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CHANGES APRIL 1, 1997 THROUGH JANUARY 30, 1998

TITLE 21—FOOD AND DRUGS

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

Chapter I Comment response **49881**
1 Authority citation revised **51512**
1.31 Removed **39440**
1.35 Removed **39440**
2 Authority citation revised **51512**
3 Authority citation revised **51512**
5 Authority citation revised **51512**
5.10 (a)(38) added **28628**
(a)(39) added **33349**
5.20 (f)(4) added **48757**
5.22 (a)(10)(i), (ii), (iv) and (v) revised **67270**
5.23 (c)(1) and (4) revised **67270**
5.25 (a)(2) and (b) revised **67270**
5.26 (c) revised **67270**
5.28 Revised **67270**
5.30 (b) and (c)(4) revised **67270**
5.31 (h) added **19493**
(c)(3) and (e)(5) revised **67271**
5.33 (b) revised **67271**
5.37 (a)(2)(i), (ii) and (iii) and (b)(1), (2) and (3) revised; (a)(2)(iv) and (b)(4) removed **67271**
5.40 Added **43471**
5.45 (b) introductory text, (c)(1), (2) and (e)(1)(i), (ii) and (iii) revised **67271**
5.46 Revised **67271**
5.47 (a)(1) and (2) revised **67271**
5.49 (a) revised **67271**
5.50 (a) revised **67271**
5.51 (a)(1) and (b)(1) revised **67271**
5.52 (a) revised **67271**
5.53 (a)(1), (b)(1)(i) and (c) revised **67271**
5.54 (a) revised **67272**
5.55 (a) revised **67272**
5.56 (a) and (b) revised **67272**
5.57 (a), (b) and (c) revised **67272**
5.59 (a)(1) revised **67272**
5.60 (a)(1) through (4) and (6) redesignated as (b)(1) through (5) **67272**
5.78 (b) revised **67272**
5.86 (a) and (b) revised; (c) removed **67272**
5.87 (a) and (b) revised; (c) removed **67272**
5.88 Revised **67272**
5.89 (a) introductory text and (b) introductory text revised **67272**
5.90 Revised **67273**
5.91 Revised **67273**
5.92 Revised **67273**
5.100 Added **48757**
7 Authority citation revised **51512**
10 Technical correction **47760**
Authority citation revised **51512**
10.30 (b) amended **40592**
10.40 (b)(1)(ix) revised **40592**
11 Authority citation revised **51512**
12 Authority citation revised **51512**
13 Authority citation revised **51512**
14 Authority citation revised **51512**
15 Authority citation revised **51512**
16 Authority citation revised **51513, 55976,**
Authority citation corrected **60614**
16.1 (b)(2) amended **40444**
(b)(2) amended; eff. 4–28–99 ..... **55976**
17 Authority citation revised **51513**
19 Authority citation revised **51513**
20 Technical correction **47760**
Authority citation revised **51513**
20.100 (c)(3) revised **40592**
20.112 (a) amended; eff. 4–6–98 ..... **52249**
21 Authority citation revised **51513**
25 Revised **40592**
Technical correction **47760**
Authority citation revised **51513**
50 Meeting **46198**
Authority citation revised **51513**
50.3 (j) removed; (k) through (n) redesignated as (j) through (m) **39440**
50.21 Removed **39440**
50.40—50.48 (Subpart C) Removed **39440**
56 Meeting **46198**
Authority citation revised **51513**
58 Authority citation revised **51513**
60 Authority citation revised **51513**
70 Authority citation revised **51513**
71 Technical correction **47760**
Authority citation revised **51513**
71.1 (c) amended **40598**
73 Authority citation revised **51513**
74 Authority citation revised **51513**
74.2101 (a) correctly revised; CFR correction **15389**
80 Authority citation revised **51513**
81 Authority citation revised **51513**
82 Authority citation revised **51513**
100 Authority citation revised **51513**

NOTE: **Boldface page numbers indicate 1997 changes.**

