



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2023-N-0963]

Nomenclature Change for Dockets Management; Technical Amendment

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to reflect a change in the name of Division of Dockets Management to Dockets Management Staff and information regarding copies. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Karen Malvin, Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

SUPPLEMENTARY INFORMATION: FDA is amending 21 CFR chapter I to update Dockets Management Staff's name change and information regarding copies.

Publication of this document constitutes final action on the changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only a technical change to update the organizational information for Dockets Management Staff.

List of Subjects

21 CFR Part 3

Administrative practice and procedure, Biologics, Drugs, Medical devices.

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 7

Administrative practice and procedure, Consumer protection, Reporting and recordkeeping requirements.

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Parts 12, 13, and 15

Administrative practice and procedure.

21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

21 CFR Part 17

Administrative practice and procedure, Penalties.

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

21 CFR Part 60

Administrative practice and procedure, Drugs, Food additives, Inventions and patents, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 100

Administrative practice and procedure, Food labeling, Food packaging, Foods, Intergovernmental relations.

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 109

Food packaging, Foods, Polychlorinated biphenyls (PCBs).

21 CFR Part 165

Beverages, Bottled water, Food grades and standards.

21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

21 CFR Part 184

Food additives.

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 328

Alcohol and alcoholic beverages, Labeling, Over-the-counter drugs.

21 CFR Part 330

Over-the-counter drugs.

21 CFR Parts 341, 350, and 355

Labeling, Over-the-counter drugs.

21 CFR Part 369

Labeling, Medical devices, Over-the-counter drugs.

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Packaging and containers,
Polychlorinated biphenyls (PCBs).

21 CFR Part 509

Animal foods, Packaging and containers, Polychlorinated biphenyls (PCBs).

21 CFR Parts 514 and 516

Administrative practice and procedure, Animal drugs, Confidential business information;
Reporting and recordkeeping requirements.

21 CFR Part 570

Animal feeds, Animal foods, Food additives.

21 CFR Part 573

Animal feeds, Food additives.

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

21 CFR Part 740

Cosmetics, Labeling.

21 CFR Part 808

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 830

Administrative practice and procedure, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 860

Administrative practice and procedure, Medical devices.

21 CFR Part 861

Administrative practice and procedure, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 895

Administrative practice and procedure, Labeling, Medical devices.

21 CFR Part 900

Electronic products, Health facilities, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

21 CFR Part 1010

Administrative practice and procedure, Electronic products, Exports, Radiation protection.

21 CFR Part 1240

Communicable diseases, Public health, Travel restrictions, Water supplies.

21 CFR Part 1250

Air carriers, Foods, Maritime carriers, Motor carriers, Public health, Railroads, Water supplies.

21 CFR Part 1271

Biologics, Communicable diseases, Drugs, HIV/AIDS, Human cells and tissue-based products, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

PART 3--PRODUCT JURISDICTION

1. The authority citation for part 3 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 353, 355, 360, 360c–360f, 360h–360j, 360gg–360ss, 360bbb–2, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262, 264.

§ 3.5 [Amended]

2. In § 3.5, amend paragraph (a)(1) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 5--ORGANIZATION

3. The authority citation for part 5 continues to read as follows:

Authority: 5 U.S.C. 552; 21 U.S.C. 301-397.

§ 5.1110 [Amended]

4. In § 5.1110, amend paragraph (a) by removing “Division of Dockets Management” wherever it appears and adding in its place “Dockets Management Staff”.

PART 7--ENFORCEMENT POLICY

5. The authority citation for part 7 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 241, 262, 263b–263n, 264.

§ 7.42 [Amended]

6. In § 7.42, amend paragraph (b)(3) introductory text by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 10--ADMINISTRATIVE PRACTICES AND PROCEDURE

7. The authority citation for part 10 continues to read as follows:

Authority: 5 U.S.C. 551-558, 701-706; 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

8. In part 10, revise all references to “Division of Dockets Management” to read “Dockets Management Staff”.

9. In §10.30, revise paragraph (b)(2) to read as follows:

§ 10.30 Citizen petition.

