

November 2015

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655.230 Added 63066
655.235 Added 63066

Proposed Rules:

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404 55050, 63717, 66843
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TITLE 21—FOOD AND DRUGS

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

1 Technical correction 22403
Compliance date clarification 71934
Authority citation revised 74340, 74650
1.94 Revised 55242
1.101 (d)(2)(i) amended 18090
1.227 Revised 56141
1.241 (a) revised 56143
1.276 (b)(9) revised 56143
1.328 Amended 56143
1.363 Revised 56144
1.500—1.514 (Subpart L) Added 74340
1.600—1.695 (Subpart M) Added 74650
11 Compliance date clarification 71934

11.1 Regulation at 79 FR 71253 and 71291 compliance date extended 39675
(i) added 56144
(j) added 56336
(l) added 74352
(k) added 74547
(m) added 74667
14.100 (c)(2) introductory text revised 18307
16 Technical correction 22403
Authority citation revised 42723
Compliance date clarification 71934
16.1 (b)(2) amended 56144, 56336
(b)(1) and (2) amended 74547
(b)(2) amended 74667
20.100 (c)(45) added 38938
25 Technical correction 70679
25.15 (a), (c) and (d) amended 57535
25.20 Introductory text revised; (o) and (p) added 57535
25.30 Introductory text amended 57535
25.35 Added 57535
25.40 (a) amended 57535
25.50 (b) amended 57535
25.52 (a) amended; (b) and (c) revised 57535
26.1—26.21 (Subpart A) Appendix E amended 18090
73.200 Regulation at 80 FR 14842 eff. date confirmed 31466
73.350 (c)(1)(ii) revised; (c)(1)(iii) added 32307
Regulation at 80 FR 32307 confirmed 46190
(c)(1)(ii)(A) revised 58602
73.530 (c) revised 50765
Regulation at 80 FR 50765 eff. date confirmed 66415
73.1530 Added 50765
Regulation at 80 FR 50765 eff. date confirmed 66415
99.201 (c)(1) amended 18090
101.8 Regulation at 79 FR 71291 compliance date extended 39675
101.9 Regulation at 79 FR 71253 and 71291 compliance date extended 39675
101.10 Regulation at 79 FR 71253 compliance date extended 39675
101.11 Regulation at 79 FR 71253 compliance date extended 39675
106 Compliance date clarification 71934