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101 Technical correction.....**47760, 55331**
Authority citation revised.....**51513**
101.2 (b) and (f) amended; (c)(1), (2), (3) and (5)(iii) removed; (c)(5)(iv) redesignated as (c)(5)(iii); (c)(4) and (5) redesignated as (c)(1) and (2).....**43074**
(b), (d)(1) and (f) revised; eff. 3–23–99.....**49847**
101.3 (g) added; eff. 3–23–99.....**49847**
101.4 (a)(1) revised; (g) and (h) added; eff. 3–23–99.....**49847**
(h)(1) corrected.....**64634**
101.8 Removed.....**43074**
101.9 (k)(2) and (5) removed; (k)(3), (4) and (6) redesignated as (k)(2), (3) and (4); (c)(8)(iii), (v), (d)(7)(i), (j)(6) and new (k)(4) revised; eff. 3–23–99.....**49848**
101.12 (h)(12) revised.....**40598**
(b) Table 2 amended; eff. 3–23–99.....**49848**
(b) Table 2 amended; eff. 1–1–00.....**63653**
(b) Table 2 corrected.....**66275**
101.13 (j)(1)(i)(B) amended.....**31339**
(a) and (b) introductory text revised; (q)(3) redesignated as (q)(3)(i); (q)(3)(ii) added; eff. 3–23–99.....**49867**
101.14 (a)(4) removed; (a)(5) and (6) redesignated as new (a)(4) and (5); (b)(3)(i) and (d)(3) revised; eff. 3–23–99.....**49867**
101.29 Removed.....**43074**
101.36 Revised; eff. 3–23–99.....**49849**
101.54 (e)(1) introductory text and (2) introductory text amended.....**31339**
(b)(1), (c)(1) and (e)(1) introductory text revised; eff. 3–23–99.....**49867**
Heading revised; (f) and (g) added; eff. 3–23–99.....**49880**
101.60 (c)(1)(iii)(A) revised; eff. 3–23–99.....**49881**
101.65 (d)(2)(ii)(C) and (4)(ii)(B) stayed; eff. 4–1–97 through 1–1–00.....**15391**
(b)(4) revised; eff. 3–23–99.....**49858**
101.69 (h) revised; (m)(1), (n)(1) and (o)(1) amended.....**40598**
101.70 (j)(4) added.....**28232**
(f) amended.....**40599**
101.80 (c)(2)(ii)(B) revised.....**63655**
101.93 (b) through (e) added; eff. 3–23–99.....**49867**
Added.....**49886**
102 Authority citation revised.....**51513**
105 Authority citation revised.....**51513**
106 Authority citation revised.....**51513**
107 Authority citation revised.....**51513**
108 Authority citation revised.....**51513**
109 Authority citation revised.....**51514**
110 Authority citation revised.....**51514**
111 Authority citation revised.....**51514**
113 Authority citation revised.....**51514**
113.40 (b)(10)(ii) amended.....**31722**
114 Authority citation revised.....**51514**
123 Authority citation revised.....**51514**
129 Authority citation revised.....**51514**
130 Authority citation revised.....**51514**
131 Authority citation revised.....**51514**
133 Authority citation revised.....**51514**
135 Authority citation revised.....**51514**
136 Authority citation revised.....**51514**
137 Authority citation revised.....**51514**
139 Authority citation revised.....**51514**
145 Authority citation revised.....**51514**
146 Authority citation revised.....**51514**
150 Authority citation revised.....**51514**
152 Authority citation revised.....**51514**
155 Authority citation revised.....**51514**
156 Authority citation revised.....**51514**
158 Authority citation revised.....**51514**
160 Authority citation revised.....**51514**
161 Authority citation revised.....**51514**
163 Authority citation revised.....**51514**
164 Authority citation revised.....**51514**
165 Authority citation revised.....**51514**
165.110 (b)(4)(i)(A) table corrected; CFR correction.....**36460**
166 Authority citation revised.....**51515**
168 Authority citation revised.....**51515**
169 Authority citation revised.....**51515**
170 Technical correction.....**47760**
