

CHANGES APRIL 1, 1998 THROUGH FEBRUARY 26, 1999

TITLE 20 Chapter III—Con.

416.1599 (c) and (e) amended	41418
416.2010 (b)(1)(iii) amended; (b)(1)(iv) revised; (b)(1)(v) through (x) added	33849
422.103 (b)(3) and (c)(3) added; (e) revised	56554
422.104 (a)(3) and (b) revised	56554
422.105 Revised	56554
422.106 (a) revised; (b) removed; (c) redesignated as (b)	56555
422.107 (a) revised; (e) amended	56555
422.110 Revised	56555
422.701—422.710 (Subpart H) Added	57058

**Chapter V—Employment and
Training Administration, Depart-
ment of Labor (Parts 600—699)**

646 Added; interim	15988
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Proposed Rules:

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TITLE 21—FOOD AND DRUGS

**Chapter I—Food and Drug Ad-
ministration, Department of
Health and Human Services
(Parts 1—1299)**

2 Authority citation revised	398
2.10 (b)(2) revised	51299
3 Authority citation revised	26697
Authority citation revised	398
3.2 (k) amended; eff. 5–20–99	398
5 Effective date confirmation	48576
5.20 (h) revised	41960
5.22 (a)(10)(v) revised; (a)(10)(vi) added	4965
5.23 (c)(5) added	4965
5.31 (f)(2)(iii) and (iv) removed	26697
(f)(2)(v), (vi) and (vii) amended; eff. 5–20–99	398
5.33 (c) reinstated; CFR correc- tion	51299
5.37 (a)(2)(iv) and (b)(4) added	4965

5.53 (a)(1) and (b)(1)(i) revised	27207
5.70 Amended; eff. 5–20–99	398
5.73 Removed	26697
5.74 Removed	26697
5.75 Removed; eff. 5–20–99	398
5.76 Removed; eff. 5–20–99	398
5.78 Removed; eff. 5–20–99	398
5.83 Heading, (c)(1), (2) and (d) re- vised	70650
5.84 Heading, (a)(1) and (3) re- vised	70650
5.98 Revised	4965
5.200 Revised	18314
5.210 Revised	18317
5.215 Revised	18317
10 Authority citation revised	32735
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10.50 (c)(10) removed	26697
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10.55 (c) amended; eff. 5–20–99	398
10.75 (b) amended	32735
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(b) redesignated as (b)(1); new (b)(2) added	63982
10.80 (g) amended; eff. 5–20–99	398
12 Authority citation revised	399
12.20 (a) introductory text and (2)(i) amended; (c) removed; eff. 5–20–99	399
12.24 (b)(6) and (c) amended; eff. 5–20–99	399
12.87 (d) amended; eff. 5–20–99	399
16 Effective date confirmation	48576
Authority citation revised	64581
16.1 (b)(2) amended	26697
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(b)(2) amended; eff. 5–20–99	399
20 Authority citation revised	399
20.100 (c)(20) and (21) removed; eff. 5–20–99	399
20.117 (a)(3) amended; eff. 5–20–99	399
25 Effective date confirmation	48576
25.5 (b)(1) amended; eff. 5–20–99	399
25.31 (f) amended	26697
(f) and (h) removed; (g) and (i) through (l) redesignated as (f) and (g) through (j); eff. 5– 20–99	399
26 Added	60141
50 Authority citation revised	26697
Effective date confirmation	48576
Authority citation revised	399

