

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Parts 56, 58, 60, 101, 107, 179, 310, 312, 314, 510, 514, 606, 610, 640, 660, 680, 720, 814, 1020, and 1040

Change in the Removal of the Office of Management and Budget (OMB) Control Numbers; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to reflect a change in the removal of OMB control numbers. This action is editorial in nature and is intended to improve the accuracy of the agency's regulations.

EFFECTIVE DATE: *[Insert date of publication in the Federal Register.]*

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in 21 CFR parts 56, 58, 60, 101, 107, 179, 310, 312, 314, 510, 514, 606, 610, 640, 660, 680, 720, 814, 1020, and 1040 to reflect a change in the removal of the outdated OMB control numbers. We no longer need to publish OMB control numbers in the CFR, because they are now displayed in a separate **Federal Register** notice announcing OMB approval for the collection of information.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

List of Subjects

21 CFR Part 56

Human research subjects, Reporting and recordkeeping requirements, Safety.

21 CFR Part 58

Laboratories, 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 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 107

Food labeling, Infants and children, Nutrition, Reporting and recordkeeping requirements, Signs and symbols.

21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, 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 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 514

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

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 660

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 680

Biologics, Blood, Reporting and recordkeeping requirements.

21 CFR Part 720

Confidential business information, Cosmetics.

21 CFR Part 814

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

21 CFR Part 1020

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

21 CFR Part 1040

Electronic products, Labeling, Lasers, Medical devices, Radiation protection, 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 parts 56, 58, 60, 101, 107, 179, 310, 312, 314, 510, 514, 606, 610, 640, 660, 680, 720, 814, 1020, and 1040 are amended as follows:

PART 56—INSTITUTIONAL REVIEW BOARDS

1. The authority citation for 21 CFR part 56 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

§ 56.108 [Amended]

2. In § 56.108 *IRB functions and operations*, remove the parenthetical phrase at the end of the section.

§ 56.115 [Amended]

3. In § 56.115 *IRB records*, remove the parenthetical phrase at the end of the section.

PART 58—GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

4. The authority citation for 21 CFR part 58 continues to read as follows:

Authority: 21 U.S.C. 342, 346, 346a, 348, 351, 352, 353, 355, 360, 360b–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 262, 263b–263n.

§ 58.35 [Amended]

5. In § 58.35 *Quality assurance unit*, remove the parenthetical phrase at the end of the section.

§ 58.63 [Amended]

6. In § 58.63 *Maintenance and calibration of equipment*, remove the parenthetical phrase at the end of the section.

§ 58.90 [Amended]

7. In § 58.90 *Animal care*, remove the parenthetical phrase at the end of the section.

§ 58.105 [Amended]

8. In § 58.105 *Test and control article characterization*, remove the parenthetical phrase at the end of the section.

§ 58.120 [Amended]

9. In § 58.120 *Protocol*, remove the parenthetical phrase at the end of the section.

§ 58.130 [Amended]

10. In § 58.130 *Conduct of a nonclinical laboratory study*, remove the parenthetical phrase at the end of the section.

§ 58.190 [Amended]

11. In § 58.190 *Storage and retrieval of records and data*, remove the parenthetical phrase at the end of the section.

PART 60—PATENT TERM RESTORATION

12. The authority citation for 21 CFR 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.

§ 60.24 [Amended]

13. In § 60.24 *Revision of regulatory review period determinations*, remove the parenthetical phrase at the end of the section.

§ 60.30 [Amended]

14. In § 60.30 *Filing, format, and content of petitions*, remove the parenthetical phrase at the end of the section.

§ 60.40 [Amended]

15. In § 60.40 *Request for hearing*, remove the parenthetical phrase at the end of the section.

PART 101—FOOD LABELING

16. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

§ 101.69 [Amended]

17. In § 101.69 *Petitions for nutrient content claims*, remove the parenthetical phrase at the end of the section.

PART 107—INFANT FORMULA

18. The authority citation for 21 CFR part 107 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 350a, 371.

§ 107.10 [Amended]

19. In § 107.10 *Nutrient information*, remove the parenthetical phrase at the end of the section.

§ 107.20 [Amended]

20. In § 107.20 *Directions for use*, remove the parenthetical phrase at the end of the section.

§ 107.50 [Amended]

21. In § 107.50 *Terms and conditions*, remove the parenthetical phrase at the end of the section.

§ 107.280 [Amended]

22. In § 107.280 *Records retention*, remove the parenthetical phrase at the end of the section.

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

23. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

§ 179.25 [Amended]

24. In § 179.25 *General provisions for food irradiation*, remove the parenthetical phrase at the end of the section.

PART 310—NEW DRUGS

25. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

§ 310.305 [Amended]

26. In § 310.305 *Records and reports concerning adverse drug experiences on marketed prescription drugs for human use without approved new drug applications*, remove the parenthetical phrase at the end of the section.

