

**FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF
AUTHORITY**

REGULATORY

**DELEGATIONS OF AUTHORITY TO THE COMMISSIONER OF FOOD AND
DRUGS**

Effective Date: August 26, 2016

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

- A. The Secretary of Health and Human Services (the Secretary) has redelegated to the Commissioner of Food and Drugs (Commissioner), with authority to redelegate (except when specifically prohibited), all authority as follows:
1. Functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act (FFD&C) (21 U.S.C. 301 *et seq.*), as amended, the Filled Milk Act (21 U.S.C. 61-63), the Federal Import Milk Act (21 U.S.C. 141 *et seq.*), the Federal Caustic Poison Act (44 Statute 1406; also Public Law 86-613, §19, formerly §18) and The Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*), under §12 of Reorganization Plan No. IV and Reorganization Plan No. 1 of 1953, including authority to administer oaths vested in the Secretary of Agriculture by 7 U.S.C. 2217.
 2. Functions vested in the Secretary under §301 (Research and Investigations); §307 (International Cooperation); and §311 (Federal-State Cooperation) of the Public Health Service (PHS) Act (42 U.S.C. 241, 242l, 243), as amended, which relate to the functions of the Food and Drug Administration (FDA).
 3. Functions vested in the Secretary under §361 of the PHS Act (42 U.S.C. 264), as amended, which relate to the law enforcement functions of FDA concerning the following products and activities: Biological (including blood and blood products); interstate travel sanitation (except interstate transportation of etiologic agents under 42 CFR Part 72); food (including milk and food service sanitation and shellfish sanitation); and drugs, devices, cosmetics, electronic products, tobacco products and other items or products regulated by FDA.

4. Functions vested in the Secretary under §351 and 352 of Part F, Subpart 1 of the PHS Act (42 U.S.C. 262 and 263), as amended (Biological Products), insofar as they relate to the functions assigned to FDA.
5. Functions vested in the Secretary under §302(a) of the PHS Act (42 U.S.C. 242(a)), as amended, which relate to the determination and reporting requirements with respect to the medicinal and scientific requirements of the United States for controlled substances.
6. Functions vested in the Secretary under §303 of the PHS Act (42 U.S.C. 242a), as amended, which relate to the authorization of persons engaged in research on the use and effect of drugs to protect the identity of their research subjects with respect to drugs scheduled under Public Law 91-513 for which an investigational new drug application is filed with FDA and with respect to all drugs not scheduled under Public Law 91-513.
7. Functions vested in the Secretary pertaining to §4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91-513, 84 Statute 1241) which relate to the determination of the safety and effectiveness of drugs or to approve new drugs to be used in the treatment of narcotic addicts.
8. Functions vested in the Secretary pertaining to §303(f) of the Controlled Substances Act (21 U.S.C. 823(f)), which relate to the merits of the research protocol and to the determination of the qualifications and competency of practitioners wishing to conduct research with controlled substances listed in Schedule I of the Act.
9. Functions vested in the Secretary pertaining to provisions of the Controlled Substances Act (21 U.S.C. 801 *et seq.*), which relate to administration of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*).
10. Functions vested in the Secretary under §409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)), which relate to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.
11. Functions vested in the Secretary under §24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f(b)), which relate to the detention of any poultry carcass, part thereof, or poultry product.
12. Functions vested in the Secretary under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

13. Functions vested in the Secretary by amendments to the foregoing statutes subsequent to Reorganization Plan No. 1 of 1953.
14. Function of issuing all regulations of FDA, except as provided in this SMG, paragraph 2, Reservation of Authority. The reservation of authority contained in Chapter 2-000 of the Department Organization Manual shall not apply.
15. Functions vested in the Secretary under §1103 of Executive Order 11490, as amended by Executive Order 11921, which relate to emergency health functions as they pertain to the operations and functional responsibilities assigned to the agency. This authority shall be exercised in accordance with §102 and pertinent sections of Part 30 of Executive Order 11490 and guidelines issued by the Federal Preparedness Agency of the General Services Administration and the Office of the Secretary.
16. Function vested in the Secretary of authorizing and approving miscellaneous and emergency expenses of enforcement activities.
17. Functions vested in the Secretary under the Federal Advisory Committee Act, Public Law 92-463, to:
 - a. Renew recharter, amend and terminate established Federal Advisory Committees;
 - b. Authority to approve waivers to appoint committee members to established Federal Advisory Committees;
 - c. Authority to close review meetings following approval by the Office of the General Counsel based on a determination that the Advisory Committee meeting or a portion thereof may be closed to the public under the provisions of 5 U.S.C. 552b(c) and §10(d) of the Federal Advisory Committee Act.

