# DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

#### 21 CFR Chapter I

[Docket No. 97N-0365]

## Code of Federal Regulations; Authority Citations

**AGENCY:** Food and Drug Administration,

HHS.

**ACTION:** Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising the authority citations for Title 21, Chapter I of the Code of Federal Regulations to conform with procedures of the Administrative Committee of the Federal Register. This action is intended to simplify FDA's authority citations. It does not represent a change in agency policy and does not increase any burdens on the public.

**DATES:** Effective October 1, 1997. Submit written comments by December 30, 1997.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

### FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2994.

SUPPLEMENTARY INFORMATION: The Office of the Federal Register, in accordance with the procedures of the Administrative Committee of the Federal Register (1 CFR 21.52), has recommended that each citation of

authority for Chapter I of Title 21 of the Code of Federal Regulations include only references to the United States Code. Therefore, FDA is revising the authority citations for 21 CFR parts 1 through 1270 to conform with these procedures. This action is intended to simplify FDA's authority citations.

FDA has determined that this final rule does not change the statutory authority applicable to the regulations issued by FDA. Because the changes that the agency is making are not substantive and are merely ministerial changes to the Code of Federal Regulations, the Commissioner of Food and Drugs finds that there is good cause not to engage in notice and public comment procedures or to delay the effective date of these amendments. FDA is merely conforming to the recommendation of the Office of the Federal Register under 1 CFR 21.51 and 21.52.

Although this rule is effective immediately, the agency is providing until December 30, 1997, to determine whether the regulation should be subsequently modified or revoked in accordance with 21 CFR 10.40(e)(1). Interested persons may submit written comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.30(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

# PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 is revised to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 343, 352, 355, 360b, 362, 371; 42 U.S.C. 216.

# PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

2. The authority citation for 21 CFR part 2 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 335, 342, 346a, 348, 351, 352, 355, 357, 360b, 361, 371, 372, 374; 15 U.S.C. 402, 409.

#### PART 3—PRODUCT JURISDICTION

3. The authority citation for 21 CFR part 3 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 356, 357, 360, 360c–360f, 360h–360j, 360gg–360ss, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262.

# PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

4. The authority citation for 21 CFR part 5 is revised to read as follows:

**Authority:** 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 61–63, 141–149, 321–394, 467f, 679(b), 801–886, 1031–1309; 35 U.S.C. 156;

42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1; 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

#### PART 7—ENFORCEMENT POLICY

5. The authority citation for 21 CFR part 7 is revised to read as follows:

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

# PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

6. The authority citation for 21 CFR part 10 is revised to read as follows:

**Authority:** 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 42 U.S.C. 201, 262, 263b, 264; 15 U.S.C. 1451–1461; 5 U.S.C. 551–558, 701–721; 28 U.S.C. 2112.

# PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

7. The authority citation for 21 CFR part 11 is revised to read as follows:

**Authority:** 21 U.S.C. 321–393; 42 U.S.C. 262

## PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

8. The authority citation for 21 CFR part 12 is revised to read as follows:

**Authority:** 21 U.S.C. 41–50, 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.

# PART 13—PUBLIC HEARING BEFORE A PUBLIC BOARD OF INQUIRY

9. The authority citation for 21 CFR part 13 is revised to read as follows:

**Authority:** 21 U.S.C. 41–50, 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.

## PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

10. The authority citation for 21 CFR part 14 is revised to read as follows:

**Authority:** 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 42 U.S.C. 201, 262, 263b, 264; 15 U.S.C. 1451–1461; 5 U.S.C. App. 2; 28 U.S.C. 2112.

# PART 15—PUBLIC HEARING BEFORE THE COMMISSIONER

11. The authority citation for 21 CFR part 15 is revised to read as follows:

**Authority:** 21 U.S.C. 41–50, 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. 553; 28 U.S.C. 2112.

### PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG **ADMINISTRATION**

12. The authority citation for 21 CFR part 16 is revised to read as follows:

Authority: 21 U.S.C. 41-50, 141-149, 321-394, 467f, 679, 821, 1034; 42 U.S.C. 201, 262, 264; 15 U.S.C. 1451-1461; 28 U.S.C. 2112.

#### PART 17—CIVIL MONEY PENALTIES **HEARINGS**

13. The authority citation for 21 CFR part 17 is revised to read as follows:

Authority: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa-28; 5 U.S.C. 554, 555, 556, 557.

#### PART 19—STANDARDS OF CONDUCT AND CONFLICTS OF INTEREST

14. The authority citation for 21 CFR part 19 is revised to read as follows:

Authority: 21 U.S.C. 371.

