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CHANGES APRIL 2, 2001 THROUGH MARCH 29, 2002

TITLE 20 Chapter V—Con.

655.731 Introductory text, (a) and (b)(1) amended **63302**
655.732 Introductory text amended **63302**
655.733 Introductory text amended **63302**
655.734 Introductory text and (b) amended; (a)(3) revised **63302**
655.736 (e) amended **63302**
655.740 (a)(1) amended; (a)(2)(i) and (ii) revised **63302**
655.750 (a) revised **63302**
655.760 (a)(1) revised **63302**
655.805 (d) revised **63302**
656 Authority citation revised **40590**
656.21 (i)(6) added **40590**

Proposed Rules:

200 ..... **46408**
217 ..... **59548**
260 15127
320 15127
345 2157
404 ..... **43136, 57009, 59306, 63634**
416 ..... **38963**
422 ..... **43136**
436 3266
439 3266
655 ..... **49328, 49329, 53745, 53746**

TITLE 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health and Human Services (Parts 1—1299)

1 Nomenclature change **56034**
Authority citation revised **65447**
1.101 Added **65447**
5 Revised **30993**
Nomenclature change **56034**
10 Nomenclature change **56034**
10.20 (f) amended **66742**
10.50 (c)(7) removed 4906
14.75 Regulation at 66 FR 1259 withdrawn **20401**
16.1 (b)(2) amended 5467
20.100 (c)(30) removed; (c)(31) through (41) redesignated as (c)(30) through (40) 13717
50 Authority citation revised **20597**
50.1 (a) amended; interim **20597**
50.3 (b)(23), (24), (25) and (n) through (s) added; interim **20597**
50.50—50.56 (Subpart D) Added; interim **20598**
56 Authority citation revised **20599**
56.101 (a) amended; interim **20599**
56.102 (b)(21), (22) and (23) added; interim **20599**
56.108 OMB number 9585
56.109 (h) added; interim **20599**
56.111 (c) added; interim **20599**
56.115 OMB number 9585
58.35 OMB number 9585
58.63 OMB number 9585
58.90 OMB number 9585
58.105 OMB number 9585
58.120 OMB number 9585
58.130 OMB number 9585
58.190 OMB number 9585
60.24 OMB number 9585
60.30 OMB number 9585
60.40 OMB number 9585
70 Nomenclature change **56034**
71 Nomenclature change **56034**
73 Nomenclature change **56034, 66742**
80 Nomenclature change **56034**
100 Nomenclature change **56034**
101 Policy statement **30311**
Comment period reopened **50824**
Nomenclature change **56034, 66742**
101.69 OMB number 9585
102 Nomenclature change **56034**
106 Nomenclature change **56034**
107 Nomenclature change **56034**
107.10 OMB number 9585
107.20 OMB number 9585
107.50 OMB number 9585
107.280 OMB number 9585
108 Nomenclature change **56034**
109 Nomenclature change **56034**
110 Nomenclature change **56034**
130 Nomenclature change **56034**
151 Regulation at 66 FR 3458 eff. date delayed **42415**
161 Nomenclature change **56034**
165 Nomenclature change **56034**
165.110 (b)(1)(ii) revised **35373**
170 Nomenclature change **56034**
172 Nomenclature change **56034, 66742**
172.615 (a) table amended **38153**
(a) table corrected **53711**
172.892 (i) introductory text revised; (i) table amended **17509**
173 Nomenclature change **56034, 66742**
173.115 Added **27022**
173.325 (b)(1)(iii), (iv) and (v) amended **22922**
(f) redesignated as (g); new (f) added **31841**