These authorities are to be exercised in accordance with the requirements of 5 U.S.C. 552b; Public Law 92-463 (Federal Advisory Committee Act); Departmental regulations (45 CFR part 11, superseded by 41 CFR part 101-6); and any other applicable statutes and regulations.

18. Functions vested in the Secretary under the second sentence of §310(a) and under §310(b) (Health Conferences and Health Education Information) of the PHS Act (42 U.S.C. 242o), as amended, to call for a conference and invite as many health authorities and officials of State

or local public or private agencies or organizations as deemed necessary or proper on subjects related to the functions of FDA, and to issue information related to health for the use of the public and other pertinent health information for the use of persons and institutions concerned with health services when such information is related to the functions of the Food and Drug Administration.

19. Functions vested in the Secretary under §2701 of the PHS Act (42 U.S.C. 238), as amended, to accept offers of gifts, excluding the acceptance of gifts of real property. (Only the authority to accept unconditional gifts of personal property valued at \$5,000 or less may be redelegated).
20. Functions vested in the Secretary under §362 of the PHS Act (42 U.S.C. 265), as amended, which relate to the prohibition of the introduction of foods, drugs, devices, cosmetics, electronic products, and other items or products regulated by FDA into the United States when it is determined that it is required in the interest of public health when such functions relate to the law enforcement functions of FDA.
21. Functions vested in the Secretary under §401(a) of the Lead-Based Paint Poisoning Prevention Act, as amended by Public Law 94-317 (42 U.S.C. 4831(a)), relating to the prohibition of the application of lead-based paint to cooking, drinking, or eating utensils.
22. Functions vested in the Secretary for the health information and health promotion program under Title XVII of the PHS Act (42 U.S.C. 300u *et seq.*), as amended, insofar as the authorities pertain to functions assigned to FDA. The delegation includes, but is not limited to, the authorities under: §1702(a)(1) and (3) and §1704(1) and (2) (42 U.S.C. 300u-1(a) and (3) and 300u-3(1) and (2)). The delegation excludes the authority to select all Senior Executive Service, supergrade and equivalent, and Schedule C (GS-12 and above) positions; issue regulations; and submit reports to the President.
23. To administer a Small Business Innovation Research Program under §9 of the Small Business Act (15 U.S.C. 638), as amended. The delegation excludes the authority to issue regulations, establish advisory councils and committees, appoint members to advisory councils and committees, and submit reports to Congress.
24. Functions vested in the Secretary under §982 and 983 of the Consumer-Patient Radiation Health and Safety Act of 1981 (the Act) (42 U.S.C. 10007 and 10008), as amended. The delegation excludes the authority to issue regulations and submit reports to Congress. The

authority delegated under §983 of the Act may only be exercised as it relates to functions assigned to the Food and Drug Administration.