### PART 20—PUBLIC INFORMATION

15. The authority citation for 21 CFR part 20 is revised to read as follows:

Authority: 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-300-5, 300aa-1; 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531-2582.

#### PART 21—PROTECTION OF PRIVACY

16. The authority citation for 21 CFR part 21 is revised to read as follows:

Authority: 21 U.S.C. 371; 5 U.S.C. 552, 552a.

### PART 25—ENVIRONMENTAL IMPACT **CONSIDERATIONS**

17. The authority citation for 21 CFR part 25 is revised 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.

### PART 50—PROTECTION OF HUMAN **SUBJECTS**

18. The authority citation for 21 CFR part 50 is revised to read as follows:

Authority: 21 U.S.C. 321, 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360c-360f, 360h-360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b-263n.

#### PART 56—INSTITUTIONAL REVIEW **BOARDS**

19. The authority citation for 21 CFR part 56 is revised to read as follows:

Authority: 21 U.S.C. 321, 346, 346a, 348, 351, 352, 353, 355, 356, 357, 360, 360c-360f, 360h-360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b-263n.

#### PART 58—GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

20. The authority citation for 21 CFR part 58 is revised to read as follows:

Authority: 21 U.S.C. 342, 346, 346a, 348, 351, 352, 353, 355, 356, 357, 360, 360b-360f, 360h-360j, 371, 379e, 381; 42 U.S.C. 216, 262, 263b-263n.

#### PART 60—PATENT TERM RESTORATION

21. The authority citation for 21 CFR part 60 is revised to read as follows:

Authority: 21 U.S.C. 348, 355, 357, 360e, 360j, 371, 379e; 35 U.S.C. 156; 42 U.S.C. 262.

#### PART 70—COLOR ADDITIVES

22. The authority citation for 21 CFR part 70 is revised to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 360b, 361, 371, 379e.

#### PART 71—COLOR ADDITIVE **PETITIONS**

23. The authority citation for 21 CFR part 71 is revised to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 351, 355, 356, 357, 360, 360b-360f, 360h-360j, 361, 371, 379e, 381; 42 U.S.C. 216, 262.

### PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM **CERTIFICATION**

24. The authority citation for 21 CFR part 73 is revised to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

### PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO **CERTIFICATION**

25. The authority citation for 21 CFR part 74 is revised to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

### PART 80—COLOR ADDITIVE CERTIFICATION

26. The authority citation for 21 CFR part 80 is revised to read as follows:

Authority: 21 U.S.C. 371, 379e.

### PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

27. The authority citation for 21 CFR part 81 is revised to read as follows:

Authority: 21 U.S.C. 371, 379e, 379e note.

### **PART 82—LISTING OF CERTIFIED** PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

28. The authority citation for 21 CFR part 82 is revised to read as follows:

Authority: 21 U.S.C. 371, 379e, 379e note.

#### PART 100—GENERAL

29. The authority citation for 21 CFR part 100 is revised to read as follows:

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

#### PART 101—FOOD LABELING

30. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371).

#### PART 102—COMMON OR USUAL NAME FOR NONSTANDARDIZED **FOODS**

31. The authority citation for 21 CFR part 102 is revised to read as follows:

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

#### PART 105—FOODS FOR SPECIAL **DIETARY USE**

32. The authority citation for 21 CFR part 105 is revised to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 350, 371, 379e.

#### PART 106—INFANT FORMULA **QUALITY CONTROL PROCEDURES**

33. The authority citation for 21 CFR part 106 is revised to read as follows:

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

#### PART 107—INFANT FORMULA

34. The authority citation for 21 CFR part 107 is revised to read as follows:

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

#### PART 108—EMERGENCY PERMIT CONTROL

35. The authority citation for 21 CFR part 108 is revised to read as follows:

Authority: 21 U.S.C. 342, 344, 371.

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

36. The authority citation for 21 CFR part 109 is revised to read as follows:

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

#### PART 110—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

37. The authority citation for 21 CFR part 110 is revised to read as follows:

**Authority:** 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.

### PART 111—CURRENT GOOD MANUFACTURING PRACTICE FOR DIETARY SUPPLEMENTS

38. The authority citation for 21 CFR part 111 is revised to read as follows:

Authority: 21 U.S.C. 321, 342, 371.

#### PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

39. The authority citation for 21 CFR part 113 is revised to read as follows:

**Authority:** 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.

#### PART 114—ACIDIFIED FOODS

40. The authority citation for 21 CFR part 114 is revised to read as follows:

**Authority:** 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.

# PART 123—FISH AND FISHERY PRODUCTS

41. The authority citation for 21 CFR part 123 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 2421, 264.

# PART 129—PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

42. The authority citation for 21 CFR part 129 is revised to read as follows:

**Authority:** 21 U.S.C. 342, 348, 371, 374; 42 U.S.C. 264.

# PART 130—FOOD STANDARDS: GENERAL

43. The authority citation for 21 CFR part 130 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 336, 341, 343, 371.

#### PART 131—MILK AND CREAM

44. The authority citation for 21 CFR part 131 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371, 379e.

# PART 133—CHEESES AND RELATED CHEESE PRODUCTS

45. The authority citation for 21 CFR part 133 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371, 379e.

#### PART 135—FROZEN DESSERTS

46. The authority citation for 21 CFR part 135 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371, 379e.

#### PART 136—BAKERY PRODUCTS

47. The authority citation for 21 CFR part 136 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371, 379e.

# PART 137—CEREAL FLOURS AND RELATED PRODUCTS

48. The authority citation for 21 CFR part 137 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371, 379e.

# PART 139—MACARONI AND NOODLE PRODUCTS

49. The authority citation for 21 CFR part 139 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371, 379e.

#### **PART 145—CANNED FRUITS**

50. The authority citation for 21 CFR part 145 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371, 379e.

#### PART 146—CANNED FRUIT JUICES

51. The authority citation for 21 CFR part 146 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371, 379e.

# PART 150—FRUIT BUTTERS, JELLIES, PRESERVES, AND RELATED PRODUCTS

52. The authority citation for 21 CFR part 150 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371, 379e.

#### **PART 152—FRUIT PIES**

53. The authority citation for 21 CFR part 152 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371, 379e.

#### **PART 155—CANNED VEGETABLES**

54. The authority citation for 21 CFR part 155 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371, 379e.

#### PART 156—VEGETABLE JUICES

55. The authority citation for 21 CFR part 156 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371

#### PART 158—FROZEN VEGETABLES

56. The authority citation for 21 CFR part 158 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371.

#### PART 160—EGGS AND EGG PRODUCTS

57. The authority citation for 21 CFR part 160 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371, 379e.

#### PART 161—FISH AND SHELLFISH

58. The authority citation for 21 CFR part 161 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371, 379e.

#### **PART 163—CACAO PRODUCTS**

59. The authority citation for 21 CFR part 163 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 341, 343, 348, 371, 379e.

# PART 164—TREE NUT AND PEANUT PRODUCTS

60. The authority citation for 21 CFR part 164 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371, 379e.

### **PART 165—BEVERAGES**

61. The authority citation for 21 CFR part 165 is revised to read as follows:

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

### PART 166—MARGARINE

62. The authority citation for 21 CFR part 166 is revised to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 347, 348, 371, 379e.

### **PART 168—SWEETENERS AND TABLE SIRUPS**

63. The authority citation for 21 CFR part 168 is revised to read as follows:

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

#### PART 169—FOOD DRESSINGS AND **FLAVORINGS**

64. The authority citation for 21 CFR part 169 is revised to read as follows:

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

#### PART 170—FOOD ADDITIVES

65. The authority citation for 21 CFR part 170 is revised to read as follows:

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

#### PART 171—FOOD ADDITIVE **PETITIONS**

66. The authority citation for 21 CFR part 171 is revised to read as follows:

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

#### PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

67. The authority citation for 21 CFR part 172 is revised to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

### PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

68. The authority citation for 21 CFR part 173 is revised to read as follows:

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

#### PART 174—INDIRECT FOOD ADDITIVES: GENERAL

69. The authority citation for 21 CFR part 174 is revised to read as follows:

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

#### PART 175—INDIRECT FOOD **ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS**

70. The authority citation for 21 CFR part 175 is revised to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

### PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

71. The authority citation for 21 CFR part 176 is revised to read as follows:

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

### PART 177—INDIRECT FOOD **ADDITIVES: POLYMERS**

72. The authority citation for 21 CFR part 177 is revised to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

### PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS. PRODUCTION AIDS, AND SANITIZERS

73. The authority citation for 21 CFR part 178 is revised to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

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

74. The authority citation for 21 CFR part 179 is revised to read as follows:

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

#### PART 180—FOOD ADDITIVES PERMITTED IN FOOD OR IN CONTACT WITH FOOD ON AN INTERIM BASIS PENDING ADDITIONAL STUDY

75. The authority citation for 21 CFR part 180 is revised to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371: 42 U.S.C. 241.