Authority citation revised.....**51515**
170.35 (c)(1)(viii) revised.....**40599**
170.39 (c)(6) and (e) amended.....**40599**
171 Technical correction.....**47760**
Authority citation revised.....**51515**
171.1 (c) amended.....**40599**
172 Authority citation revised.....**51515**
172.712 Added.....**26228**
172.841 (c) revised.....**30985**
173 Authority citation revised.....**51515**
173.150 (a)(5) added.....**59284**
174 Authority citation revised.....**51515**
175 Authority citation revised.....**51515**
175.105 (c)(5) table amended.....**33996, 39937**

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175.125 (a)(7) added; (b)(1) revised 3463
175.300 (b)(3)(viii)(*b*) **43076**
176 Authority citation revised **51515**
176.170 (a)(5) table amended **39939**
176.200 (d)(3) table amended **39772**
177 Authority citation revised **51515**
177.1345 (d) amended **34628**
177.1395 (b)(4) table amended **53958**
177.1500 (c) redesignated as (d); new (c) added; new (d)(5)(ii) amended **22886**
177.1520 (b) table corrected; CFR correction **42050, 49908**
178 Authority citation revised **51515**
178.2010 (b) table amended ...**29009, 30455, 34629, 34630, 36983, 39441, 41272**
178.3130 (b) table amended **31511**
178.3297 (e) table amended **19221, 25476**
(e) table amended 3464
178.3400 (c) table amended **33997, 42051**
179 Authority citation revised **51515**
Effective date confirmation **64102**
179.26 (b) table amended **64121**
180 Authority citation revised **51515**
181 Authority citation revised **51515**
182 Authority citation revised **51515**
184 Authority citation revised **51515**
184.1472 Revised **30756**
186 Authority citation revised **51515**
189 Authority citation revised **51515**
190 Added **49891**
200 Authority citation revised **51515**
201 Authority citation revised **51515**
201.57 (f)(10) added; eff. 8–27–98 ....**45325**
201.64 (a) through (h) stayed; (i) revised **19925**
202 Authority citation revised **51515**
205 Authority citation revised **51515**
206 Authority citation revised **51515**
207 Authority citation revised **51515**
210 Authority citation revised **51516**
211 Compliance date extension **40447**
Authority citation revised **51516**
211.1 (d) added **19497**
(d) removed **66522**
225 Authority citation revised **51516**
226 Authority citation revised **51516**
250 Authority citation revised **51516**
290 Authority citation revised **51516**
291 Authority citation revised **51516**
299 Authority citation revised **51516**
300 Authority citation revised **51516**
310 Authority citation revised **51516**
310.305 (a) and (f)(1) revised; (b)(5) and (c)(4) removed; (c)(5) and (6) redesignated as (c)(4) and (5); new (c)(4) amended **34167**
(a), (d)(2), (3) introductory text and (i) amended; (b), (c), (d)(1), (3)(ii) and (4) revised; eff. 4–6–98 ....**52249**
312 Meeting **46198**
Technical correction **47760**
Authority citation revised **51516**
312.20 (c) amended **32479**
312.23 (a)(7)(iv)(*e*) revised **40599**
312.32 (a), (b), (c)(1)(i), (2) and (d)(3) revised; (c)(3) and (e) amended; eff. 4–6–98 ....**52250**
312.70 (a) and (b) amended **46876**
314 Meeting **44891, 46198**
Technical correction **47760**
Authority citation revised **51516**
Clarification **63268**
314.50 (d)(1)(iii) revised **40599**
314.70 (g) added **39900**
314.80 (c)(1)(ii) removed; (c)(1)(iii) and (iv) redesignated as (c)(1)(ii) and (iii); (a), new (c)(1)(ii) introductory text, (d)(1) and (l) amended; (f)(1) revised **34168**