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173.368 Added **33830**
(d) corrected 271
173.370 (b) and (c) revised **48208**
175 Nomenclature change **56034**
176 Nomenclature change **56034**
177 Nomenclature change **56034, 66742**
178 Nomenclature change **56034, 66742**
179.21 (a)(4), (b)(1)(iii) and (2)(iv) added **18539**
179.25 OMB number 9585
180 Nomenclature change **56034**
181 Nomenclature change **56034**
184 Nomenclature change **56034, 66742**
189 Nomenclature change **56034**
190 Nomenclature change **56034**
201.10 (a) amended 4906
201.16 Revised 4906
201.100 (b)(1) amended 4906
201.120 (b)(2) amended 4906
201.122 Introductory text amended 4906
201.306 (b)(1) amended 4906
203.3 Regulation at 64 FR 67761 eff. date delayed in part to 4–1–03 6645
203.50 Regulation at 64 FR 67761 eff. date delayed to 4–1–03 6645
207 Authority citation revised **59156**
207.3 (a)(5) revised; (a)(11) added **59156**
207.7 (a) revised **59156**
207.10 Heading and introductory text revised **59156**
207.20 (a) and (c) revised **59157**
207.21 (a) revised **59157**
207.37 (a) introductory text and (b) revised **59157**
207.40 Revised **59157**
211 Nomenclature change **56034**
211.198 (a) amended; interim 5056
226.1 Existing text redesignated as (a); (b) added; interim 5056
250.100 (b) amended 4906
250.101 (b) amended 4906
250.105 Amended 4906
250.108 (c)(1) and (2) amended 4906
250.201 (d) amended 4906
250.250 (c)(1) and (4)(i) amended 4906
290.1 Added 4906
290.2 Added 4907
310 Technical correction **53088**
310.103 (a)(3)(i) amended 4907
310.305 OMB number 9585
310.545 (a)(6)(iv)(D) and (d)(33) added; (d) introductory text revised **49277**
312.7 OMB number 9585
312.10 OMB number 9585
312.23 OMB number 9585
312.30 OMB number 9585
312.31 OMB number 9585
312.32 OMB number 9585
312.33 OMB number 9585
312.35 OMB number 9585
312.36 OMB number 9585
312.38 OMB number 9586
312.41 OMB number 9586
312.44 OMB number 9586
312.45 OMB number 9586
312.47 OMB number 9586
312.53 OMB number 9586
312.55 OMB number 9586
312.56 OMB number 9586
312.57 OMB number 9586
312.59 OMB number 9586
312.62 OMB number 9586
312.64 OMB number 9586
312.66 OMB number 9586
312.70 OMB number 9586
312.110 OMB number 9586
312.120 OMB number 9586
312.140 OMB number 9586
312.160 OMB number 9586
314.50 OMB number 9586
314.70 OMB number 9586
314.71 OMB number 9586
314.72 OMB number 9586
314.80 OMB number 9586
314.90 OMB number 9586
314.126 OMB number 9586
314.200 OMB number 9586
314.420 OMB number 9586
329 Removed 4907
330.10 Amended 3073
330.13 (e) added 3074
330.14 Added 3074
333 Technical correction 11571
333.210 (g) added 5943
341 Policy statement **49276**
341.14 (a)(2) amended 4907
352 Stayed **67485**
361.1 (f)(1) amended 4907
369.22 Removed 4907
510.300 Removed; interim 5056
510.302 Removed; interim 5057
510.455 OMB number 9586
510.600 (c)(1) table and (2) table amended ... **17510, 22117, 22118, 23588, 32739, 36162, 43773, 46367, 46368, 46519, 47960, 56035, 63163, 63164, 63500, 66742**
(c)(1) table amended 13717