25. Functions vested in the Secretary under §156 of Title 35 of the U.S. Code (35 U.S.C. 156), as amended, which allows for the extension of patent terms for human drug products, medical devices, food additives, and color additives subject to the FFD&C. These authorities may be redelegated, except the authority to make due diligence determinations under §156(d)(2)(B), which may not be redelegated to an Office below the Office of the Commissioner of Food and Drugs.
26. Functions vested in the Secretary under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 *et seq.*) (the Act), as amended, and under Executive Order 12591 of April 10, 1987, as they pertain to the functions of FDA. The delegation excludes the authority to issue regulations and submit reports to Congress; under §11(a)(2) of the Act (15 U.S.C. 3710a(a)(2)) to approve agreements and contracts with invention management organizations; and under §11(c)(3)(B) of the Act (15 U.S.C. 3710a(c)(3)(B)) to propose necessary statutory changes regarding conflict of interest.
 - a. The authorities under §11(c)(5) (A) and (B) of the Act (15 U.S.C. 3710a (c)(5) (A) and (B)) to disapprove or require the modification of cooperative research and development agreements and licensing agreements after the agreement is presented to the Commissioner by the head of the laboratory concerned, and to transmit written explanation of such disapproval or modification to the head of the laboratory concerned, may be redelegated only to a senior official in the immediate Office of the Commissioner.
 - b. The following authorities may not be redelegated:
 - i. The authority under §11(b)(3)(D) of the Act (15 U.S.C. 3710a(b)(3)(D)) to waive a right of ownership which the Federal Government may have to an invention made under a cooperative research and development agreement;
 - ii. The authority under §11(b)(3)(C) of the Act (15 U.S.C. 3710a(b)(3)(C)) to permit employees or former employees to participate in efforts to commercialize inventions they made while in the service of the United States;
 - iii. The authority under §11(c)(3)(A) of the Act (15 U.S.C. 3710a(c)(3)(A)) to review employee standards of conduct for resolving potential conflicts of interest;

- iv. The authority under §13(a)(1) of the Act (15 U.S.C. 3710c(a)(1)) to retain any royalties or other income, except as provided in §13(a)(2) of the Act (15 U.S.C. 3710c(a)(2)); and
 - v. The authority under §13(a)(1)(A)(i) of the Act (15 U.S.C. 3710c(a)(1) (A)(i)) to pay royalties or other income the Agency receives on account of an invention to the inventor if the inventor was an employee of the Agency at the time the invention was made.
27. Functions vested in the Secretary under §4702, 4703, and 4704 of the Pesticide Monitoring Improvements Act of 1988 (21 U.S.C. 1401-1403) that relate to pesticide monitoring and enforcement information, foreign pesticide information, and pesticide analytical methods. The delegation excludes the authority to submit reports to Congress.
28. Functions vested in the Secretary under §2312(a)(1) and (2)(B), (b), and (c) (Use of Investigational New Drugs with Respect to Acquired Immunodeficiency Syndrome); 2314(c) (Scientific and Ethical Guidelines for Certain Treatments); and 2317(d) and (e) (Information Services) of Title XXIII of the PHS Act (42 U.S.C. 300cc-12(a)(1) and (2)(B), (b) and (c), 300cc-14(c) and 300cc-17 (d) and (e)), as amended, insofar as these authorities pertain to the functions assigned to FDA. The delegation excludes the authority to issue regulations, submit reports to the Congress, establish advisory committees or national commissions, and appoint members to such committees or commissions.
29. Functions vested in the Secretary under §2672(a)(1) (A) and (B) (Provisions Relating to Blood Banks) and §2672(a)(2) (Information and Training Programs) of the PHS Act (42 U.S.C. 300ff-72(a)(1)(A) and (B) and (a)(2) et seq.), as amended, insofar as these authorities pertain to the functions assigned to FDA. The delegations exclude the authority to issue regulations, submit reports to the Congress, establish advisory committees or national commissioners, and appoint members to such committees or commissions.
30. Functions vested in the Secretary under §1322(b) and (c) of the Food, Agriculture, Conservation, and Trade Act of 1990 (the National Laboratory Accreditation Program) (7 U.S.C. 138a), as amended hereafter, which relate to setting standards for the National Laboratory Accreditation Program and approving State agencies or private, nonprofit entities as accrediting bodies to implement certification and quality assurance programs in accordance with the requirements of this section. The delegation excludes the authority to submit reports to Congress.