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

27. The authority citation for 21 CFR part 312 continues to read as follows:

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

§ 312.7 [Amended]

28. In § 312.7 *Promotion and charging for investigational drugs*, remove the parenthetical phrase at the end of the section.

§ 312.10 [Amended]

29. In § 312.10 *Waivers*, remove the parenthetical phrase at the end of the section.

§ 312.23 [Amended]

30. In § 312.23 *IND content and format*, remove the parenthetical phrase at the end of the section.

§ 312.30 [Amended]

31. In § 312.30 *Protocol amendments*, remove the parenthetical phrase at the end of the section.

§ 312.31 [Amended]

32. In § 312.31 *Information amendments*, remove the parenthetical phrase at the end of the section.

§ 312.32 [Amended]

33. In § 312.32 *IND safety reports*, remove the parenthetical phrase at the end of the section.

§ 312.33 [Amended]

34. In § 312.33 *Annual reports*, remove the parenthetical phrase at the end of the section.

§ 312.35 [Amended]

35. In § 312.35 *Submissions for treatment use*, remove the parenthetical phrase at the end of the section.

§ 312.36 [Amended]

36. In § 312.36 *Emergency use of an investigational new drug*, remove the parenthetical phrase at the end of the section.

§ 312.38 [Amended]

37. In § 312.38 *Withdrawal of an IND*, remove the parenthetical phrase at the end of the section.

§ 312.41 [Amended]

38. In § 312.41 *Comment and advice on an IND*, remove the parenthetical phrase at the end of the section.

§ 312.44 [Amended]

39. In § 312.44 *Termination*, remove the parenthetical phrase at the end of the section.

§ 312.45 [Amended]

40. In § 312.45 *Inactive status*, remove the parenthetical phrase at the end of the section.

§ 312.47 [Amended]

41. In § 312.47 *Meetings*, remove the parenthetical phrase at the end of the section.

§ 312.53 [Amended]

42. In § 312.53 *Selecting investigators and monitors*, remove the parenthetical phrase at the end of the section.

§ 312.55 [Amended]

43. In § 312.55 *Informing investigators*, remove the parenthetical phrase at the end of the section.

§ 312.56 [Amended]

44. In § 312.56 *Review of ongoing investigations*, remove the parenthetical phrase at the end of the section.

§ 312.57 [Amended]

45. In § 312.57 *Recordkeeping and record retention*, remove the parenthetical phrase at the end of the section.

§ 312.59 [Amended]

46. In § 312.59 *Disposition of unused supply of investigational drug*, remove the parenthetical phrase at the end of the section.

§ 312.62 [Amended]

47. In § 312.62 *Investigator recordkeeping and record retention*, remove the parenthetical phrase at the end of the section.

§ 312.64 [Amended]

48. In § 312.64 *Investigator reports*, remove the parenthetical phrase at the end of the section.

§ 312.66 [Amended]

49. In § 312.66 *Assurance of IRB review*, remove the parenthetical phrase at the end of the section.

§ 312.70 [Amended]

50. In § 312.70 *Disqualification of a clinical investigator*, remove the parenthetical phrase at the end of the section.

§ 312.110 [Amended]

51. In § 312.110 *Import and export requirements*, remove the parenthetical phrase at the end of the section.

§ 312.120 [Amended]

52. In § 312.120 *Foreign clinical studies not conducted under an IND*, remove the parenthetical phrase at the end of the section.

§ 312.140 [Amended]

53. In § 312.140 *Address for correspondence*, remove the parenthetical phrase at the end of the section.

§ 312.160 [Amended]

54. In § 312.160 *Drugs for investigational use in laboratory research animals or in vitro tests*, remove the parenthetical phrase at the end of the section.

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

55. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 356, 356a, 356b, 356c, 371, 374, 379e.

§ 314.50 [Amended]

56. In § 314.50 *Content and format of an application*, remove the parenthetical phrase at the end of the section.

§ 314.70 [Amended]

57. In § 314.70 *Supplements and other changes to an approved application*, remove the parenthetical phrase at the end of the section.

§ 314.71 [Amended]

58. In § 314.71 *Procedures for submission of a supplement to an approved application*, remove the parenthetical phrase at the end of the section.

§ 314.72 [Amended]

59. In § 314.72 *Changes in ownership of an application*, remove the parenthetical phrase at the end of the section.

§ 314.80 [Amended]

60. In § 314.80 *Postmarketing reporting of adverse drug experiences*, remove the parenthetical phrase at the end of the section.