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514 Authority citation revised 5057
514.1 OMB number 9586
514.3 Added; interim 5057
514.8 (a)(1), (5), and (ix) amended; (a)(6) revised; interim 5057
514.11 (a) amended; interim 5057
514.15 (b) amended; interim 5057
514.80 Added; interim 5057
520.48 Revised **47960**
520.309 (a) amended; (d) revised **63165**
(a) amended; (d)(1) revised 6866
520.445b (b) and (d)(4)(iii)(C) amended **35898**
520.905a (b) amended **47960**
520.905b (b) amended **47960**
520.905c (b) amended **47960**
520.905d (b) amended **47960**
520.905e (b) amended **47960**
520.1010 Revised **47960**
520.1010a Removed **47961**
520.1010b Removed **47961**
520.1010c Removed **47961**
520.1193 Revised 11230
520.1195 (b), (c)(2) and (3) amended; (c) heading and (1) revised **63166**
520.1196 (b) amended **35756**
520.1310 (a) and (d) revised **46369**
520.1660d (d)(1)(ii)(A)(*3*), (B)(*3*), (C)(*3*) and (iii)(C) amended **21282**
(d)(1)(iii)(C) amended **29020**
(a)(9), (d)(1)(ii)(A)(*3*), (B)(*3*), (C)(*3*) and (iii)(C) amended **58935**
(a)(6), (d)(1)(ii)(A)(*3*), (B)(*3*), (C)(*3*) and (iii)(C) amended 5469
520.1840 (a), (b) and (c) revised **47963**
520.1855 Added **43774**
520.2095 Removed **21282**
520.2460 Removed **22117**
520.2460a Removed **22117**
520.2460b Removed **22117**
520.2520a Removed **23588**
522.313 Heading revised; (d)(8) added **21283**
(d)(1)(i) amended **32540**
522.575 (b) amended **46705**
522.840 (b) amended **56035**
522.955 Section heading, (a), (d)(1)(i), (ii) and (iii) revised 6866
522.970 (d) redesignated as (e); new (d) added; (a), (b), new (e)(1)(i), (iii), (2)(i) and (iii) revised 9400
522.1010 Revised **47961**
522.1081 (b) removed **22117**
522.1183 (c) removed **22117**
522.1258 Removed **23588**
522.1451 Added **35756**
522.1660 (d)(1)(iii) amended 12471
522.1680 (b) amended **22117**
522.1704 (b) removed **23588**
522.1884 (c) amended; (d)(2)(iv) removed **23589**
522.2095 Removed **21282**
522.2120 (b) amended **22118**
522.2476 Revised **47961**
522.2477 (b) revised **47961**
(d)(2)(i)(C) added 5724
522.2640b Revised **22117**
522.2680 (a), (d)(1)(i), (2)(i), (3)(i) and (ii) revised; (d)(4) added 6867
524.321 Revised **22117**
524.390c Removed **42731**
524.402 Revised 8860
524.520 (b) amended **46706**
524.1193 (b) and (e)(2) amended **63165**
524.1451 (d) redesignated as (e); new (d) added; new (e)(2) revised; new (e)(3) amended **46370**
524.2140 Removed **42731**
524.2620 (a)(2) amended **46369**
524.2640 Removed **22117**
529.40 Added 7072
529.360 Removed **22117**
529.1186 (b) amended **17510**
530.41 (a)(7) and (8) amended 5471
556.163 Revised **35544**
556.175 Redesignated as 556.185 .....**62917**
556.185 Redesignated from 556.175; (b)(1) revised; (b)(2) added **62917**
556.347 Revised **19854**
556.428 Revised **23589**
556.500 (b) revised **46370**
556.594 Removed **21282**
556.760 (a) and (b) redesignated as (b)(1) and (2); new (b)(1) revised; (a) added 6867
558.4 (d) amended **21862**
558.55 (d)(2) table amended **20083, 20402**
(d)(2)(iii) table amended **47962**
558.58 (d)(1) table amended; (d)(1)(v) removed **46519**
(d)(1)(iii) table amended **46706, 47963**
(d)(1)(ii) table and (iii) table amended **47962**
558.62 (c)(1) table amended **57873**
558.76 (d)(1)(iv) table amended **46706**
558.78 (a)(1) revised; (a)(2) removed; (a)(3) redesignated as