* * * * *

(b) * * *

(2) *Mail, delivery services, or other non-electronic submissions.* A petition (including any attachments), that is not electronically submitted under paragraph (b)(1) of this section, must be submitted in accordance with paragraph (b)(3) of this section and § 10.20 and delivered to this address: Dockets Management Staff, Department of Health and Human Services, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit two copies (original and redacted version) for confidential petitions. Otherwise, only one copy is necessary.

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PART 12--FORMAL EVIDENTIARY PUBLIC HEARING

10. The authority citation for part 12 continues to read as follows:

Authority: 21 U.S.C. 141-149, 321-393, 467f, 679, 821, 1034; 42 U.S.C. 201, 262, 263b-263n, 264; 15 U.S.C. 1451-1461; 5 U.S.C. 551-558, 701-721; 28 U.S.C. 2112.

11. In part 12, revise all references to “Division of Dockets Management” to read “Dockets Management Staff”.

12. In § 12.80, revise paragraph (a) to read as follows:

§ 12.80 Filing and service of submissions.

(a) Submissions, including pleadings in a hearing, are to be filed with Dockets Management Staff under § 10.20 of this chapter except that two copies need be submitted (original and redacted version) for confidential petitions. Otherwise, only one copy is necessary. To

determine compliance with filing deadlines in a hearing, a submission is considered submitted on the date it is actually received by Dockets Management Staff. When this part allows a response to a submission and prescribes a period of time for the filing of the response, an additional 3 days are allowed for the filing of the response if the submission is served by mail.

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PART 13--PUBLIC HEARING BEFORE A PUBLIC BOARD OF INQUIRY

13. The authority citation for part 13 continues to read as follows:

Authority: 5 U.S.C. 551-558, 701-721; 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-393, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b-263n, 264.

14. In part 13, revise all references to “Division of Dockets Management” to read “Dockets Management Staff”.

PART 14--PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

15. The authority citation for part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451-1461, 21 U.S.C. 41-50, 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107-109; Pub. L. 108-155; Pub. L. 113-54.

16. In part 14, revise all references to “Division of Dockets Management” to read “Dockets Management Staff”.

PART 15--PUBLIC HEARING BEFORE THE COMMISSIONER

17. The authority citation for part 15 continues to read as follows:

Authority: 5 U.S.C. 553; 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-393, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b-263n, 264.

18. In part 15, revise all references to “Division of Dockets Management” to read “Dockets Management Staff”.

PART 17--CIVIL MONEY PENALTIES HEARINGS

19. The authority citation for part 17 is revised to read as follows:

Authority: 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201-262, 263b, 364.

20. In part 17, revise all references to “Division of Dockets Management” to read “Dockets Management Staff”.

21. In § 17.31, revise paragraph (a)(1) to read as follows:

§ 17.31 Form, filing, and service of papers.

(a) * * *

(1) Documents filed with Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, shall include two copies (original and redacted version) for confidential petitions. Otherwise, only one copy is necessary.

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PART 20--PUBLIC INFORMATION

22. The authority citation for part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531-2582; 21 U.S.C. 321-393, 1401-1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b-263n, 264, 265, 300u-300u-5, 300aa-1.

§ 20.120 [Amended]

23. In § 20.120, amend paragraphs (c) introductory text and (c)(3) by removing “Division of Dockets Management’s” and adding in its place “Dockets Management Staff’s”.

PART 25--ENVIRONMENTAL IMPACT CONSIDERATIONS

24. The authority citation for part 25 continues to read as follows:

Authority: 21 U.S.C. 321-393; 42 U.S.C. 262, 263b-264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500-1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531-533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123-124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356-360.

25. In part 25, revise all references to “Division of Dockets Management” to read “Dockets Management Staff”.

PART 60--PATENT TERM RESTORATION

26. The authority citation for part 60 continues to read as follows:

Authority: 21 U.S.C. 348, 355, 360e, 360j, 371, 379e; 35 U.S.C. 156; 42 U.S.C. 262.

27. In part 60, revise all references to “Division of Dockets Management” to read “Dockets Management Staff”.

PART 100--GENERAL

28. The authority citation for part 100 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 337, 342, 343, 348, 371.

§ 100.1 [Amended]

29. In § 100.1, amend paragraphs (d)(3) and (f)(3) and (4) by removing “Division of Dockets Management” wherever it appears and adding in its place “Dockets Management Staff”.