(a), (c) introductory text, (1), (f)(1), (3)(ii) and (4) revised; (b), (c)(2)(ii)(*b*), (d)(2), (f) heading, (2) and (3) amended; (j) removed; (k) and (l) redesignated as (j) and (k); eff. 4–6–98 ....**52251**
314.101 (d)(4) revised **40599**
314.110 (a)(3) and (b) amended **43639**
314.120 (a)(3) amended **43639**
314.440 (a)(3) amended **43639**
316 Authority citation revised **51516**
320 Authority citation revised **51516**
329 Authority citation revised **51516**
330 Authority citation revised **51516**
331 Authority citation revised **51516**
331.10 (a) correctly revised; CFR correction **52659**
332 Authority citation revised **51516**
333 Authority citation revised **51516**
336 Authority citation revised **51516**
338 Authority citation revised **51516**
340 Authority citation revised **51516**
341 Authority citation revised **51516**
344 Authority citation revised **51517**
346 Authority citation revised **51517**
347 Authority citation revised **51517**
348 Authority citation revised **51517**

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349 Authority citation revised **51517**
352 Announcement **23350**
355 Authority citation revised **51517**
357 Authority citation revised **51517**
358 Authority citation revised **51517**
361 Authority citation revised **51517**
369 Authority citation revised **51517**
429 Authority citation revised **51517**
430 Authority citation revised **51517**
431 Authority citation revised **51517**
432 Authority citation revised **51517**
433 Authority citation revised **51517**
436 Authority citation revised **51517**
436.215 (c)(16)(iv) and (18)(iv) corrected; CFR correction **52659**
440 Authority citation revised **51517**
441 Authority citation revised **51517**
442 Authority citation revised **51517**
443 Authority citation revised **51517**
444 Authority citation revised **51517**
446 Authority citation revised **51517**
448 Authority citation revised **51517**
449 Authority citation revised **51517**
450 Authority citation revised **51518**
452 Authority citation revised **51518**
453 Authority citation revised **51518**
455 Authority citation revised **51518**
460 Authority citation revised **51518**
500 Authority citation revised **51518**
500.80 (b) amended **66983**
501 Authority citation revised **51518**
502 Authority citation revised **51518**
509 Authority citation revised **51518**
510 Technical correction **23534**
Authority citation revised **51518**
Technical correction 408
510.515 (c) table corrected; CFR correction **52659**
510.600 Regulation at 62 FR 14300 eff. date corrected to 4–7–97 ..... **15751**
(c)(1) table and (2) table amended ... **22887, 27691, 29010, 34631, 35075, 38906, 39442, 40931, 48939, 55159, 60781, 61624, 61626, 62241, 63270**
511 Technical correction **47760**
Authority citation revised **51518**
511.1 (b)(10) revised **40599**
514 Technical correction **47760**
Authority citation revised **51518**
514.1 (b)(14) revised **40599**
514.8 (a)(1) amended **40600**
514.110 (b)(10) revised **40600**
514.111 (a)(9) revised **40600**
520 Authority citation revised **51518**
Technical correction 408
520.23 (a)(2) amended **35075**
520.82a (b) amended **61624**
520.82b (b) amended **61624**
520.100a (b) amended **63270**
520.100b (b) amended **63270**
520.100c (b) amended **63270**
520.222 (c) amended **61624**
520.300a (b) amended **63270**
520.300b (b) amended **63270**
520.300c (b) amended **63270**
520.390a (a)(2) amended **35076**
520.420c (a)(2) amended **63270**
520.445b (b) amended **27691, 35076, 60656**
520.447 (b) revised **46669**