31. Functions vested in the Secretary under Part C, Subtitle 2 of Title XXI of the PHS Act (42 U.S.C. 300aa-25 *et seq.*), as amended, and the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa-1 note), as amended hereafter, as follows:
- a. §2125 of the PHS Act (42 U.S.C. 300aa-25)--Recording and reporting of information;
 - b. §2127 of the PHS Act (42 U.S.C. 300aa-27)---Mandate for safer childhood vaccines;
 - c. §2128 of the PHS Act (42 U.S.C. 300aa-28)--Manufacturer recordkeeping and reporting;
 - d. §312 of the National Childhood Vaccine Injury Act of 1986--Related studies (42 U.S.C. 300aa-1 note);
 - e. §313 of the National Childhood Vaccine Injury Act of 1986--Study of other vaccine risks (42 U.S.C. 300aa-1 note);
 - f. § Review of warnings, use instructions, and precautionary information (42 U.S.C. 300aa-1 note); and

The delegation excludes the authority to issue regulations and submit reports to Congress.

32. Functions vested in the Secretary under §201(h)(4) of the Controlled Substances Act (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended) (21 U.S.C. 811(h)(4)) to provide responses to the Drug Enforcement Administration's temporary scheduling notices. The delegation excludes the authority to submit reports to Congress.
33. Functions vested in the Secretary under the Safe Medical Devices Act of 1990 (Pub. L. 101-629), as amended hereafter (e.g., 21 U.S.C. 360c note, 360i note, and 360j note). The delegation excludes the authority to submit reports to Congress.
34. Functions vested in the Secretary under §601 of Public Law 104-180 (Effective Medication Guides of the Agriculture, Rural Development, FDA, and Related Agencies Appropriations Act of 1997), as amended hereafter. The delegation excludes the authority to issue reports to Congress.

35. Authority to take final action on matters pertaining to §203 of the Equal Access to Justice Act (5 U.S.C. 504), and to develop procedures and regulations where necessary to supplement the Department's regulations, 45 CFR Part 13.
36. Authority to administer and make decisions regarding the invention and patent program as they pertain to the functions of FDA and to make determinations of rights in inventions and patents in which the Department has an interest. This delegation excludes the authority to submit reports to Congress and further, it excludes those authorities under the Stevenson-Wydler Technology Innovation Act of 1980, as amended by the Federal Technology Transfer Act of 1986 and the National Technology Transfer and Advancement Act of 1995, which are governed by a separate delegation (under this SMG A.26.). All authorities other than the authority under 35 U.S.C. §203 (March-In Rights) may be redelegated.
37. Functions vested in the Secretary under Title III, §354, of the PHS Act (42 U.S.C. 262 *et seq.*), as amended. The authority pertains to FDA's oversight of mammography facilities.
38. Authority under 45 CFR 5b.8 regulations, to take final action upon an individual's appeal of a refusal to correct or amend the individual's record when the appeal has been made by the individual under Privacy Act regulations (Part 21 of this chapter and 45 CFR Part 5b). The authority may not be redelegated.
39. Authority under Public Law 107-108 (Best Pharmaceuticals for Children Act), as amended by §3(b)(2) of Public Law 108-155 (Pediatric Research Equity Act of 2003), to charter, convene, consult, and appoint members to an advisory committee on pediatric therapeutics.
40. Functions vested in the Secretary under §353 of the Public Health Service Act (42 U.S.C. 263a), as amended, to implement Clinical Laboratory Improvements Amendments' (CLIA's) complexity categorization provisions as they apply to commercially available tests to the Commissioner of Food and Drugs. This authority includes, but is not limited to the following:
 - a. Interpreting the CLIA provisions related to complexity categorization;
 - b. Holding public workshops and meetings on CLIA complexity categorization; and;

- c. Developing and issuing implementing rules and guidance for CLIA complexity categorization.

The Administrator of the Centers for Medicare and Medicaid Services (CMS) will provide funding to implement CLIA's complexity categorization provisions as set forth in the Agency Agreement between FDA and CMS (CMS IA-04-01, FDA 224-04-6052), as amended. Except as provided above, the existing delegation of authority to the Administrator of CMS concerning CLIA is unaffected. This delegation shall be exercised under the Department's existing delegation and policy on regulations.