PART 109--UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN CONSUMPTION AND FOOD-PACKAGING MATERIAL

30. The authority citation for part 109 continues to read as follows:

Authority: 21 U.S.C. 321, 336, 342, 346, 346a, 348, 371.

31. In part 109, revise all references to “Division of Dockets Management” to read “Dockets Management Staff”.

PART 165--BEVERAGES

32. The authority citation for part 165 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 343–1, 348, 349, 371, 379e.

§ 165.110 [Amended]

33. In § 165.110, amend paragraph (b)(4)(iii)(F) introductory text by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 201--LABELING

34. The authority citation for part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 343, 351, 352, 353, 355, 358, 360, 360b, 360ccc, 360ccc–1, 360ee, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

§ 201.63 [Amended]

35. In § 201.63, amend paragraph (d) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 312--INVESTIGATIONAL NEW DRUG APPLICATION

36. The authority citation for part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371; 42 U.S.C. 262.

37. In part 312, revise all references to “Division of Dockets Management” to read “Dockets Management Staff”.

PART 314--APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

38. The authority citation for part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 355f, 356, 356a, 356b, 356c, 356e, 360cc, 371, 374, 379e, 379k-1.

39. In part 314, revise all references to “Division of Dockets Management” to read “Dockets Management Staff”.

PART 328--OVER-THE-COUNTER DRUG PRODUCTS INTENDED FOR ORAL INGESTION THAT CONTAIN ALCOHOL

40. The authority citation for part 328 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371.

§ 328.10 [Amended]

41. In § 328.10, amend paragraph (e) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 330--OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY
RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

42. The authority citation for part 330 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360fff-6, 371.

43. In part 330, revise all references to “Division of Dockets Management” to read
“Dockets Management Staff”.

PART 341--COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTI-ASTHMATIC
DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

44. The authority citation for part 341 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

§ 341.85 [Amended]

45. In § 341.85, amend paragraph (c)(4) by removing “Division of Dockets
Management” and adding in its place “Dockets Management Staff”.

PART 350--ANTIPERSPIRANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN
USE

46. The authority citation for part 350 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

§ 350.60 [Amended]

47. In § 350.60, remove “Dockets Management Branch” and add in its place “Dockets
Management Staff”.

PART 355--ANTICARIES DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

48. The authority citation for part 355 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

§ 355.70 [Amended]

49. In § 355.70, amend paragraph (a) by removing “Division of Dockets Management”
and adding in its place “Dockets Management Staff”.

PART 369--INTERPRETIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES
FOR OVER-THE-COUNTER SALE

50. The authority citation for part 369 is revised to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

§ 369.21 [Amended]

51. In § 369.21, remove “Division of Dockets Management” and add in its place “Dockets Management Staff”.

PART 500--GENERAL

52. The authority citation for part 500 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 379e.

§ 500.80 [Amended]

53. In § 500.80, amend paragraph (a) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 509--UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD-
PACKAGING MATERIAL

54. The authority citation for part 509 continues to read as follows:

Authority: 21 U.S.C. 336, 342, 346, 346a, 348, 371.

55. In part 509, revise all references to “Division of Dockets Management” to read “Dockets Management Staff”.

PART 514--NEW ANIMAL DRUG APPLICATIONS

56. The authority citation for part 514 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 354, 356a, 360b, 360ccc, 371, 379e, 381.

§ 514.200 [Amended]

57. In § 514.200, amend paragraph (c)(1) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 516--NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

58. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

§ 516.28 [Amended]

59. In § 516.28, amend the introductory text by removing “Division of Dockets Management” and adding “Dockets Management Staff” in its place.

PART 570--FOOD ADDITIVES

60. The authority citation for part 570 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

61. In part 570, revise all references to “Division of Dockets Management” to read “Dockets Management Staff”.

§ 570.35 [Amended]

62. In § 570.35, amend paragraph (b)(2) by removing “Division of Dockets Management’s” and adding in its place “Dockets Management Staff’s”.