### PART 181—PRIOR-SANCTIONED **FOOD INGREDIENTS**

76. The authority citation for 21 CFR part 181 is revised to read as follows:

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

### **PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE**

77. The authority citation for 21 CFR part 182 is revised to read as follows:

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

### PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS **GENERALLY RECOGNIZED AS SAFE**

78. The authority citation for 21 CFR part 184 is revised to read as follows:

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

### **PART 186—INDIRECT FOOD** SUBSTANCES AFFIRMED AS **GENERALLY RECOGNIZED AS SAFE**

79. The authority citation for 21 CFR part 186 is revised to read as follows:

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

#### PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN **FOOD**

80. The authority citation for 21 CFR part 189 is revised to read as follows:

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

#### **PART 200—GENERAL**

81. The authority citation for 21 CFR part 200 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360e, 371, 374, 375.

#### **PART 201—LABELING**

82. The authority citation for 21 CFR part 201 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360, 360b, 360gg-360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

#### PART 202—PRESCRIPTION DRUG **ADVERTISING**

83. The authority citation for 21 CFR part 202 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 352, 355, 357, 360b, 371.

### PART 205—GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS

84. The authority citation for 21 CFR part 205 is revised to read as follows:

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

### PART 206—IMPRINTING OF SOLID ORAL DOSAGE FROM DRUG PRODUCTS FOR HUMAN USE

85. The authority citation for 21 CFR part 206 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 357, 371; 42 U.S.C. 262.

### PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL **DISTRIBUTION**

86. The authority citation for 21 CFR part 207 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 355, 356, 357, 360, 360b, 371, 374; 42 U.S.C. 262.

### PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL

87. The authority citation for 21 CFR part 210 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 355, 356, 357, 360b, 371, 374.

### PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

88. The authority citation for 21 CFR part 211 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 355, 356, 357, 360b, 371, 374.

#### PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

89. The authority citation for 21 CFR part 225 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 352, 360b, 371, 374

### PART 226—CURRENT GOOD MANUFACTURING PRACTICE FOR TYPE A MEDICATED ARTICLES

90. The authority citation for 21 CFR part 226 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 352, 360b, 371, 374.

# PART 250—SPECIAL REQUIREMENTS FOR SPECIFIC HUMAN DRUGS

91. The authority citation for 21 CFR part 250 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 336, 342, 352, 353, 355, 361(a), 362(a) and (c), 371, 375(b).

#### PART 290—CONTROLLED DRUGS

92. The authority citation for 21 CFR part 290 is revised to read as follows:

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

# PART 291—DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS

93. The authority citation for 21 CFR part 291 is revised to read as follows:

**Authority:** 21 U.S.C. 355, 371, 823; 42 U.S.C. 241(d), 257a, 290ee–3, 300y–11.

# PART 299—DRUGS; OFFICIAL NAMES AND ESTABLISHED NAMES

94. The authority citation for 21 CFR part 299 is revised to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 355, 358, 360b, 371.

#### **PART 300—GENERAL**

95. The authority citation for 21 CFR part 300 is revised to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 355, 357, 360b, 361, 371.

#### PART 310—NEW DRUGS

96. The authority citation for 21 CFR part 310 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

# PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

97. The authority citation for 21 CFR part 312 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371; 42 U.S.C. 262.

#### PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

98. The authority citation for 21 CFR part 314 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 374, 379e.

### PART 316—ORPHAN DRUGS

99. The authority citation for 21 CFR part 316 is revised to read as follows:

**Authority:** 21 U.S.C. 360aa, 360bb, 360cc, 360dd, 371.

# PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

100. The authority citation for 21 CFR part 320 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 355, 357, 371.

### PART 329—HABIT-FORMING DRUGS

101. The authority citation for 21 CFR part 329 is revised to read as follows:

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

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

102. The authority citation for 21 CFR part 330 is revised to read as follows:

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

# PART 331—ANTACID PRODUCTS FOR OVER-THE-COUNTER (OTC) HUMAN USE

103. The authority citation for 21 CFR part 331 is revised to read as follows:

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

# PART 332—ANTIFLATULENT PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

104. The authority citation for 21 CFR part 332 is revised to read as follows:

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

### PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

105. The authority citation for 21 CFR part 333 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371, unless otherwise noted.