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106.100 (n) revised	56144	123.5 (a) revised.....	56167
107.10 (a)(2) revised	35840	123.11 (b) introductory text re-	
Regulation at 80 FR 35840 eff.		vised.....	56167
date confirmed; eff. 6-22-16	61293	129 Compliance date clarifica-	
107.100 (a) revised.....	35841	tion.....	71934
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date confirmed; eff. 6-22-16	61293	150.141 Removed.....	72585
110 Removed; eff. 9-17-18	56144	150.161 Removed.....	72585
Compliance date clarification		161.170 (a)(5)(ii)(b) removed;	
.....	71934	(a)(5)(ii)(a) redesignated as	
111.5 Amended	74352	(a)(5)(ii)	41436
112 Added	74547	172.185 (a) revised; (b) and (c) re-	
Policy statement.....	74670	designated as (c) and (d); new	
114 Compliance date clarifica-		(b) added.....	34276
tion.....	71934	179 Compliance date clarifica-	
114.5 Revised.....	56144	tion.....	71934
117 Added.....	56145	179.25 (a) revised	56168
Policy statement.....	56358	201.25 (d)(2) amended.....	18090
Compliance date clarification		201.58 Amended	18090
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117.3 Eff. date pending in part	56145	203.37 (e) revised	18090
117.5 Eff. date pending in part	56145	203.70 (b)(2) revised	18091
Regulation at 80 FR 56145 eff.		206.7 (b)(1)(i) amended	18091
date confirmed in part	74354	207.7 (a) amended.....	18091
117.8 Eff. date pending in part	56145	211 Compliance date clarifica-	
Regulation at 80 FR 56145 eff.		tion.....	71934
date confirmed in part	74354	211.1 (c) amended	56168
117.95 Added.....	56337	310 Authority citation revised.....	38938
117.405 Eff. date pending in part		310.305 Regulation at 79 FR 33087	
.....	56145	eff. date delayed	30151
Regulation at 80 FR 56145 eff.		310.306 Added	38938
date confirmed in part	74354	310.503 (f)(3) amended.....	18091
117.410 Eff. date pending in part		312.140 (a)(3) amended	18091
.....	56145	312.145 (b) amended.....	18091
Regulation at 80 FR 56145 eff.		312.310 (d)(1) amended.....	18091
date confirmed in part	74354	314 Regulation at 79 FR 33088 eff.	
117.430 Eff. date pending in part		date delayed	30151
.....	56145	Authority citation revised	38938
Regulation at 80 FR 56145 eff.		314.80 Regulation at 79 FR 33088	
date confirmed in part	74354	eff. date delayed	30151
117.435 Eff. date pending in part		314.81 (b)(3)(iii) revised	38938
.....	56145	314.91 Removed	38939
117.475 Eff. date pending in part		314.98 Regulation at 79 FR 33089	
.....	56145	eff. date delayed	30151
Regulation at 80 FR 56145 eff.		314.440 (b) introductory text re-	
date confirmed in part	74354	vised.....	18091
120 Compliance date clarifica-		317 Order.....	50559
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120.3 Introductory text amended		date delayed	30151
.....	56167	500.23 Revised	56337
120.5 Revised.....	56167	507 Added.....	56337
120.6 (b) amended.....	56167	Policy statement.....	56360
123 Compliance date clarifica-		507.3 Eff. date pending in part	56337
tion.....	71934	507.12 Eff. date pending in part	
123.3 Introductory text amended			56337
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Regulation at 80 FR 56145 eff. date confirmed in part 74354	522.167 Added 18776
507.105 Eff. date pending in part 56337	522.230 (b) amended 18776
Regulation at 80 FR 56145 eff. date confirmed in part 74354	522.690 (d)(1) and (2) redesignated as (d)(2) and (4); new (d)(1) added; new (d)(2)(ii) and (3)(ii) amended; (a), (b), (c) and new (d)(4) introductory text revised 61296
507.110 Eff. date pending in part 56337	522.812 (b)(3) added 18776 (b)(2) revised 61296
Regulation at 80 FR 56145 eff. date confirmed in part 74354	522.955 (a), (b), (d)(1) heading, (i) introductory text, (C), (ii) introductory text and (C) re- vised 61296
507.130 Eff. date pending in part 56337	522.1004 Removed 18776
Regulation at 80 FR 56145 eff. date confirmed in part 74354	522.1073 Removed 34278
507.135 Eff. date pending in part 56337	522.1075 Removed 34278
507.175 Eff. date pending in part 56337	522.1077 Revised 34279
Regulation at 80 FR 56145 eff. date confirmed in part 74354	522.1145 (e)(2)(i) amended 34279
510.600 (c)(1) table and (2) table amended 18775, 34278, 61295, 73104	522.1289 (a) amended 61297
514 Authority citation revised 31733	522.2005 (b)(2) revised; (b)(3) re- moved 18776
514.1 (b)(9) revised 31733	522.2075 Added 61297
520.43 (c)(2) revised 18775	522.2470 (b) revised 34279
520.48 (b) revised 34278	522.2483 (b) revised 34279
520.88g (c)(2)(i) amended 34278	524.154 (a)(1), (2) and (b)(2) re- vised 61297
520.154a Heading revised; (d)(1)(ii), (2)(i)(A), (ii)(A), (3)(ii) and (4)(ii) amended 34278	524.1044a Revised 18776
520.304 (b)(3) amended 34278	524.1450 (a), (b) and (d) revised; (e) removed 53460
(b)(2) amended 61296	524.1484g (a) and (b) revised 61297
520.441 (b)(4) amended 18775	526.313 (d)(1)(ii) revised 34279
520.804 (c)(i), (ii) and (iii) redesignated as (c)(1), (2) and (3) 34278	528.1070 (b) amended 34279
520.1156 Added 18775	528.1092 Added 73104
520.1315 (c)(1) revised 53459	529.1186 (b) amended 18776
520.1367 (b)(2) amended 53459	529.1350 (b) amended 18776
520.1443 (b) amended 18776	529.2150 (b) amended 18776
520.1447 (b) amended 18776	556.68 Added 61297
520.1510 Heading and (b) revised; (d)(1)(ii)(B) amended 18776	558 Authority citation revised 31733
520.1660d (a)(4) revised 34278	Policy statement 58602
520.1855 (b) amended 34278	Drug application approvals withdrawn 61298
(c)(1) revised 53459	558.3 (b)(1)(ii), (6), (7), (9) and (11) revised; (b)(12) added 31733
520.2158 (b) amended 18776	558.4 (d) table amended 61297
(d)(1) and (2) revised; (d)(3) added 61296	558.6 Revised 31733
520.2218 (d)(1)(i)(A), (B), (2)(i)(A) and (B) revised 34278	(b)(5) and (c) introductory text corrected 35841
520.2261b (d)(4)(iii) amended 61296	558.68 Added 61297
520.2598 (a) amended 53460	558.95 (d)(4)(ii) table amended 53460
520.2640 (e)(2)(iii) and (3)(iii) amended 34278	558.128 (b)(2), (e)(1) table, (2) table, (3) table, (iv) and (4) table amended 18776
522 Drug application approval withdrawn 18777	558.460 (a) and (b) revised 61298