PART 573--FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

63. The authority citation for part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

§ 573.460 [Amended]

64. In § 573.460, amend paragraphs (a)(1)(i) and (a)(2)(i) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 601--LICENSING

65. The authority citation for part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

§ 601.51 [Amended]

66. In § 601.51, amend paragraph (d)(2) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 740--COSMETIC PRODUCT WARNING STATEMENTS

67. The authority citation for part 740 is revised to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec. 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

§ 740.2 [Amended]

68. In § 740.2, amend paragraph (b) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 808--EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

69. The authority citation for part 808 continues to read as follows:

Authority: 21 U.S.C. 360j, 360k, 371.

Section 808.1 also issued under Sec. 709, Public Law 115–52, 131 Stat. 1065–67.

70. In part 808, revise all references to “Division of Dockets Management” to read “Dockets Management Staff”.

PART 814--PREMARKET APPROVAL OF MEDICAL DEVICES

71. The authority citation for part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 360bbb–8b, 371, 372, 373, 374, 375, 379, 379e, 379k–1, 381.

§ 814.9 [Amended]

72. In § 814.9, amend paragraph (d)(2) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 830--UNIQUE DEVICE IDENTIFICATION

73. The authority citation for part 830 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 352, 353, 360, 360d, 360i, 360j, 371.

§ 830.10 [Amended]

74. In § 830.10, amend paragraph (a) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 860--MEDICAL DEVICE CLASSIFICATION PROCEDURES

75. The authority citation for part 860 continues to read as follows:

Authority: 21 U.S.C. 321(h), 353(g), 360c, 360d, 360e, 360i, 360j, 371, 374.

§ 860.5 [Amended]

76. In § 860.5, amend paragraphs (c)(2) and (d)(2) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 861--PROCEDURES FOR PERFORMANCE STANDARDS DEVELOPMENT

77. The authority citation for part 861 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360c, 360d, 360gg–360ss, 371, 374; 42 U.S.C. 262, 264.

§ 861.38 [Amended]

78. In § 861.38, amend paragraph (c) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 895--BANNED DEVICES

79. The authority citation for part 895 continues to read as follows:

Authority: 21 U.S.C. 352, 360f, 360h, 360i, 371.

§ 895.21 [Amended]

80. In § 895.21, amend paragraph (d)(8) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 900--MAMMOGRAPHY

81. The authority citation for part 900 continues to read as follows:

Authority: 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

§ 900.18 [Amended]

82. In § 900.18, amend paragraphs (d)(2) and (4) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 1010--PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

83. The authority citation for part 1010 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e-360j, 360hh-360ss, 371, 381.

§ 1010.4 [Amended]

84. In § 1010.4, amend paragraph (c)(3) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

85. In § 1010.5, revise paragraph (c) introductory text to read as follows:

§ 1010.5 Exemptions for products intended for United States Government use.

* * * * *

(c) *Application for exemption.* If you are submitting an application for exemption, or for amendment or extension thereof, you must submit two copies (original and redacted version) for confidential petitions to Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Otherwise, only one copy is necessary. For an exemption under the criteria prescribed in paragraph (a)(1) of this section, the application shall include the information prescribed in paragraphs (c)(1) through (13) of this section. For an exemption under the criteria prescribed in paragraph (a)(2) of this section, the application shall include the information prescribed in paragraphs (c)(3) through (13) of this section. An application for exemption, or for amendment or extension thereof, and correspondence relating to such application shall be made available for public disclosure in Dockets Management Staff, except for confidential or proprietary information submitted in accordance with part 20 of this chapter. Information classified for reasons of national security shall not be included in the application. Except as indicated in this paragraph (c), the application for exemption shall include the following:

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PART 1240--CONTROL OF COMMUNICABLE DISEASES

86. The authority citation for part 1240 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 264, 271.

§ 1240.62 [Amended]

87. In § 1240.62, amend paragraph (d) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 1250--INTERSTATE CONVEYANCE SANITATION

88. The authority citation for part 1250 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 264, 271.

§ 1250.51 [Amended]

89. In § 1250.51, amend paragraph (f)(4)(ii) by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

PART 1271--HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

90. The authority citation for part 1271 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 263a, 264, 271.

§ 1271.37 [Amended]

91. In § 1271.37, amend paragraph (a) introductory text by removing “Division of Dockets Management” and adding in its place “Dockets Management Staff”.

Dated: July 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.