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50.1 (a) amended.....	26697	101.14 (e)(3) amended.....	26980
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50.3 (b)(11) removed; (c) amended; eff. 5-20-99	399	(g)(7)(i)(B) corrected.....	63982
50.23 (d)(1) amended; eff. 5-20-99	399	101.36 (b)(3)(ii)(B), (C) and (iii) revised	30620
54 Effective date confirmation	48576	101.54 (d)(2) revised	26980
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54.2 (d) and (e) revised	72181	101.69 (c), (d), (l), (m)(4), (n)(3), (4), (o)(3) and (4) amended; (m)(3) revised; (m)(4)(iii) and (5) added	26719
54.4 (a) corrected	35134	(m)(3) and (4)(iii) corrected	40024
(a) amended; eff. 5-20-99	399	101.70 (j)(2) and (4)(ii) revised; (j)(3)(iii) added	26719
56 Authority citation revised.....	26698	(j)(3)(iii) corrected	40024
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56.101 (a) amended; eff. 5-20-99.....	399	165.110 (b)(4)(iii)(A) table and (C) table amended; (b)(4)(iii)(G)(3)(iv) note re- moved.....	25769
56.102 (b)(10) removed; (b)(11) through (21) redesignated as (b)(10) through (20); (c) amended; eff. 5-20-99.....	399	Regulation at 63 FR 25769 eff. date corrected to 2-2-98	30621
58 Authority citation revised.....	26698	172.155 (c)(1) revised.....	66015
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58.1 (a) amended; eff. 5-20-99.....	399	172.665 (d)(2) revised	1758
58.3 (e)(9) removed; eff. 5-20-99.....	399	172.723 (b)(3) revised	1759
60 Authority citation revised.....	399	172.800 Regulation at 60 FR 21702 eff. date confirmed; (c)(13) added	36362
60.3 (b)(5), (10), (11)(i) and (12)(i) amended; eff. 5-20-99.....	399	172.831 Added	16433
60.22 (a)(1) and (2) revised; eff. 5- 20-99.....	400	172.841 (a)(2) and (b) revised	57597
70.10 Heading and (b) heading re- vised; (b)(1), (2) and (3) amended; eff. 5-20-99.....	400	172.878 (c) table amended	66014
71 Authority citation revised.....	26698	173.300 (b) revised	38747
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71.2 (a) amended; eff. 5-20-99.....	400	173.340 (a)(4) introductory text revised; (a)(4) table amended	29134
73 Technical correction.....	51299	175.105 (c)(5) table amended.....	37248, 51527, 56788
73.75 Regulation at 63 FR 14817 confirmed.....	51299	175.125 (a)(8) added; (b)(1) revised	51528
74.3602 (b)(2)(v) added	20098	175.300 (b)(3)(vii)(a) amended	59707
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99 Added.....	64581	(b)(3)(vii)(a) corrected; CFR correction	4535
101 Technical correction.....	17327	175.320 (b)(3) table amended	71017
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101.13 (g) introductory text and (h) introductory text re- moved; (g)(1), (2) and (3) re- designated as (h)(4)(i), (ii) and (iii); (h)(1) and new (4)(i), (ii) and (iii) revised; (j)(2)(ii), (p)(2), (q)(2), (3)(ii), (5)(i) and (6) amended	26980		

