

Bend, OR, KBDN, VOR RWY 16, Amdt 11
 Florence, SC, KFLO, ILS OR LOC RWY 9, Amdt 13
 Florence, SC, KFLO, RNAV (GPS) RWY 1, Amdt 1
 Florence, SC, KFLO, RNAV (GPS) RWY 9, Amdt 1
 Florence, SC, KFLO, RNAV (GPS) RWY 19, Amdt 1
 Florence, SC, KFLO, RNAV (GPS) RWY 27, Amdt 1
 Sumter, SC, KSMS, ILS OR LOC RWY 23, Amdt 2
 Sumter, SC, KSMS, Takeoff Minimums and Obstacle DP, Amdt 1A
 Seattle, WA, KBFI, RNAV (GPS) Y RWY 14R, Orig
 Seattle, WA, KBFI, RNAV (GPS) Y RWY 14R, Amdt 1A, CANCELED
 Seattle, WA, KBFI, RNAV (GPS) Y RWY 32L, Orig
 Seattle, WA, KBFI, RNAV (RNP) Z RWY 14R, Orig
 Seattle, WA, KBFI, RNAV (RNP) Z RWY 14R, Amdt 1A, CANCELED
 Seattle, WA, KBFI, RNAV (RNP) Z RWY 32L, Orig

Rescinded: On June 21, 2023 (88 FR 40081), the FAA published an Amendment in Docket No. 31490, Amdt No. 4063, to part 97 of the Federal Aviation Regulations under §§ 97.23, 97.29, and 97.33. The following entries for Northway, AK, San Francisco, CA, and Cross Keys, NJ, effective August 10, 2023, are hereby rescinded in their entirety:

Northway, AK, PAOR, RNAV (GPS) RWY 6, Amdt 1
 Northway, AK, PAOR, RNAV (GPS) RWY 24, Amdt 2
 San Francisco, CA, KSFO, GLS RWY 19L, Amdt 1
 San Francisco, CA, KSFO, GLS RWY 19R, Amdt 1
 Cross Keys, NJ, 17N, VOR OR GPS RWY 9, Amdt 6B, CANCELED

[FR Doc. 2023-14932 Filed 7-13-23; 8:45 am]

BILLING CODE 4910-13-P

FEDERAL TRADE COMMISSION

16 CFR Parts 0, 1, 2, 3 and 4

Rules of Practice

In rule document 2023-12630 beginning on page 42872 in the issue of Wednesday, July 5, 2023, make the following corrections:

On page 42872, in the third column, under **DATES**, in the first and fourth lines “June 5, 2023” should read “July 5, 2023”.

[FR Doc. C1-2023-12630 Filed 7-13-23; 8:45 am]

BILLING CODE 0099-10-D

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 July 14, 2023.

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.

* * * * *

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”.

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, 360ff-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:

* * * * *

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.

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DEPARTMENT OF STATE

22 CFR Parts 41 and 42

[Public Notice: 12080]

RIN 1400–AF53

Visas: Nonimmigrant Visas; Immigrant Visas

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State (Department) amends its regulations governing nonimmigrant and immigrant visas to update classification symbols and descriptions for certain immigrant and nonimmigrant visas.

DATES: This final rule is effective on September 12, 2023.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. What changes to 22 CFR 41.12, 41.84, and 42.11 does this Final Rule make?

The Department is amending 22 CFR 41.12 to include classification symbols and related descriptions for the CW–1, CW–2, E–2C, and T–6 visa classifications. The Department is also amending 22 CFR 42.11 to include classification symbols and related descriptions for surviving spouses and children, as described in Section 403(a) of the Emergency Security Supplemental Appropriations Act, 2021 (“ESSAA”), Public Law 117–31, 135 Stat. 309, as well as classification symbols and related descriptions for EB–5 immigrant visas initiated by the EB–5 Reform and Integrity Act of 2022, Division BB of the Consolidated Appropriations Act, 2022, Public Law 117–103 (“EB–5 Reform and Integrity Act”). The changes in the classification descriptions under this Final Rule will have no impact on who may qualify for such a visa; as such, this Final Rule will not practically impact any current applicant for any visa. This rule also makes technical corrections to the classification symbols for visa classifications to ensure the accurate inclusion of all active immigrant visa classifications.