520.462 (b) amended **63270**
520.580 (b)(2) amended **35076, 61624**
520.600 (c) amended **35076**
520.622a (a)(6) amended **35076**
520.622b (c)(2) amended **35076**
(a)(2) amended **38906**
520.622c (b)(6) amended **35076**
(b)(6) corrected **40932**
(b)(5) amended **61624**
520.763a (c) amended **35076**
520.763b (c) amended **35076**
520.763c (b) amended **35076**
520.784 (b) amended **61624**
520.804 (b) amended **63270**
520.812 (c) redesignated as (d); new (d) revised **38906**
520.863 (b) amended **61624**
520.1010a (b) amended **35076**
520.1044a (b) amended **34169**
520.1044b (b) amended **29011**
520.1044c (b) amended **29013**
520.1120a (c) amended **61624**
520.1120b (c) amended **61625**
520.1192 (b) amended **63270**
520.1193 (b) amended **63270**
520.1194 (b) amended **63270**
520.1195 (b) amended **63270**
520.1196 (b) amended **63270**
520.1197 (b) amended **63270**
520.1242a (c)(2) amended **61625**
520.1242b (c) amended **61625**
520.1242g (e) amended **55160**
(c) amended **61625**
520.1263c (b) amended **65020**
520.1320 (c) amended **61625**
520.1326a (b) amended **61625**
520.1326b (b) amended **61625**
520.1408 (b) amended **35076**
520.1446 Added **28629**
520.1451 Added **37713**

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520.1452 Added **42902**
520.1484 (b) and (c)(3) amended **55160**
520.1485 (d)(3) amended **60657**
520.1616 Added **29012**
(d)(1) heading and (iii) amended **61626**
520.1660d (a)(8) and (b)(6) added **23356**
(b)(3), (e)(1)(ii)(A)(*3*), (B)(*3*) and (C)(*3*) amended **35076**
520.1696b (b) amended **55160**
520.1720a (b)(1) amended **61625**
520.1720b (b) amended **61625**
520.1720c (b) amended **61625**
520.1805 (b) amended **61625**
520.1880 (a) amended 148
520.1900 (b) amended **35076**
520.2043 (b)(2) revised **37712**
520.2098 Added **34632**
(d) heading and (2) corrected **55159**
520.2170 (c) amended **63270**
520.2220a (b) amended **23357, 40932**
520.2220b (b)(3) amended **61625**
520.2220c (c) amended **61625**
520.2260b (f)(1) and (h)(1) amended **35076**
520.2325a (a)(4) added **37712**
520.2345d (a)(1), (d)(1)(iii) and (2)(iii) amended **35076**
(a)(1) amended **46668**
(a)(1), (4), (d)(1)(iii) and (2)(iii) amended **55160**
520.2362 (c) amended **61625**
520.2380a (c)(2) amended **63271**
520.2380b (c) amended **63271**
520.2380c (b) amended **63271**
520.2380d (b) amended **63271**
520.2380f (b) amended **63271**
520.2455 (b) amended **35076**
520.2456 (b) amended **35076**
520.2481 (b) amended **35076**
520.2610 (b) amended **61625**
520.2611 (b) amended **61625**
520.2612 (b) amended **61625**
520.2640 (e)(1)(iii), (2)(iii) and (3)(iii) amended **39443**
522 Authority citation revised **51518**
522.23 (c) amended **35076**
522.56 (b) amended **23357**
522.82 (b) amended **61625**
522.150 (b) amended **61625**
522.518 (b) amended **28630**
522.540 (a)(2) amended **37713**
522.770 (d)(2) revised **44410**
(d) heading revised; (d)(1), (2) and (3) redesignated as (d)(1)(i), (ii) and (iii); (d)(2) added **62242**
522.784 (b) amended **61625**
522.812 (c) redesignated as (d); new (d)(2) revised **38907**
522.863 (b) amended **61625**
522.970 (b) revised **22888**
522.1002 (b)(2) amended **62242**
522.1010 (b) amended **35076**
522.1044 (b)(3) amended **35076**
(b)(3) and (4) added **45157**
522.1044b (b) amended **22889**
522.1150 (b) amended **63271**
522.1155 (b) amended **61625**
522.1156 Added **66984**
522.1182 (b)(2)(i) amended **35076**
522.1183 (e)(1) amended **35076**
522.1192 (b) amended **63271**