§ 314.90 [Amended]

61. In § 314.90 *Waivers*, remove the parenthetical phrase at the end of the section

§ 314.126 [Amended]

62. In § 314.126 *Adequate and well-controlled studies*, remove the parenthetical phrase at the end of the section.

§ 314.200 [Amended]

63. In § 314.200 *Notice of opportunity for hearing; notice of participation and request for hearing; grant or denial of hearing*, remove the parenthetical phrase at the end of the section.

§ 314.420 [Amended]

64. In § 314.420 *Drug master files*, remove the parenthetical phrase at the end of the section.

PART 510—NEW ANIMAL DRUGS

65. The authority citation for 21 CFR part 510 continues to read as follows:

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

§ 510.455 [Amended]

66. In § 510.455 *New animal drug requirements regarding free-choice administration in feeds*, remove the parenthetical phrase at the end of the section.

PART 514—NEW ANIMAL DRUG APPLICATIONS

67. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360b, 371, 379e, 381.

§ 514.1 [Amended]

68. In § 514.1 *Applications*, remove the parenthetical phrase at the end of the section.

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

69. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

§ 606.170 [Amended]

70. In § 606.170 *Adverse reaction file*, remove the parenthetical phrase at the end of the section.

PART 610—GENERAL BIOLOGICAL PRODUCTS

71. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 610.2 [Amended]

72. In § 610.2 *Requests for samples and protocols; official release*, remove the parenthetical phrase at the end of the section

§ 610.12 [Amended]

73. In § 610.12 *Sterility*, remove the parenthetical phrase at the end of the section.

§ 610.13 [Amended]

74. In § 610.13 *Purity*, remove the parenthetical phrase at the end of the section.

§ 610.18 [Amended]

75. In § 610.18 *Cultures*, remove the parenthetical phrase at the end of the section.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

76. The authority citation for 21 CFR part 640 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 640.2 [Amended]

77. In § 640.2 *General requirements*, remove the parenthetical phrase at the end of the section

§ 640.72 [Amended]

78. In § 640.72 *Records*, remove the parenthetical phrase at the end of the section.

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

79. The authority citation for 21 CFR part 660 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 660.21 [Amended]

80. In § 660.21 *Processing*, remove the parenthetical phrase at the end of the section.

§ 660.22 [Amended]

81. In § 660.22 *Potency requirements with reference preparations*, remove the parenthetical phrase at the end of the section.

§ 660.25 [Amended]

82. In § 660.25 *Potency tests without reference preparations*, remove the parenthetical phrase at the end of the section.

§ 660.26 [Amended]

83. In § 660.26 *Specificity tests and avidity tests*, remove the parenthetical phrase at the end of the section.

§ 660.28 [Amended]

84. In § 660.28 *Labeling*, remove the parenthetical phrase at the end of the section.

§ 660.34 [Amended]

85. In § 660.34 *Processing*, remove the parenthetical phrase at the end of the section.

§ 660.35 [Amended]

86. In § 660.35 *Labeling*, remove the parenthetical phrase at the end of the section.

§ 660.36 [Amended]

87. In § 660.36 *Samples and protocols*, remove the parenthetical phrase at the end of the section.

§ 660.51 [Amended]

88. In § 660.51 *Processing*, remove the parenthetical phrase at the end of the section.

§ 660.52 [Amended]

89. In § 660.52 *Reference preparations*, remove the parenthetical phrase at the end of the section.

§ 660.53 [Amended]

90. In § 660.53 *Controls for serological procedures*, remove the parenthetical phrase at the end of the section.

§ 660.54 [Amended]

91. In § 660.54 *Potency tests, specificity tests, tests for heterospecific antibodies, and additional tests for nonspecific properties*, remove the parenthetical phrase at the end of the section.

§ 660.55 [Amended]

92. In § 660.55 *Labeling*, remove the parenthetical phrase at the end of the section.

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

93. The authority citation for 21 CFR part 680 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 680.1 [Amended]

94. In § 680.1 *Allergenic products*, remove the parenthetical phrase at the end of the section.

§ 680.2 [Amended]

95. In § 680.2 *Manufacture of allergenic products*, remove the parenthetical phrase in paragraph (f) of this section.

§ 680.3 [Amended]

96. In § 680.3 *Tests*, remove the parenthetical phrase at the end of the section.

PART 720—VOLUNTARY FILING OF COSMETIC PRODUCT INGREDIENT COMPOSITION STATEMENTS

97. The authority citation for 21 CFR part 720 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 361, 362, 371, 374.

§ 720.6 [Amended]