II Why is the Department promulgating this Final Rule?

A. T Visas, Victims of Trafficking in Persons

The Trafficking Victims Protection Reauthorization Act of 2008, Public Law 106–386 amended Section 101(a)(15)(T)(ii)(III) of the INA to include parents and unmarried siblings under the age of 18 whose eligibility for T derivative classification is not tied to the age of the principal applicant, but rather to their present danger of retaliation as a result of the principal’s escape from trafficking or cooperation with law enforcement, as determined by U.S. Citizenship and Immigration Services. These derivatives receive T–4 and T–5 visa classifications. Additionally, Section 1221 of the Violence Against Women Reauthorization Act of 2013, Public Law 113–4, amended Section 101(a)(15)(T)(ii)(III) of the INA by adding the T–6 derivative classification, which is available to an eligible adult or minor child of a T–1 principal applicant’s derivative family member, if such derivative’s adult or minor child themselves faces a present danger of retaliation as a result of the principal’s escape from trafficking or cooperation with law enforcement.

Classification symbols in existing regulations at 22 CFR 41.12 do not reflect the 2013 expansion of eligibility for the adult or minor child of a derivative beneficiary, and to address this, this rule amends 22 CFR 41.12 to add the T–6 classification symbol and description. This rule also adds details to existing descriptions of the T–4 and T–5 visa classification to better reflect the statutory criteria. The rule further amends 22 CFR 41.84 to reflect the current language more closely in INA section 101(a)(15)(T)(ii) which describes the family members who may qualify for T nonimmigrant status as certain accompanying or following-to-join derivative family members of a principal T–1 nonimmigrant. These classification codes are consistent with those used by the Department of Homeland Security.

B. CW Visas—Commonwealth of Northern Mariana Islands (CNMI) Transitional Workers

Section 6 of the Covenant to Establish a Commonwealth of the Northern Mariana Islands in Political Union with the United States of America, Public Law 94–241, as amended by Section 702(a) of the Consolidated Natural Resources Act of 2008, Public Law 110–229, provides for nonimmigrant visas for certain CNMI transitional workers,

investors, and their spouses and children. The Department classifies CNMI transitional workers as CW–1, spouses, or children of a CW–1 as a CW–2, and CNMI investors and their spouses or children as E–2C. This rule adds these nonimmigrant visa classifications to 22 CFR 41.12. These classification codes are consistent with those used by the Department of Homeland Security.

C. SS1 Classification—Surviving Spouses and Children of United States Government Employees Abroad

Section 403(a) of the ESSAA amended INA Section 101(a)(27)(D), 8 U.S.C. 1101(a)(27)(D), to change the definition of a special immigrant to include “the surviving spouse or child of an employee of the United States Government abroad: *Provided*, [t]hat the employee performed faithful service for a total of not less than 15 years or was killed in the line of duty.” The Department classifies each surviving spouse and child of an employee of the United States Government abroad as an SS1. While this Final Rule does not address the parameters under which a noncitizen may qualify for issuance of an SS1 immigrant visa, this rule adds these special immigrant visa classifications to 22 CFR 42.11.

D. EB–5 Program Changes

The EB–5 Reform and Integrity Act made substantial changes to Section 203(b)(5) of the INA, 8 U.S.C. 1153(b)(5). The EB–5 Reform and Integrity Act sets forth an allocation of visas to qualified immigrant investors who invest in new commercial enterprises and satisfy applicable job creation requirements. Certain percentages of these visas are reserved for investors in rural areas, investors in areas designated by the Department of Homeland Security (DHS) as high unemployment areas, and investors in infrastructure projects.

The EB–5 Reform and Integrity Act repealed the former Regional Center Program under section 610 of Public Law 102–395 and authorized a new Regional Center Program. As a result of the new legislation, the Visa Office is adding new EB–5 classification symbols. An investor in a non-regional center for an unreserved visa is classified as NU–1 and the spouse and children of an NU–1 applicant are classified as an NU–2 and NU–3, respectively. An investor in a regional center for an unreserved visa is classified as an RU–1 applicant, and the spouse and children of an RU–1 applicant are classified as an RU–2 and RU–3, respectively. An applicant for a reserved visa who is an investor in a