- 41. Functions vested in the Secretary under Title III, §317R of the Public Health Service Act (42 U.S.C. 247b-20), titled "Food Safety Grants," as amended, which is to award grants to States and Indian tribes (as defined in §4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))), to expand participation in networks to enhance Federal, State, and local food safety efforts, including meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation. This delegation shall be exercised under the Department's existing delegation and policy on regulations. Limitation: This authority must be implemented with prior consultation of the Office of Public Health Emergency Preparedness, Office of the Secretary.
- 42. Functions vested in the Secretary under §402(j)(5)(c)(ii) of the Public Health Service Act, 42 U.S.C. 282(j)(5)(C)(ii) to determine that any clinical trial information was not submitted as required under 42 U.S.C. 282(j) or was submitted but is false or misleading in any particular and to notify the responsible party and give such party an opportunity to remedy non-compliance by submitting required revised clinical trial information not later than 30 days after such notification.
- 43. Authorities under Public Law 111-31; 123 Statute 1776.
- 44. Authorities under §105 of the Drug Quality and Security Act of 2013, Public Law 113-54.
- 45. Authorities under §1002, 1003, 1004, 1005(f), 1006(b) and 1006(d) of the Food and Drug Administration Amendments Act (FDAAA) of 2007, Public Law 110-85.
- 46. Authorities under §102(b)(2), (c); 103(b), (c), (d), (h); 104; 105(b); 106(b), (c); 113(b); 114(d); 115; 201(c); 202(b); 204; 205(b)(2), (c); 206(b); 207(b); 304(b); 305; 306(b); 308; and 309 of the FDA Food Safety Modernization Act of 2011 (FSMA), Public Law 111-353.

- B. The Deputy Assistant Secretary for Health Management Operations, Public Health Service, has redelegated to the Commissioner of Food and Drugs, with authority to redelegate (except when specifically prohibited), all authority as follows:
1. To certify true copies of any books, records, or other documents on file within FDA, or extracts from such.
 2. To certify that true copies are true copies of the entire file of the Administration
 3. To certify the complete original record or to certify the nonexistence of records on file within the Administration.
 4. To cause the Seal of the Department to be affixed to such certifications and to agreements, awards, citations, diplomas, and similar documents.
- C. The Chief Counsel of FDA is authorized to report apparent violations to the Department of Justice for the institution of criminal proceedings, under §305 of the FFD&C Act (21 U.S.C. 335), §4 of the Federal Import Milk Act (21 U.S.C. 144), and §9(b) of the Federal Caustic Poison Act.

2. RESERVATION OF AUTHORITY.

- A. Notwithstanding provisions of this SMG, paragraph 1 or any previous delegations of authority to the contrary, the Secretary reserves the authority to approve regulations of FDA, except regulations to which §556 and 557 of Title 5 U.S.C. apply, which:
1. Establish procedural rules applicable to a general class of foods, drugs, cosmetics, medical devices, tobacco products, 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.
- B. Nothing in this section precludes the Secretary from approving a regulation, or being notified in advance of an action, to which §556 and 557 of Title 5 U.S.C. apply, which meets one of the criteria in paragraph A. of this Reservation of Authority.
- C. This reservation of authority is intended only to improve the internal management of the Department of Health and Human Services, and it is

not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, the Department of Health and Human Services, the FDA, any Agency, officer, or employee of the United States, or any person. Regulations issued by FDA without the approval of the Secretary are to be conclusively viewed as falling outside the scope of this reservation of authority.

3. REDELEGATION

These authorities may be redelegated except where specifically prohibited.

4. EFFECTIVE DATE.

The delegations become effective upon date of signature. The Secretary, DHHS, approved these delegations of authority, via memorandum, on August 26, 2016.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	09/05/2012	N/a	OO/OBS	Kathleen Sebelius, Secretary of the Department of Health and Human Services
Revision	04/11/2014	N/a	OO/OHR/MASS	Kathleen Sebelius, Secretary of the Department of Health and Human Services
Revision	11/17/2015	N/a	OO/OHR/MASS	Sylvia M. Burwell, Secretary of the Department of Health and Human Services
Revision	08/26/2016	N/a	OO/OHR/MASS	Sylvia M. Burwell, Secretary of the Department of Health and Human Services

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