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(a)(2); (d)(1) table and (2)(ii) amended **46706**
558.95 (d)(5)(iv) and (v) amended **27022**
(d)(1)(x) removed; (d)(1)(xi)(*b*), (xii)(*b*) and (xiv)(*b*) amended **46706**
(a)(1), (2), (5), (d)(1)(vi)(*b*), (vii)(*b*), (xi)(*b*) and (xii)(*b*) amended **47962**
558.108 (b) and (d)(1) amended; (d)(2) added **62917**
558.115 (a) amended **47963**
558.120 (d)(1)(iii)(*b*) amended **46706**
558.128 (a) revised; (d)(1) table and (2) amended **46706**
(a)(1) and (d)(1) table amended **47963**
558.140 (a) amended **46706**
558.145 (a)(1) and (2) amended **46706**
558.155 (a)(1) and (2) amended **46706**
558.195 (d) table amended **46706**
558.198 (d)(1)(iii) table amended **47962**
(d)(1)(iv) table and (v) table amended **47963**
(b) and (d)(1) amended; (d)(2) added **62917**
558.258 (a) amended **47962**
Revised **58935**
558.265 (a) amended **47962**
558.274 (a)(5) removed; (a)(7), (c)(1)(i) and (ii) amended **22118**
(a)(2), (4) and (c)(1) table amended; (a)(3) removed **23589**
558.305 (a) amended **46706**
558.311 (e)(1) table amended **29020**
(e)(1) table amended **46371**
(b) and (e) amended **46706**
(d)(7) added; (e)(1) table, (2)(iv) and (3)(iv) amended; (e)(1)(ix), (xii), (2)(iii) and (3)(iii) revised **47076**
(b)(2) and (e)(1)(xv) amended **47963**
558.340 (a) amended **46706**
558.355 (b)(8), (9), (f)(1)(iv)(*b*), (v)(*b*), (xiv)(*b*), (xv)(*b*) and (xvi)(*b*) amended **46706**
(b)(5), (12), (f)(1)(xiii)(*b*), (xx)(*b*), (xxi)(*b*), (xxii)(*b*) and (2)(iv)(*b*) amended **47963**
(b)(10), (f)(2)(v)(*b*), (vi)(*b*) amended **47962**
(f)(3)(v)(*a*) revised **63500**
558.360 (a) amended **47963**
558.363 (d)(1)(xii) added **27022**
(a)(7) and (d)(1)(x)(B) amended **46706**
(a)(4), (5), (d)(1)(vii)(B), (xii)(B) amended **47962**
558.365 (d)(1)(ii) and (iii) removed; (d)(1)(i)((*a*) and (*b*) redesignated as new (d)(1)(ii) and (iii) **45167**
558.366 (c) table amended **46706, 47962**
(a) revised; (b) and (c) redesignated as (c) and (d); new (b) added; (d) table amended **63500**
558.435 (a) amended **47963**
558.450 (a)(1), (d)(1) table and (2) table amended **32740**
(d)(1) Table 1 amended **47963**
(d)(1)(iv) table and (vi) table amended **45167**
558.460 (b) amended **47963**
558.465 (a) amended **47963**
558.485 (a), (b) and (d)(1) revised **47963**
558.500 (d)(1) revised **21284**
558.515 (a) and (d) amended **46706**
(d) table amended **47963**
558.550 (a)(1), (d)(1) and (3) amended; (a)(3) removed **46707**
(d)(1)(x)(*c*) and (xii)(*c*) amended **47964**
(a)(2), (d)(1)(xv)(*c*) and (xvi)(*c*) amended **47962**
558.555 (a) revised; (c) removed; (b) redesignated as new (c); new (b) added; (d) amended **47964**
558.575 (a)(1) and (2) amended **46707**
558.582 (a) amended **46707**
558.600 (c)(4)(ii) amended **46707**
Revised 7268
558.625 (f)(2)(vii) added **21284**
(b)(2), (13) and (73) removed **22117**
(b)(16), (19) and (34) removed; (b)(79) amended **22118**
(b)(17) removed **23589**
(b)(9) removed **36162**
(b)(25) amended **47964**
558.630 (b)(8) amended **22118**
(b)(4) removed; (b)(10) amended **23589**
(b)(10) amended **36162**
558.635 (a)(1) amended **47964**
558.680 (a), (b) and (c) redesignated as (b), (c) and (d); new (a) added; new (b) revised; (d)(1) table amended 6868