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(c)(1)(i)(e) redesignated as (c)(1)(i)(f); new (c)(1)(i)(e) added	4785	201.50 (b) amended.....	26698
177.1430 (b) table amended	36175	201.57 (f)(2) revised; eff. 6-1-99.....	66396
177.1500 (b) table amended	4786	201.59 (a)(1) revised; eff. 5-20-99	400
177.2415 Added	20315	201.100 (c)(2) amended	26698
178.2010 (b) table amended... 27836, 29136, 35135, 36177, 36178, 43875, 45716, 55945		(c)(2) and (d)(1) amended; eff. 5-20-99.....	400
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178.3130 (b) table amended	38748	201.322 Added; eff. 4-23-99.....	56801
(b) corrected; CFR correction	4535	202 Authority citation revised.....	400
178.3295 Table amended	56789, 68392	202.1 (e)(4)(ii) removed; (e)(4)(iii) redesignated as (e)(4)(ii); new (e)(4)(ii), (6)(i), (ii)(a), (b) and (xvii) amended; eff. 5-20-99	400
178.3297 (e) table amended... 43874, 55946, 59215, 59710		206 Authority citation revised.....	400
178.3400 (c) table amended	29551	207 Authority citation revised	26698
178.3620 (c)(3) corrected; CFR correction	4535	Effective date confirmation.....	48576
178.3725 Table amended	35799	Authority citation revised	400
178.3910 (a)(2) table corrected; CFR correction	4535	207.20 (c) amended; eff. 5-20-99	400
179 Technical correction.....	46388	207.21 (a) amended; eff. 5-20-99.....	400
179.26 (c)(1) amended	43876	207.25 (b)(2), (4), (5) and (6) amended	26698
184.1007 (b)(1), (6) and (7) revised	1759	(b)(2), (4), (5) and (6) amended; eff. 5-20-99	400
184.1257 (b) introductory text and (1) revised	1759	207.31 (a)(1), (2), (3) and (c) amended	26698
184.1259 (b)(3) revised.....	1760	(a)(1), (2), (3) and (c) amended; eff. 5-20-99	400
184.1282 (b) revised.....	1760	207.37 (a)(2)(i) amended; eff. 5-20- 99	400
184.1293 (b) revised.....	1760	208 Added; eff. 6-1-99	66396
184.1420 Added	24419	210 Authority citation revised	26698
184.1428 (a) amended	405	Authority citation revised	401
184.1530 (b) revised.....	1760	211 Authority citation revised	26698
184.1699 (b) revised.....	1760	Authority citation revised	401
184.1702 Added	28895	211.132 Heading revised; (a), (d) introductory text and (2) amended; (b) and (c) revised	59470
184.1979 (b)(1) introductory text and (2) revised.....	1760	299.4 (d) amended; eff. 5-20-99	401
184.1979a (b)(1) introductory text and (2) revised.....	1761	300 Authority citation revised.....	401
184.1979b (b)(1) introductory text and (2) revised.....	1761	300.50 (b) amended; eff. 5-20-99.....	401
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184.1979c (b)(1) introductory text and (2) revised.....	1761	Authority citation revised	401
200 Authority citation revised	26698	310.502 (a) introductory text re- vised; (b) removed; eff. 5-20- 99	401
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Authority citation revised	400	(a)(6)(ii)(B) amended	40649
200.15 Revised	26698	(a)(23) and (24) redesignated as (a)(23)(i) and (24)(i); (a)(23)(i) heading, (ii), (24)(i) heading, ...	
201 Authority citation revised	26698		
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201.23 Added	66668		