### PART 336—ANTIEMETIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

106. The authority citation for 21 CFR part 336 is revised to read as follows:

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

#### PART 338—NIGHTTIME SLEEP-AID DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

107. The authority citation for 21 CFR part 338 is revised to read as follows:

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

### PART 340—STIMULANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

108. The authority citation for 21 CFR part 340 is revised to read as follows:

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

### PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

109. The authority citation for 21 CFR part 341 is revised to read as follows:

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

#### PART 344—TOPICAL OTIC DRUG PRODUCTS FOR OVER-THE-**COUNTER HUMAN USE**

110. The authority citation for 21 CFR part 344 is revised to read as follows:

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

### PART 346—ANORECTAL DRUG PRODUCTS FOR OVER-THE-**COUNTER HUMAN USE**

111. The authority citation for 21 CFR part 346 is revised to read as follows:

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

### PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-**COUNTER HUMAN USE**

112. The authority citation for 21 CFR part 347 is revised to read as follows:

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

### PART 348—EXTERNAL ANALGESIC DRUG PRODUCTS FOR OVER-THE-**COUNTER HUMAN USE**

113. The authority citation for 21 CFR part 348 is revised to read as follows:

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

### PART 349—OPHTHALMIC DRUG PRODUCTS FOR OVER-THE-**COUNTER HUMAN USE**

114. The authority citation for 21 CFR part 349 is revised to read as follows:

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

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

115. The authority citation for 21 CFR part 355 is revised to read as follows;

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

### **PART 357—MISCELLANEOUS** INTERNAL DRUG PRODUCTS FOR **OVER-THE-COUNTER HUMAN USE**

116. The authority citation for 21 CFR part 357 is revised to read as follows:

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

### PART 358—MISCELLANEOUS EXTERNAL DRUG PRODUCTS FOR **OVER-THE-COUNTER HUMAN USE**

117. The authority citation for 21 CFR part 358 is revised to read as follows:

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

### PART 361—PRESCRIPTION DRUGS FOR HUMAN USE GENERALLY **RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED:** DRUGS USED IN RESEARCH

118. The authority citation for 21 CFR part 361 is revised to read as follows:

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

### **PART 369—INTERPRETATIVE** STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

119. The authority citation for 21 CFR part 369 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371.

### PART 429—DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN

120. The authority citation for 21 CFR part 429 is revised to read as follows:

Authority: 21 U.S.C. 352, 356, 371.

#### PART 430—ANTIBIOTIC DRUGS; **GENERAL**

121. The authority citation for 21 CFR part 430 is revised to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 357, 371; 42 U.S.C. 216, 241, 262.

### PART 431—CERTIFICATION OF **ANTIBIOTIC DRUGS**

122. The authority citation for 21 CFR part 431 is revised to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 355, 357, 379e; 42 U.S.C. 216, 241, 262; 5 U.S.C.

### PART 432—PACKAGING AND LABELING OF ANTIBIOTIC DRUGS

123. The authority citation for 21 CFR part 432 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 352, 353, 357, 371, 381.

### **PART 433—EXEMPTIONS FROM** ANTIBIOTIC CERTIFICATION AND LABELING REQUIREMENTS

124. The authority citation for 21 CFR part 433 is revised to read as follows:

Authority: 21 U.S.C. 352, 355, 357.

#### PART 436—TESTS AND METHODS OF **ASSAY OF ANTIBIOTIC AND** ANTIBIOTIC-CONTAINING DRUGS

125. The authority citation for 21 CFR part 436 is revised to read as follows:

Authority: 21 U.S.C. 357.

### PART 440—PENICILLIN ANTIBIOTIC **DRUGS**

126. The authority citation for 21 CFR part 440 is revised to read as follows:

Authority: 21 U.S.C. 357.

#### PART 441—PENEM ANTIBIOTIC **DRUGS**

127. The authority citation for 21 CFR part 441 is revised to read as follows:

Authority: 21 U.S.C. 357.

#### PART 442—CEPHA ANTIBIOTIC **DRUGS**

128. The authority citation for 21 CFR part 442 is revised to read as follows:

Authority: 21 U.S.C. 357.

### PART 443—CARBACEPHEM **ANTIBIOTIC DRUGS**

129. The authority citation for 21 CFR part 443 is revised to read as follows:

Authority: 21 U.S.C. 357.

### PART 444—OLIGOSACCHARIDE **ANTIBIOTIC DRUGS**

130. The authority citation for 21 CFR part 444 is revised to read as follows:

Authority: 21 U.S.C. 357.

#### PART 446—TETRACYCLINE ANTIBIOTIC DRUGS

131. The authority citation for 21 CFR part 446 is revised to read as follows:

Authority: 21 U.S.C. 357.

#### PART 448—PEPTIDE ANTIBIOTIC **DRUGS**

132. The authority citation for 21 CFR part 448 is revised to read as follows:

Authority: 21 U.S.C. 357.

#### PART 449—ANTIFUNGAL ANTIBIOTIC **DRUGS**

133. The authority citation for 21 CFR part 449 is revised to read as follows:

Authority: 21 U.S.C. 357.