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579.22 Heading, introductory text and (b) revised **18540**
606.3 (j) revised **40889**
606.100 (b)(20) added **31176**
606.121 (e)(5)(ii) revised; (g) removed; (h)(2) and (3) amended **31162**
(c)(8)(i) revised 4907
606.151 (b) and (c) revised **40889**
606.160 (b)(1)(ix), (x) and (xi) added **31176**
606.170 OMB number 9586
607 Authority citation revised **59158**
607.3 (b) and (e) revised; (j) added **59158**
607.7 (b) and (c) revised **59158**
607.20 (a) revised **59158**
607.22 Revised **59158**
607.25 (a) amended; (b)(3) revised **59158**
607.26 Amended **59158**
607.31 Revised **59158**
607.35 (a) revised **59159**
607.37 (a) introductory text and (b) revised **59159**
607.40 Revised **59159**
607.65 (g) removed **31162**
Introductory text revised **59159**
610.2 OMB number 9587
610.12 OMB number 9587
610.13 OMB number 9587
610.18 OMB number 9587
610.40—610.47 (Subpart E) Heading revised **31162**
610.40 Revised **31162**
610.41 Revised **31164**
610.42 Added **31164**
610.44 Added **31164**
610.45 Removed **31165**
610.60 (a)(6) amended 4907
610.61 (s) amended 4907
630 Added **31176**
640.2 (d) removed **31165**
(b) revised **40889**
OMB number 9587
640.3 (c)(1) revised **40889**
640.4 (g) introductory text, (1), (2), (4) and (5) revised **40889**
640.5 (f) revised **31165**
Introductory text and (c) revised **40889**
640.14 Amended **31165**
640.15 Revised **40890**
640.16 (a) revised **40890**
640.23 (a) amended **31165**
640.24 (b) revised **40890**
640.33 (a) amended **31165**
640.34 (a) through (d) and (e)(1) revised **40890**
640.53 (a) amended **31165**
640.54 (a)(2) revised **40890**
640.63 (c)(11) revised **40890**
640.67 Revised **31165**
640.70 (a)(2) revised **31165**
640.72 OMB number 9587
660.20 Regulation at 65 FR 77499 confirmed **20402**
660.21 Regulation at 65 FR 77499 confirmed **20402**
OMB number 9587
660.22 OMB number 9587
660.25 OMB number 9587
660.26 OMB number 9587
660.28 OMB number 9587
660.34 OMB number 9587
660.35 OMB number 9587
660.36 OMB number 9587
660.42 Removed **31165**
660.50 Regulation at 65 FR 77499 confirmed **20402**
660.51 Regulation at 65 FR 77499 confirmed **20402**
OMB number 9587
660.52 OMB number 9587
660.53 OMB number 9587
660.54 OMB number 9587
660.55 OMB number 9587
680.1 OMB number 9587
680.2 OMB number 9587
680.3 OMB number 9587
701 Nomenclature change **56034**
720.6 OMB number 9587
803.3 (f) and (r)(2)(ii) revised; second (ee) redesignated as (ff) **23156**
803.10 (b) revised; (c)(5) removed **23157**
803.17 (b)(3) revised **23157**
803.19 (a)(2) revised **23157**
803.20 (a) introductory text, (2) and (c)(1) revised **23157**
803.50 (b)(1)(i) and (2) revised **23157**
803.52 (d)(1), (f)(11)(i) and (ii) revised **23157**
803.58 (b)(3) removed; (b)(4), (5) and (6) redesignated as new (b)(3), (4) and (5) **23157**
807 Authority citation revised **59159**
807.3 (b) and (r) revised **59159**
807.20—807.39 (Subpart B) Heading revised **59160**
807.20 (a) revised **59160**