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558.500 (e)(1)(ii), (iii), (iv), (2)(iv), (ix), (x) and (xiii) amended	61298	610.39—610.48 (Subpart E) Heading revised.....	29896
558.618 (e)(2)(i) amended.....	61298	610.39 Added.....	29896
558.665 (e)(9) added	18776	610.40 (a), (b), (c) heading, (e) revised; (c)(2) and (i) removed; (c)(3) and (4) redesignated as new (c)(2) and (3); new (c)(2)(i), (d), (f), (g) introductory text, (h)(1), (2)(ii) introductory text, (C), (iv) introductory text, (A), (vi) and (vii) amended.....	29896
573.490 Added	35569	610.41 (a) introductory text, (2) through (5) and (b) amended; (a)(1) revised.....	29897
579.12 Amended	56356	610.42 (a) amended	29897
600 Regulation at 79 FR 33090 eff. date delayed	30151	610.44 (a)(1) and (2) amended	29897
Authority citation revised	38939	610.46 (a)(2), (3), (4), (b)(2) and (3) amended	29897
600.2 (a), (c)(1) and (2) amended	18091	610.47 (a)(2), (3), (4), (b)(2) and (3) amended	29897
Regulation at 79 FR 33090 eff. date delayed	30151	630 Heading revised	29898
600.11 (f)(6) amended	18092	630.1—630.3 (Subpart A) Added.....	29898
600.14 (e)(1) revised	18092	630.5—630.35 (Subpart B) Added	29898
600.22 (e) amended.....	18092	630.40 (Subpart C) Subpart and heading added.....	29898
600.80 Regulation at 79 FR 33090 eff. date delayed	30151	630.6 Redesignated as 630.40	29898
600.81 Regulation at 79 FR 33091 eff. date delayed	30151	630.40 Redesignated from 630.10; Heading revised; (a), (b) introductory text, (1), (3), (c), (d)(1) introductory text, (i) and (iii) amended	29898
600.82 Added.....	38939	640.3 Removed.....	29904
600.90 Regulation at 79 FR 33092 eff. date delayed	30151	640.4 (a) removed; (e) amended	29904
601.2 (a) amended	18092	640.5 Introductory text and (f) amended; (a) removed	29904
(c)(1) amended	37974	640.12 Revised	29904
601.12 (f)(4) amended	18092	640.14 Amended	29904
601.15 Amended	18092	640.21 Revised	29904
601.22 Amended	37974	640.22 (c) revised	29904
601.28 Introductory text amended	18092	640.23 (a) amended	29904
601.29 (b) amended	18092	640.27 Removed	29904
601.70 (d) amended	18092	640.31 Revised	29904
606.3 (a) and (c) revised.....	29894	640.32 (b) amended	29905
606.40 (a)(1) amended.....	29895	640.33 (a) amended	29905
606.100 (b) introductory text and (20) revised; (b)(1) amended; (b)(21) and (22) added	29895	640.51 Revised	29905
606.110 (a) and (b) amended	29895	640.52 (b) amended	29905
606.121 (c)(11), (12), (h)(2), (3) and (i)(5) amended.....	29895	640.53 (a) amended	29905
606.122 (e) amended	29895	640.61 Removed	29905
606.145 Added	29895	640.62 Removed	29905
606.160 (b)(1)(ix), (x), (xi) and (e) revised.....	29895	640.63 Removed	29905
606.170 (b) amended.....	18092	640.64 (a) removed.....	29905
601.171 (e) revised.....	18092		
607.7 (b) and (c) amended	18092		
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610.11 (g)(2) amended.....	18093		
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610.15 (a)(3) amended.....	18093		