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(ii) and (d)(26) added; (d)(11) revised	44998	314.92 (a)(2) removed; eff. 5-20-99	401
(a)(12)(iv) redesignated as (a)(12)(iv)(A); (a)(12)(iv)(A) heading, (d) introductory text and (1) revised; (a)(12)(iv)(B) and (d)(29) added	4540	314.94 (a)(8) revised; eff. 6-1-99	66399
312 Authority citation revised	26698, 68678	(c) and (d)(3) removed; eff. 5-20-99	401
Authority citation revised	401	314.96 (c) removed; eff. 5-20-99	401
312.2 (a) and (d) amended; eff. 5-20-99	401	314.98 (a) and (c) amended; eff. 5-20-99	401
312.3 Amended; eff. 5-20-99	401	314.100 (a) amended; eff. 5-20-99	402
312.23 (a)(10)(iii) redesignated as (a)(10)(iv); new (a)(10)(iii) added	66669	314.101 Heading revised; (a)(2) amended; eff. 5-20-99	402
312.42 (e) revised; eff. 4-28-99	68678	314.105 (a) and (b) amended; eff. 5-20-99	402
312.47 (b)(1)(i) and (2) heading revised; (b)(1)(iv), (v) and (2) introductory text amended; (b)(2)(iii) redesignated as (b)(2)(iv); new (b)(2)(iii) added	66669	314.107 (c)(1) and (4) amended; interim	59712
312.80—312.88 (Subpart E) Authority citation revised	401	314.110 (a)(2), (4) and (5) amended; eff. 5-20-99	402
312.81 Introductory text amended; eff. 5-20-99	401	314.120 (a) introductory text, (3) and (5) amended; (a)(4) removed; eff. 5-20-99	402
312.82 (a) and (b) amended	66669	314.125 Heading revised; (a) introductory text, (2) and (b)(2) amended; eff. 5-20-99	402
312.110 (b)(4) revised; (b)(5) removed; eff. 5-20-99	401	314.126 (a) amended; eff. 5-20-99	402
312.120 (a) amended; eff. 5-20-99	401	314.150 (a) introductory text and (b) introductory text amended; eff. 5-20-99	402
312.130 (b) amended; eff. 5-20-99	401	314.170 Amended	26698
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Authority citation revised	401	314.430 (f)(6) amended	26698
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314.1 (a) revised; eff. 5-20-99	401	314.500 Amended; eff. 5-20-99	402
314.50 Introductory text, (d)(5)(vi)(b) and (l)(1) amended; (c)(2)(i) and (e)(2)(ii) revised; eff. 6-1-99	66398	314.530 (a) amended; eff. 5-20-99	402
(d)(7) added	66670	316.3 (b)(9) amended; eff. 5-20-99	402
(d) introductory text amended; eff. 5-20-99	401	320 Authority citation revised	402
314.55 Added	66670	320.38 (a) amended; eff. 5-20-99	402
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314.81 (b)(2)(i) and (vii) revised; (b)(2)(vi)(c) added	66670	333.103 (a) and (b) designation removed; eff. 5-20-99	403
(a) amended; eff. 5-20-99	401	333.110 (a) through (f) amended; eff. 5-20-99	403
		333.120 (a)(1) through (12) and (b)(1) through (6) amended; eff. 5-20-99	403
		341.20 (b)(1) revised	40650