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807.25 (a) amended **59160**
807.40 Revised **59160**
807.65 Introductory text revised **59160**
809.20 (b) revised **31165**
814.20 OMB number 9587
814.39 OMB number 9587
814.84 OMB number 9587
821.1 (a) and (b) revised; (c) removed; (d) and (e) redesignated as new (c) and (d) (OMB number pending) 5951
821.2 (d) removed (OMB number pending) 5951
821.3 (b) and (f) revised (OMB number pending) 5951
821.20 Revised (OMB number pending) 5951
821.25 (a)(2) introductory text, (iii), (3) introductory text and (iv) revised (OMB number pending) 5951
821.30 (b)(3) and (c)(1)(ii) amended (OMB number pending) 5952
821.55 (a) and (b) redesignated as (b) and (c); new (a) added (OMB number pending) 5952
862.1190 (b) revised **38787**
862.1210 (b) revised **38787**
862.1255 (b) revised **38787**
862.1290 (b) revised **38787**
862.1305 (b) revised **38787**
862.1320 (b) revised **38787**
862.1365 (b) revised **38787**
862.1380 (b) revised **38787**
862.1420 (b) revised **38788**
862.1470 (b) revised **38788**
862.1490 (b) revised **38788**
862.1515 (b) revised **38788**
862.1565 (b) revised **38788**
862.1575 (b) revised **38788**
862.1640 (b) revised **38788**
862.1670 (b) revised **38788**
862.1720 (b) revised **38788**
862.1815 (b) revised **38788**
862.2050 (b) revised **38788**
862.2100 (b) revised **38788**
862.2230 (b) revised **38788**
862.2310 (b) revised **38788**
862.2320 (b) revised **38788**
862.2485 (b) revised **38788**
862.2720 (b) revised **38788**
862.2800 (b) revised **38788**
862.2920 (b) revised **38788**
864.1850 (b) revised **38789**
864.2220 (a) revised **27024**
(b) revised **38789**
864.2240 (b) revised **38789**
864.2260 (b) revised **38789**
864.2360 (b) revised **38789**
864.2800 (b) revised **38789**
864.2875 (b) revised **38789**
864.3010 (b) revised **38789**
864.3300 (b) revised **38789**
864.3400 (b) revised **38789**
864.3600 (b) revised **38789**
864.3800 (b) revised **38789**
864.3875 (b) revised **38789**
864.4010 (b) revised **38789**
864.4400 (b) revised **38789**
864.5220 Revised 1607
864.5350 (b) revised **38789**
864.5800 (b) revised **38790**
864.5850 (b) revised **38790**
864.6160 (b) revised **38790**
864.6600 (b) revised **38790**
864.6700 (b) revised **38790**
864.7660 (b) revised **38790**
864.7675 (b) revised **38790**
864.7900 (b) revised **38790**
864.8200 (b) revised **38790**
864.8500 (b) revised **38790**
864.8540 (b) revised **38790**
866.2050 (b) revised **38790**
866.2120 (b) revised **38790**
866.2160 (b) revised **38790**
866.2170 (b) revised **38790**
866.2180 (b) revised **38790**
866.2300 (b) revised **38790**
866.2320 (b) revised **38790**
866.2330 (b) revised **38791**
866.2350 (b) revised **38791**
866.2360 (b) revised **38791**
866.2440 (b) revised **38791**
866.2450 (b) revised **38791**
866.2480 (b) revised **38791**
866.2500 (b) revised **38791**
866.2540 (b) revised **38791**
866.2580 (b) revised **38791**
866.2600 (b) revised **38791**
866.3010 (b) revised **38791**
866.3020 (b) revised **38791**
866.3035 (b) revised **38791**
866.3065 (b) revised **38791**
866.3125 (b) revised **38791**
866.3205 (b) revised **38791**
866.3250 (b) revised **38791**
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1308.35 Undesignated center heading and section added **51544**
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1309.22 (b) revised; eff. 4–29–02 14860
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1310.03 (c) added; eff. 4–29–02 14861
1310.04 Regulation at 65 FR 47316 confirmed **42944**
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1310.05 (e) added; eff. 4–29–02 14862
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1310.08 Regulation at 65 FR 47316 confirmed **42944**
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1310.09 (d) added **52675**
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41.12 Table amended **32742**
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41.24 (a) revised; interim 1414