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640.65 (b)(1)(i), (ii), (2)(iii) and (iv) amended; (b)(2)(i) revised	29905	890.5290 (a)(1) and (b) revised; (c) removed.....	61302
640.66 Amended	29905	895.30 (c) revised	31300
640.67 Amended	29905	1020.32 (b)(4)(ii)(A) revised	19532
640.69 (e) and (f) added	29905	Regulation at 80 FR 19532 eff. date confirmed	43320
640.71 (a) introductory text and (b)(1) amended; (a)(1) through (4) removed	29905	1271.22 (b)(1), (3), (c)(1) and (2) amended	18094
640.72 (a)(2), (3) and (4) revised	29905	1271.37 Revised.....	18094
640.120 Revised.....	29906	1271.350 (a)(5) amended; (b)(3) revised	18095
640.125—640.130 (Subpart M) Added	29906	Chapter II—Drug Enforcement Administration, Department of Justice (Parts 1300—1399)	
660.3 Amended	18093	1308 Policy statement.....	27854, 70658
660.6 (a)(2) and (c) heading amended	18093	Technical correction	70680
660.22 (b) amended	18093	1308.11 (h)(24) added	42385
660.31 Revised	29906	1308.12 (b)(4) revised.....	54718
660.36 (a) introductory text, (b) and (c) amended	18093	1308.14 (g)(3) added	69864
660.46 (a)(2) introductory text amended	18093	1308.22 Table amended; interim	65634, 65637
660.52 Amended	18093	Chapter III—Office of National Drug Control Policy (Parts 1400—1499)	
680.1 (b)(2)(iii), (3)(iv) and (c) amended	18093	1403 Regulation at 79 FR 76106 confirmed	57383
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801.55 (b)(1) amended.....	18093	1405 Regulation at 79 FR 76106 confirmed	57383
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812.19 (a)(2) amended.....	18094	1 19160, 43987, 55802, 57136	
814.20 (h)(2) amended	18094	2.....36937	
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TITLE 22—FOREIGN RELATIONS**Chapter I—Department of State
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11 Revised.....	64320
22.1 Regulation at 79 FR 51253 confirmed.....	51466
Amended; interim.....	53709
Correctly amended; eff. date corrected.....	55243
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35 Authority citation revised.....	49139
35.2 (r) revised.....	49139
41 Authority citation revised.....	69589
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41.113 Revised.....	67315
51.3 (b) revised; interim.....	27857
51.20 (a) revised.....	72592
51.56 (a) revised.....	72592
62 Policy statement.....	48687
96.60 Revised.....	50196
121.1 Amended.....	37975
126.1 (p) removed.....	30615
135 Regulation at 79 FR 76019 confirmed.....	31299
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TITLE 23—HIGHWAYS**Chapter I—Federal Highway Ad-
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172 Added.....	29927
625.4 (a), (b) and (d) revised; (e) added.....	61307
650 Authority citation revised.....	41368
650.501—650.517 (Subpart E) Added.....	41368

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