98. In § 720.6 *Amendments to statement*, remove the parenthetical phrase at the end of the section.

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

99. The authority citation for 21 CFR part 814 continues to read as follows:

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

§ 814.20 [Amended]

100. In § 814.20 *Application*, remove the parenthetical phrase at the end of the section.

§ 814.39 [Amended]

101. In § 814.39 *PMA supplements*, remove the parenthetical phrase at the end of the section.

§ 814.84 [Amended]

102. In § 814.84 *Reports*, remove the parenthetical phrase at the end of the section.

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

103. The authority citation for 21 CFR part 1020 continues to read as follows:

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

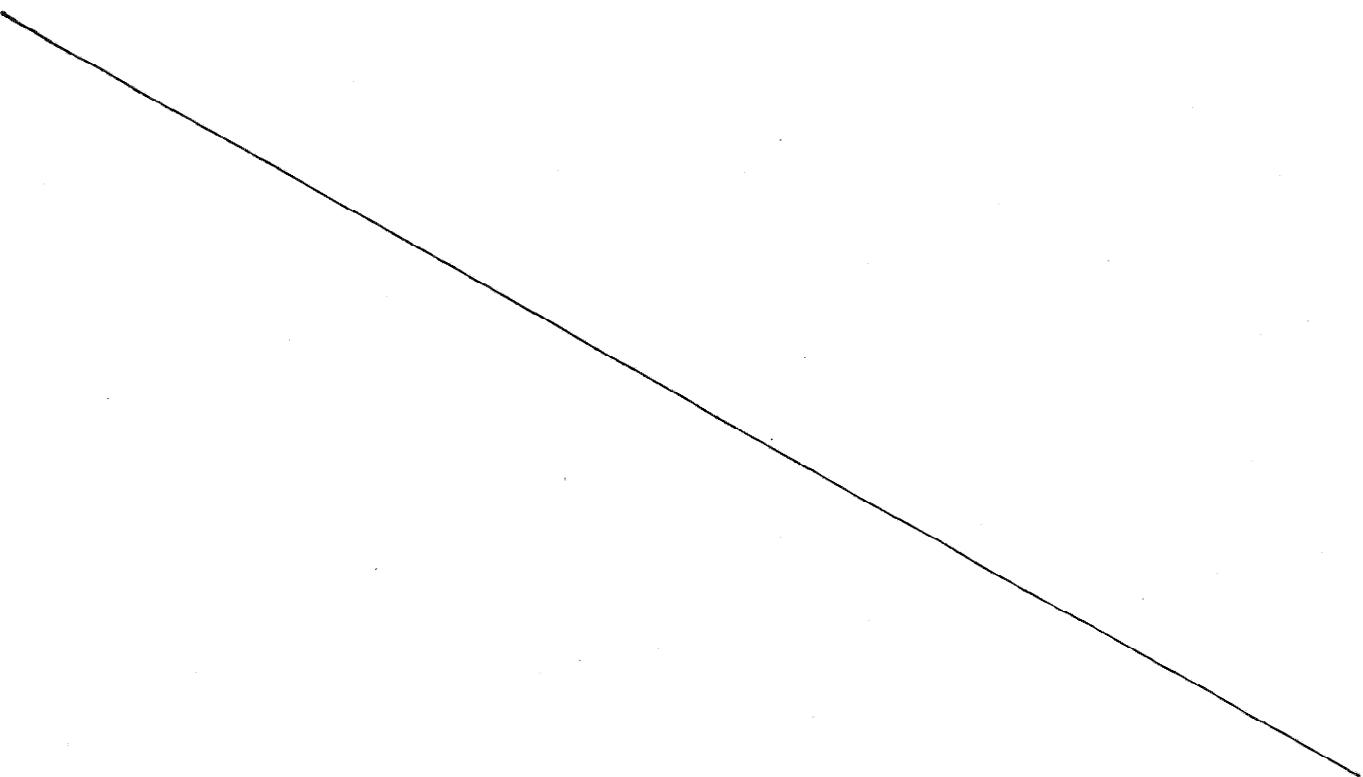
§ 1020.33 [Amended]

104. In § 1020.33 *Computed tomography (CT) equipment*, remove the parenthetical phrase at the end of the section.

PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

105. The authority citation for 21 CFR part 1040 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e–360j, 371, 381; 42 U.S.C. 263b–263n.



§ 1040.20 [Amended]

106. In § 1040.20 *Sunlamp products and ultraviolet lamps intended for use in sunlamp products*, remove the parenthetical phrase at the end of the section.

Dated: 2-20-02

February 20, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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