to import and export of articles within its jurisdiction. In connection with imports, FDA, in cooperation with the U.S. Customs and Border Protection, conducts inspections of foreign goods presented for entry into the United States;[109] the agency also has responsibility to inspect, or arrange for inspection of, foreign facilities that manufacture or process goods for importation into the United States.[110] In connection with exports, the agency reviews applications for export approval where required,[111] and provides export certificates.[112] The agency also has active programs to achieve harmonization of its regulatory requirements with those of other countries with sophisticated regulatory systems.[113]

Food and Drug Law and Regulation, and the Practice of the Healing Arts

Although the food and drug laws and FDA's regulations apply to articles that affect health and to articles that are used to protect, promote, and restore health, they do not apply directly to the practice of medicine or other healing arts. In general, physicians, dentists, pharmacists, and other providers of healthcare are regulated by their respective professional societies and by state governmental agencies; and, in general, FDA does not regulate medical professionals except when they engage in clinical research, and when they manufacture, prepare, dispense, or market products within FDA's jurisdiction.[114]

Food and drug laws and regulations do directly affect the practice of the healing arts. FDA's regulation of drugs (including biological products), medical devices, and medical foods determines their availability to practitioners and patients. The FDA-approved labeling for such products influences the ways they are used. As a matter of food and drug law and regulation, practitioners are free to use such products outside the conditions stated in their labeling,[115] but they are responsible for such use under state law. Thus, for example, FDA regulates devices used in surgical and other medical procedures, but does not regulate the procedures, themselves; and physicians are free to use such devices in ways not recommended in their FDA-approved labeling.

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109 *See* FDCA § 801(a)-(d), 21 U.S.C. § 381(a)-(d).

110 *See* FDCA § 510(i)(3), 21 U.S.C. § 360(i)(3); ORA Field Management Directive No. 13A: Foreign Inspection Program (rev. Oct. 5, 2010), *available at* http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/UCM056644 (last updated May 2, 2011).

111 *See* FDCA §§ 801(e)(2), (4), 802, 21 U.S.C. §§ 381(e)(2), (4), 382.

112 FDA, Guidance for Industry: FDA Export Certificates (July 2004) (Corr. copy Apr. 2005), *available at* http://www.fda.gov/regulatoryinformation/guidances/ucm125789.htm (last visited Jan. 18, 2015). *See also* Export Certificates, http://www.fda.gov/InternationalPrograms/ExportsandExportCertificates/ucm130041.htm (last updated Feb. 13, 2014).

113 *See generally* Chapter 23, *infra*.

114 *See generally* Chapter 19, *infra*.

115 FDCA § 1006, 21 U.S.C. § 396; Proposed New Drug, Antibiotic, and Biologic Drug Product Regulations, 48 Fed. Reg. 26,720, 26,733 (June 9, 1983); *Use of Approved Drugs for Unlabeled Indications*, 12 FDA Drug Bull. 4 (1982); Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration, 37 Fed. Reg. 16,503 (Aug. 15, 1972).

FDA does regulate clinical trials of unapproved drugs and devices conducted in the United States, and clinical trials on approved drugs and devices (including clinical trials on unapproved drugs and devices outside the United States) where the sponsors of the trials intend to submit data from them to the agency in support of applications for approval or other authorization for distribution in interstate commerce.[116] When practitioners participate in such trials, their participation is regulated by FDA.[117] Moreover, when medical professionals step outside their normal therapeutic roles and misbrand or adulterate drugs or devices or engage in what FDA considers regulated activities indistinguishable from manufacturing and marketing drugs or devices, the agency may take regulatory action against them.[118]

Physicians and other healthcare practitioners play significant roles in FDA's activities. In recent decades, FDA Commissioners have been physicians or have had related academic credentials. Many senior and other officials of FDA, particularly those responsible for reviews of new medical products, are physicians. FDA's advisory committees, whose advice the agency usually accepts, consist principally of physicians, most with academic appointments. Moreover, physicians design, oversee, and conduct virtually all of the clinical research on which FDA regulatory decisions about specific products are based.

State Regulation of Foods and Drugs

Most states have food and drug laws that are similar to the FDCA. States regulate intrastate products and activities, and work cooperatively with FDA on matters of mutual interest. State Attorneys General, from time to time, also have taken enforcement action with respect to matters within the general area of food and drug law and regulation.

Additional Sources of Information About FDA

FDA's website address is www.fda.gov. FDA regulatory documents are posted at www.regulations.gov. Other governmental agencies and congressional committees that interact with FDA have their own websites, on which materials relevant to FDA can be found.

The Food and Drug Law Institute publishes the *Food and Drug Law Journal*, a magazine, books, and an e-mail newsletter; conducts conferences and educational programs relating to

116 *See generally* FDCA §§ 505(i), 520(g), 21 U.S.C. §§ 355(i), 360j(g).

117 *See generally* 21 C.F.R. pts. 50, 54, 56, 312, 812 (2014).