522.1193 (b) amended **63271**
522.1222a (c) amended **22888, 35076**
522.1244 (b) amended **61625**
522.1410 (b) amended **35076**
522.1452 (b) amended **63271**
522.1503 (b) amended **61625**
522.1660 (c) redesignated as (d); new (d)(1) heading, new (ii), new (iii) and new (2)(ii) amended **27692**
522.1662a (a)(2), (g)(2) and (h)(2) amended **35076**
522.1680 (b) amended **35076, 38906**
522.1704 (a)(2) amended **61625**
522.1720 (b)(2) amended **38906**
(b)(1) amended **61625**
522.1850 (d) added **45158**
522.1885 (b) amended **63271**
522.2005 (b) amended **61625**
522.2220 (a)(2)(iii) added **23128**
(c)(2) amended **35076**
522.2424 (b) amended **35076**
522.2476 (b) amended **29013**
522.2477 (a) revised **28629**
522.2483 (b) amended **35077**
522.2610 (b)(2) corrected; CFR correction **41272**
(a)(2) amended **61625**
522.2640a (b)(2) amended **35077**
522.2662 (b) amended **35077**
522.2680 (b) amended **61625**
524 Authority citation revised **51518**
524.154 (a)(2) amended **61625**
524.155 (a)(1) amended **61626**
524.575 (c)(2) revised **48940**
524.770 Added **65753**

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524.814 Added **33997**
524.900 (e) amended **55161**
(c) amended **61626**
524.981a (b) amended **40932**
524.981b (b) amended **40932**
524.981c (b) amended **40932**
524.1193 (d)(2) amended **38908**
(b) amended **63271**
524.1240 (b) amended **61626**
524.1443 (b) revised **55161**
(b) amended **61626**
524.1484g (b) amended **63271**
524.1580b (b) amended **35077**
524.1580c (b) amended **35077**
524.1742 (b) amended **61626**
524.1883 (b) amended **63271**
526 Authority citation revised **51518**
529 Authority citation revised **51518**
529.50 (b) amended **23358**
529.1044a (b) amended **35077**
529.1115 (b) amended **29014**
530 Authority citation revised **51518**
530.41 Revised **27947**
556 Authority citation revised **51518**
556.52 Revised **40933**
556.75 Corrected **15391**
556.225 Revised **62242**
556.227 Added **33998**
556.273 Added **55161**
558 Technical correction **23534, 44892**
Authority citation revised **51518**
Technical correction 408
558.4 (d) table amended **25477, 60657**
558.55 (a) amended **63271**
558.58 (d)(1)(iii) table amended **60658, 61627**
(d)(1) table amended **63271, 66987**
558.78 (a) revised; (d)(1) table amended **55162**
558.95 (d)(1)(ii)(*b*), (iii)(*b*), (iv)(*b*), (v)(*b*) and (xiii)(*b*) amended **63271**
558.120 (c) redesignated as (d); new (d)(1)(iii)(*b*) amended **61011**
558.128 (a)(4) and (d)(1) table amended **27692**
(d)(1) table and (2) amended **61628**
558.155 (a)(1) and (2) amended **35077**
(a)(1) amended **67725**
(a)(2) amended 2307
558.175 (c)(1)(iii)(*b*) and (iv)(*b*) amended **61626**
(c) redesignated as (d); new (d)(1)(iv)(*b*) amended **61912**
(d)(1)(iii)(*b*) amended **62243**
558.195 (c)(2) added; (d) table amended **23129**
(d) amended **61626**
(d) table amended **66523, 67273**
(a) and (d) table amended **67725**
558.205 (a) amended **35077**
558.235 (a) amended **63271**
558.254 (c) amended **55161**
(a) amended **61626**
558.274 Regulation at 62 FR 14301 eff. date corrected to 4–7–97 ..... **15751**
(a)(7) and (c)(1) table amended **27692**
(a)(8), (c)(1)(i) table and (ii) table amended **55160**
558.300 (a)(1) and (2) amended **63271**
558.311 (e)(3)(i) table amended **28630**
(e)(1)(ii) table amended **61626**
(f)(1)(xv)(*b*) and (xvi)(*b*) amended **61912**
558.366 (a) and (c) table amended **29011**
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