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341.80 (c)(2)(ii), (vii), (d)(2)(i) and (viii) heading revised.....	40650	510.600 (c)(1) table and (2) table amended.....	24106, 25164, 26981, 27844, 27845, 29551, 31624, 31931, 36178, 41188, 44381, 44382, 51821, 59216, 65553
343 Added; eff. 10-25-99.....	56814	514.10 Removed; eff. 5-20-99.....	403
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358 Technical correction.....	46389	520.154a (a) amended; (d)(4) added.....	38474
358.610 Revised.....	43303	520.452 Added.....	41419
369 Authority citation revised.....	26698	520.455 Added.....	1762
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Authority citation revised.....	403	520.870 Added.....	51300
369.5 Removed.....	26698	520.905a (a) removed; (b), (c) and (d)(3) redesignated as (a), (b) and (d)(4); (d)(2) heading revised; (d)(2)(i)(A), (B), (ii) introductory text, (A) and (B) redesignated as (d)(2)(ii), (iii), (3)(i), (ii) and (iii); new (c) and new (d)(3) heading added.....	63983
369.21 Amended.....	26698	520.905c (d)(1)(iii) added.....	31624
429 Removed.....	26698	520.1195 (b) amended.....	38474
Effective date confirmation.....	48576	520.1204 (a) amended; eff. 5-20-99.....	403
430 Removed.....	26068	520.1242a (a) and (d) removed; (b), (c), (e) and (f) redesignated as (a) through (d); new (a), (b), (c), (d)(1)(i), (iii) and (2)(i) revised; new (d)(2)(iii) added.....	59713
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431 Removed.....	26068	520.1263b (a) amended; eff. 5-20-99.....	403
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432 Removed.....	26068	520.1445 (a) and (c) heading revised; (d) added.....	29352
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433 Removed.....	26068	520.1446 (c) redesignated as (d); new (d) revised.....	41190
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436 Removed.....	26068	520.1485 (d)(3) amended.....	45944
Effective date confirmation.....	48576	520.1660c Heading, (a) and (b) revised; (c) removed; (d) and (e) redesignated as (c) and (d); new (d)(3) amended.....	70334
440 Removed.....	26068	520.1660d (a)(3) revised.....	44384
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441 Removed.....	26068	520.2043 (a)(2) revised.....	39727
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442 Removed.....	26068		
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510.105 (c)(2) revised.....	32980		
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520.2098 (b) amended	29551	524.1193 (b) and (d)(2) revised	44385
(d)(2) and (d)(3) redesignated as		524.1200a (a)(1) and (2) designa-	
(d)(1)(i) and (ii); new (d)(2)		tion removed; eff. 5-20-99.....	404
added	2122	524.1200b (a) revised; eff. 5-20-99	
520.2158a (b) amended	51821		404
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CFR correction	4540	(ii), (iii) and (3) redesignated	
520.2220a (a) revised; (b) removed;		as (a)(1)(i), (ii), (iii) and (2);	
(c), (d) and (e) redesignated		eff. 5-20-99	404
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522 Technical correction	46652	529.360 (a) amended; eff. 5-20-99	
522.84 Added	44382		404
522.90b (b) revised	41420	529.469 Added	25164
522.246 (b) revised	66432	529.1030 (c) redesignated as (d);	
522.314 (d)(2) added	53578	(b)(1), (2), new (d) introduc-	
522.770 (d)(1)(ii) revised	68183	tory text, (1) and (2)(i) re-	
522.533 Added	44383	vised; (d)(2)(iv) and (v) added	
522.812 (a) revised; (d)(1), (2) and			38304
(3) redesignated as (d)(1)(i),		529.1186 (b) revised	24106
(ii) and (iii); (c), new (d)(1)		556.34 Revised	1504
heading and new (2) added	49003	556.113 Revised	53579
522.955 (d)(1)(iii) amended	26981	556.150 Revised	52158
(d)(1)(i) revised; (d)(1)(iii)		(b) revised	57246
amended	41191	556.225 Revised	68184
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gnated as (d)(1)(i)(B);		556.228 Undesignated text desig-	
(d)(1)(ii)(A) and (B) added	5596	gnated as (a); new introduc-	
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522.970 (c) redesignated as (d);		added	49003
new (c) added; (b) and new		556.283 Revised	41191
(d) revised	38749	556.286 Added	38750
522.1044 (b)(3) amended	59714	556.344 Revised	54352
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522.1081 (a)(2)(ii) amended	51822	556.500 Revised	52158, 57246
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gnated as (d).....	29352	(c) corrected	38304
522.1145 (a)(2) revised; (f) added		556.720 Revised	52158, 57246
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522.1183 (b) removed; (e)(1)		amended	992
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522.1204 (a) revised; eff. 5-20-99.....	403	558.76 (d)(3)(xv) added	38475
522.1222a (c) amended	51822, 65553	(d)(3)(xv) added	38750
522.1289 Added	29552	(d)(3)(xvi) added	39028
522.1484 (a) amended; eff. 5-20-99		(d)(1) table amended	40825, 44385
.....	403	(d)(3)(xvii) correctly des-	
522.1660 (c) added; (d)(1) heading		ignated	48576
revised; (d)(1)(iii) amended	52158	(d)(3)(xviii) added	51824
522.1940 (d)(3) added	45945	(d)(3)(xix) added	4966
522.2005 (b) amended	24420	558.78 (d)(3) revised	19185
522.2120 Amended	24107	(a)(2), (d)(1) table and (2)(ii)	
522.2121 Added	24107	amended	27845
522.2478 (c)(2) added	63789	558.95 (d)(4)(iv) added	18836
524.770 (d)(2) revised	68183	(d)(1)(xi)(b) and (xii)(b) amend-	
524.814 (d)(2) revised	59715	ed	27845
524.1044g (b) amended	31932		

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