118 *See, e.g.*, United States v. Sullivan, 332 U.S. 689 (1948) (criminal prosecution of retail pharmacist for misbranding drug after it had been shipped in interstate commerce); United States v. Regenerative Services, LLC, 741 F.3d 1314, 1320 (D.C. Cir. 2014) (affirming injunction against two physicians, their laboratory director, and a related corporation for producing and administering, as part of their medical practice, a substance consisting of a mixture of a patient's stem cells and an antibiotic); United States v. Diapulse Corp. of America, 514 F.2d 1097, 1098 (2d Cir. 1975) (per curiam) (devices in offices of medical practitioners for use in treatment of patients are "held for sale" within the meaning of FDCA § 301(k), 21 U.S.C. § 331(k)); United States v. Kaadt, 171 F.2d 600 (7th Cir. 1948) (prosecution of physicians for distributing misbranded drugs); United States v. Sene X Eleemosynary Corp., 479 F. Supp. 970 (S.D. Fla. 1979) (enjoining compounding, promotion, and distribution of certain drugs by pharmacist and others).

food and drug regulation; maintains a directory of professional services; and provides other educational services. Its activities cover the full range of products regulated by FDA. Its website is www.fdli.org. The Drug Information Association provides similar services with respect to drugs, medical devices, and related products. Its website is http://www.diahome.org/DIAHome/Home.aspx. Both organizations are neutral and not-for-profit.

Many trade publications report on FDA's activities, including:

- CCH (reporters on food, drugs, devices, cosmetics), http://health.cch.com/news/food-drug-devices/041211.asp;
- FDA Week, http://insidehealthpolicy.com;
- FDANews (a variety of newsletters), http://www.fdanews.com/newsletters;
- FDC Reports (a variety of newsletters), http://www.pharmamedtechbi.com/;
- Food Chemical News, http://www.agra-net.com/portal2/fcn/home.jsp;
- Supermarket News (has a legislation/regulation section), http://supermarketnews.com/news/laws-regulations;
- NewsRx (has a news section on food and drug law; offers pay-as-you-go and some free news stories/alerts), http://www.newsrx.com/NewsRxCorp/;
- Rx Compliance Report, http://www.rxcompliancereport.com/;
- FDA Enforcement Manual, http://www.thompson.com/public/offerpage.jsp?prod=FEDS; and
- Dickinson's FDA Review, http://www.fdareview.com/.

FDA lists trade publications relating to cosmetics at http://www.fda.gov/cosmetics/resourcesforyou/industry/ucm077674.htm. Many medical journals also publish, in addition to scientific reports, editorials and comments relating to food and drug law and regulation.

Blogs relating to food and drug law include:

- FDA Law Blog, www.fdalawblog.net;
- Drug and Device Law, druganddevicelaw.blogspot.com;
- Orange Book Blog, www.orangebookblog.com;
- The Rest of the Story, http://tobaccoanalysis.blogspot.com; and
- WSJ Health Blog, http://blogs.wsj.com/health/ (from the *Wall Street Journal*—general health/industry).

Many trade associations, public interest groups, and other organizations interact frequently with FDA or are otherwise involved in food and drug regulation, and thus may be useful sources of information on some matters relating to FDA. Here is a partial list (excluding, *inter alia*, the numerous medical professional colleges and societies and also organizations focused on particular medical conditions):

- Abigail Alliance for Better Access to Developmental Drugs, www.abigail-alliance.org;
- AdvaMed, www.advamed.org;
- Alliance for a Stronger FDA, http://strengthenfda.org;
- American Clinical Laboratories Association, www.acla.com;
- American Herbal Products Association, www.ahpa.org;
- American Hospital Association, www.aha.org;
- American Public Health Association, www.apha.org;
- Association for the Advancement of Medical Instrumentation, www.aami.org;
- Association of Food and Drug Officials, http://www.afdo.org;
- Association of Food Industries, Inc., www.afius.org;
- Association of Health Care Journalists, www.healthjournalism.org;
- Association of Medical Diagnostics Manufacturers, www.amdm.org;
- Campaign for Tobacco-Free Kids, www.tobaccofreekids.org;
- Center for Public Integrity, www.publicintegrity.org;
- Center for Regulatory Effectiveness, www.thecre.com;
- Center for Science in the Public Interest, www.cspinet.org;
- Center for Tobacco Control Research & Education, http://www.ucsf.edu;
- Consumer Healthcare Products Association, www.chpa-info.org;
- Consumers Union, www.consumersunion.org;
- Council for Responsible Nutrition, www.crnusa.org;
- ECRI Institute, www.ecri.org;
- European Public Health Alliance, www.epha.org;
- Food Animals Concerns Trust, www.foodanimalconcerns.org;
- Generic Pharmaceutical Association, www.gphaonline.org;
- Grocery Manufacturers of America, www.gmaonline.org;
- Healthcare Distribution Management Association, www.healthcaredistribution.org;
- Institute for Agriculture & Trade Policy, www.iatp.org;
- Medical Device Manufacturers Association, www.medicaldevices.org;
- National Community Pharmacists Association, www.ncpanet.org;
- Natural Products Association, www.npainfo.org;
- Personalized Medicine Coalition, www.personalizedmedicinecoalition.org;
- Pharmaceutical Research and Manufacturers of America, www.phrma.org;
- Physicians for Social Responsibility, www.psr.org;
- Public Citizen Health Research Group, www.citizen.org;

- Regulatory Affairs Professionals Society, www.raps.org;
- Research! America, www.researchamerica.org;
- Union of Concerned Scientists, www.ucsusa.org;
- Utah Natural Products Alliance, www.unpa.com; and
- World Watch Institute, Global Resources Action Center for the Environment, http://www.worldwatch.org/node/1458.

A list by FDA of trade and professional associations of interest to the cosmetics industry is available at http://www.fda.gov/cosmetics/resourcesforyou/industry/ucm077669.htm (last updated June 23, 2014).