## PART 450—ANTITUMOR ANTIBIOTIC DRUGS

134. The authority citation for 21 CFR part 450 is revised to read as follows:

**Authority:** 21 U.S.C. 357.

# PART 452—MACROLIDE ANTIBIOTIC DRUGS

135. The authority citation for 21 CFR part 452 is revised to read as follows:

Authority: 21 U.S.C. 357.

# PART 453—LINCOMYCIN ANTIBIOTIC DRUGS

136. The authority citation for 21 CFR part 453 is revised to read as follows:

Authority: 21 U.S.C. 357.

# PART 455—CERTAIN OTHER ANTIBIOTICS DRUGS

137. The authority citation for 21 CFR part 455 is revised to read as follows:

Authority: 21 U.S.C. 357.

### PART 460—ANTIBIOTICS DRUGS INTENDED FOR USE IN LABORATORY DIAGNOSIS OF DISEASE

138. The authority citation for 21 CFR part 460 is revised to read as follows:

Authority: 21 U.S.C. 357.

### **PART 500—GENERAL**

139. The authority citation for 21 CFR part 500 is revised to read as follows:

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

#### PART 501—ANIMAL FOOD LABELING

140. The authority citation for 21 CFR part 501 is revised to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

# PART 502—COMMON OR USUAL NAMES FOR NONSTANDARDIZED ANIMAL FOODS

141. The authority citation for 21 CFR part 502 is revised to read as follows:

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

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

142. The authority citation for 21 CFR part 509 is revised to read as follows:

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

#### PART 510—NEW ANIMAL DRUGS

143. The authority citation for 21 CFR part 510 is revised to read as follows:

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

# PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

144. The authority citation for 21 CFR part 511 is revised to read as follows:

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

### PART 514—NEW ANIMAL DRUG APPLICATIONS

145. The authority citation for 21 CFR part 514 is revised to read as follows:

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

# PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

146. The authority citation for 21 CFR part 520 is revised to read as follows:

Authority: 21 U.S.C. 360b.

# PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

147. The authority citation for 21 CFR part 522 is revised to read as follows:

Authority: 21 U.S.C. 360b.

# PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

148. The authority citation for 21 CFR part 524 is revised to read as follows:

Authority: 21 U.S.C. 360b.

# PART 526—INTRAMAMMARY DOSAGE FORMS

149. The authority citation for 21 CFR part 526 is revised to read as follows:

Authority: 21 U.S.C. 360b.

# PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

150. The authority citation for 21 CFR part 529 is revised to read as follows:

Authority: 21 U.S.C. 360b.

# PART 530—EXTRALABEL DRUG USE IN ANIMALS

151. The authority citation for 21 CFR part 530 is revised to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 360b, 371, 379e.

# PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

152. The authority citation for 21 CFR part 556 is revised to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

# PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

153. The authority citation for 21 CFR part 558 is revised to read as follows:

Authority: 21 U.S.C. 360b, 371.

# PART 564—DEFINITIONS AND STANDARDS FOR ANIMAL FOOD

154. The authority citation for 21 CFR part 564 is revised to read as follows:

Authority: 21 U.S.C. 341, 343, 371.

#### PART 570—FOOD ADDITIVES

155. The authority citation for 21 CFR part 570 is revised to read as follows:

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

## PART 571—FOOD ADDITIVE PETITIONS

156. The authority citation for 21 CFR part 571 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 342, 348, 371; 42 U.S.C. 241.

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

157. The authority citation for 21 CFR part 573 is revised to read as follows:

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

#### PART 579—IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF ANIMAL FEED AND PET FOOD

158. The authority citation for 21 CFR part 579 is revised to read as follows:

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

## PART 582—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

159. The authority citation for 21 CFR part 582 is revised to read as follows:

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

### PART 584—FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE IN FEED AND DRINKING WATER OF ANIMALS

160. The authority citation for 21 CFR part 584 is revised to read as follows:

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

### PART 589—SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

161. The authority citation for 21 CFR part 589 is revised to read as follows:

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

#### PART 600—BIOLOGICAL PRODUCTS: GENERAL

162. The authority citation for 21 CFR part 600 is revised to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa-25.

### **PART 601—LICENSING**

163. The authority citation for 21 CFR part 601 is revised to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360c-360f, 360h-360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263; 15 U.S.C. 1451-1561.

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

164. The authority citation for 21 CFR part 606 is revised 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.

#### PART 607—ESTABLISHMENT **REGISTRATION AND PRODUCT** LISTING FOR MANUFACTURERS OF **HUMAN BLOOD AND BLOOD PRODUCTS**

165. The authority citation for 21 CFR part 607 is revised to read as follows:

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

#### PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

166. The authority citation for 21 CFR part 610 is revised 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.

### PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD **PRODUCTS**

167. The authority citation for 21 CFR part 640 is revised 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.

#### PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

168. The authority citation for 21 CFR part 660 is revised 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.

### PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

169. The authority citation for 21 CFR part 680 is revised to read as follows:

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

#### PART 700—GENERAL

170. The authority citation for 21 CFR part 700 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 352, 355, 361, 362, 371, 374.

#### PART 701—COSMETIC LABELING

171. The authority citation for 21 CFR part 701 is revised to read as follows:

Authority: 21 U.S.C. 321, 352, 361, 362, 363, 371, 374; 15 U.S.C. 1454, 1455.

### PART 710—VOLUNTARY REGISTRATION OF COSMETIC PRODUCT ESTABLISHMENTS

172. The authority citation for 21 CFR part 710 is revised to read as follows:

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

### PART 720—VOLUNTARY FILING OF COSMETIC PRODUCT INGREDIENT AND COSMETIC RAW MATERIAL **COMPOSITION STATEMENTS**

173. The authority citation for 21 CFR part 720 is revised to read as follows:

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

### PART 730—VOLUNTARY FILING OF **COSMETIC PRODUCT EXPERIENCES**

174. The authority citation for 21 CFR part 730 is revised to read as follows:

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

### PART 740—COSMETIC PRODUCT WARNING STATEMENTS

175. The authority citation for 21 CFR part 740 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 352, 355, 361, 362, 371, 374.

#### PART 800—GENERAL

176. The authority citation for 21 CFR part 800 is revised to read as follows:

Authority: 21 U.S.C. 321, 334, 351, 352, 355, 356, 357, 360e, 360i, 360k, 361, 362, 371.

#### **PART 801—LABELING**

177. The authority citation for 21 CFR part 801 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374.

#### PART 803—MEDICAL DEVICE **REPORTING**

178. The authority citation for 21 CFR part 803 is revised to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

#### PART 804—MEDICAL DEVICE **DISTRIBUTOR REPORTING**

179. The authority citation for 21 CFR part 804 is revised to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

#### PART 805—CARDIAC PACEMAKER **REGISTRY**

180. The authority citation for 21 CFR part 805 is revised to read as follows:

Authority: 42 U.S.C. 1395y(h), 1395y note.

### PART 806—MEDICAL DEVICE **CORRECTIONS AND REMOVALS**

181. The authority citation for 21 CFR part 806 is revised to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360i, 371, 374.

### PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND **DISTRIBUTORS OF DEVICES**

182. The authority citation for 21 CFR part 807 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374.

### PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE **REQUIREMENTS**

183. The authority citation for 21 CFR part 808 is revised to read as follows:

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

# PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

184. The authority citation for 21 CFR part 809 is revised to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 355, 357, 360b, 360c, 360d, 360h, 360i, 360j, 371, 372, 374, 381.

# PART 810—MEDICAL DEVICE RECALL AUTHORITY

185. The authority citation for 21 CFR part 810 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 332, 333, 334, 351, 352, 360h, 371, 374, 375.

# PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

186. The authority citation for 21 CFR part 812 is revised to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 353, 355, 356, 357, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

# PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

187. The authority citation for 21 CFR part 814 is revised to read as follows:

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

# PART 820—QUALITY SYSTEM REGULATION

188. The authority citation for 21 CFR part 820 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383.

# PART 821—MEDICAL DEVICE TRACKING REQUIREMENTS

189. The authority citation for 21 CFR part 821 is revised to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 360, 360e, 360h, 360i, 371, 374.

# PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

190. The authority citation for 21 CFR part 860 is revised to read as follows:

**Authority:** 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

# PART 861—PROCEDURES FOR PERFORMANCE STANDARDS DEVELOPMENT

191. The authority citation for 21 CFR part 861 is revised to read as follows:

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

#### PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

192. The authority citation for 21 CFR part 862 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

# PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

193. The authority citation for 21 CFR part 864 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

# PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

194. The authority citation for 21 CFR part 866 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

## PART 868—ANESTHESIOLOGY DEVICES

195. The authority citation for 21 CFR part 868 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

# PART 870—CARDIOVASCULAR DEVICES

196. The authority citation for 21 CFR part 870 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

#### **PART 872—DENTAL DEVICES**

197. The authority citation for 21 CFR part 872 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

## PART 874—EAR, NOSE, AND THROAT DEVICES

198. The authority citation for 21 CFR part 874 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

#### PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

199. The authority citation for 21 CFR part 876 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

# PART 878—GENERAL AND PLASTIC SURGERY DEVICES

200. The authority citation for 21 CFR part 878 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

# PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

201. The authority citation for 21 CFR part 880 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

#### PART 882—NEUROLOGICAL DEVICES

202. The authority citation for 21 CFR part 882 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

# PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

203. The authority citation for 21 CFR part 884 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

#### PART 886—OPHTHALMIC DEVICES

204. The authority citation for 21 CFR part 886 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

#### PART 888—ORTHOPEDIC DEVICES

205. The authority citation for 21 CFR part 888 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

## PART 890—PHYSICAL MEDICINE DEVICES

206. The authority citation for 21 CFR part 890 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

### **PART 892—RADIOLOGY DEVICES**

207. The authority citation for 21 CFR part 892 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

#### PART 895—BANNED DEVICES

208. The authority citation for 21 CFR part 895 is revised to read as follows:

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

# PART 897—CIGARETTES AND SMOKELESS TOBACCO

209. The authority citation for 21 CFR part 897 is revised to read as follows:

**Authority:** 21 U.S.C. 352, 360, 360h, 360i, 360j, 371, 374, 393.

#### PART 898—PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES

210. The authority citation for 21 CFR part 898 is revised to read as follows:

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

#### PART 900—MAMMOGRAPHY

211. The authority citation for 21 CFR part 900 is revised to read as follows:

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

#### PART 1000—GENERAL

212. The authority citation for 21 CFR part 1000 is revised to read as follows:

Authority: 21 U.S.C. 360hh-360ss.

#### PART 1002—RECORDS AND REPORTS

213. The authority citation for 21 CFR part 1002 is revised to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 360hh-360ss, 371, 374.

#### PART 1003—NOTIFICATION OF **DEFECTS OR FAILURE TO COMPLY**

214. The authority citation for 21 CFR part 1003 is revised to read as follows:

Authority: 42 U.S.C. 263b-263n.

#### PART 1004—REPURCHASE, REPAIRS, OR REPLACEMENT OF ELECTRONIC **PRODUCTS**

215. The authority citation for 21 CFR part 1004 is revised to read as follows:

Authority: 42 U.S.C. 263b-263n.

#### PART 1005—IMPORTATION OF **ELECTRONIC PRODUCTS**

216. The authority citation for 21 CFR part 1005 is revised to read as follows:

Authority: 42 U.S.C. 263d, 263h.

#### PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

217. The authority citation for 21 CFR part 1010 is revised to read as follows:

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

### PART 1020—PERFORMANCE STANDARDS FOR IONIZING **RADIATION EMITTING PRODUCTS**

218. The authority citation for 21 CFR part 1020 is revised to read as follows:

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

#### PART 1030—PERFORMANCE STANDARDS FOR MICROWAVE AND RADIO FREQUENCY EMITTING **PRODUCTS**

219. The authority citation for 21 CFR part 1030 is revised to read as follows:

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

### PART 1040 —PERFORMANCE STANDARDS FOR LIGHT-EMITTING **PRODUCTS**

220. The authority citation for 21 CFR part 1040 is revised to read as follows:

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

### PART 1050—PERFORMANCE STANDARDS FOR SONIC, INFRASONIC, AND ULTRASONIC RADIATION-EMITTING PRODUCTS

221. The authority citation for 21 CFR part 1050 is revised to read as follows:

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

#### **PART 1210—REGULATIONS UNDER** THE FEDERAL IMPORT MILK ACT

222. The authority citation for 21 CFR part 1210 is revised to read as follows: Authority: 21 U.S.C. 141-149.

#### PART 1220—REGULATIONS UNDER THE TEA IMPORTATION ACT

223. The authority citation for 21 CFR part 1220 is revised to read as follows:

Authority: 21 U.S.C. 41-50; 19 U.S.C.

#### PART 1230—REGULATIONS UNDER THE FEDERAL CAUSTIC POISON ACT

224. The authority citation for 21 CFR part 1230 is revised to read as follows: Authority: 15 U.S.C. 1261-1276.

### PART 1240—CONTROL OF **COMMUNICABLE DISEASES**

225. The authority citation for 21 CFR part 1240 is revised to read as follows:

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

#### PART 1250—INTERSTATE **CONVEYANCE SANITATION**

226. The authority citation for 21 CFR part 1250 is revised to read as follows:

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

#### PART 1270—HUMAN TISSUE INTENDED FOR TRANSPLANTATION

227. The authority citation for 21 CFR part 1270 is revised to read as follows:

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

Dated: September 12, 1997.

### William K. Hubbard,

Associate Commissioner for Policy Coordination.

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