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CHANGES APRIL 1, 2015 THROUGH JANUARY 29, 2016

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**
Amended 3715
1.241 (a) revised **56143**
1.276 (b)(9) revised **56143**
1.328 Amended **56143**
Amended 3715
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**
Regulation at 80 FR 58602 eff. date confirmed **76859**
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**
91.5 Amended **75804**
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**
106.100 (n) revised **56144**
107.10 (a)(2) revised **35840**
Regulation at 80 FR 35840 eff. date confirmed; eff. 6-22-16 ..... **61293**
107.100 (a) revised **35841**
Regulation at 80 FR 35841 eff. date confirmed; eff. 6-22-16 ..... **61293**
110 Removed; eff. 9-17-18 ..... **56144**
Compliance date clarification **71934**
111.5 Amended **74352**
112 Added **74547**
Policy statement **74670**
114 Compliance date clarification **71934**
114.5 Revised **56144**
117 Added **56145**
Policy statement **56358**
Compliance date clarification **71934**
117.1 (b) revised 3715
117.3 Eff. date pending in part **56145**
Amended 3715
117.5 Eff. date pending in part **56145**
Regulation at 80 FR 56145 eff. date confirmed in part **74354**
(a) amended; (h)(3)(v) revised 3716

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117.8 Eff. date pending in part **56145**
Regulation at 80 FR 56145 eff. date confirmed in part **74354**
Correctly revised 3956
117.95 Added **56337**
117.136 (a)(2) introductory text, (5) and (b)(5) revised 3716
117.145 (a) revised 3716
117.201 (b)(2)(i)(B) and (ii) revised 3716
117.257 (e) revised 3716
117.264 (a)(1) revised 3716
117.405 Eff. date pending in part **56145**
Regulation at 80 FR 56145 eff. date confirmed in part **74354**
(c) introductory text corrected 3956
117.410 Eff. date pending in part **56145**
Regulation at 80 FR 56145 eff. date confirmed in part **74354**
117.430 Eff. date pending in part **56145**
Regulation at 80 FR 56145 eff. date confirmed in part **74354**
117.435 Eff. date pending in part **56145**
117.475 Eff. date pending in part **56145**
Regulation at 80 FR 56145 eff. date confirmed in part **74354**
120 Compliance date clarification **71934**
120.3 Introductory text amended **56167**
120.5 Revised **56167**
120.6 (b) amended **56167**
123 Compliance date clarification **71934**
123.3 Introductory text amended **56167**
123.5 (a) revised **56167**
123.11 (b) introductory text revised **56167**
129 Compliance date clarification **71934**
129.1 Revised **56167**
150.141 Removed **72585**
150.161 Removed **72585**
161.170 (a)(5)(ii)(*b*) removed; (a)(5)(ii)(*a*) redesignated as (a)(5)(ii) **41436**
172.185 (a) revised; (b) and (c) redesignated as (c) and (d); new (b) added **34276**
176.170 (a)(5) table amended 8
179 Compliance date clarification **71934**
179.25 (a) revised **56168**
201.25 (d)(2) amended **18090**
201.58 Amended **18090**
203.12 Revised **18090**
203.37 (e) revised **18090**
203.70 (b)(2) revised **18091**
206.7 (b)(1)(i) amended **18091**
207.7 (a) amended **18091**
211 Compliance date clarification **71934**
211.1 (c) amended **56168**
310 Authority citation revised **38938**
310.305 Regulation at 79 FR 33087 eff. date delayed **30151**
310.306 Added **38938**
310.503 (f)(3) amended **18091**
312.140 (a)(3) amended **18091**
312.145 (b) amended **18091**
312.310 (d)(1) amended **18091**
314 Regulation at 79 FR 33088 eff. date delayed **30151**
Authority citation revised **38938**
314.80 Regulation at 79 FR 33088 eff. date delayed **30151**
314.81 (b)(3)(iii) revised **38938**
314.91 Removed **38939**
314.98 Regulation at 79 FR 33089 eff. date delayed **30151**
314.440 (b) introductory text revised **18091**
317 Order **50559**
329 Regulation at 79 FR 33089 eff. date delayed **30151**
500.23 Revised **56337**
507 Added **56337**
Policy statement **56360**
507.3 Eff. date pending in part **56337**
Amended 3717
507.5 (e)(5) revised 3717
507.7 (b)(2)(i)(B) and (ii) revised 3717
507.12 Eff. date pending in part **56337**
Regulation at 80 FR 56145 eff. date confirmed in part **74354**
507.19 (b)(2) revised 3717
507.27 (b) revised 3717
507.33 (c)(1) revised 3717
507.36 (a)(2) introductory text, (3) introductory text, (5) and (b)(5) revised 3717
507.47 (b)(1)(i)(A) and (B)(*1*) revised 3718

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507.50 (c)(1) revised 3718
507.51 (a)(4)(iii) revised 3718
507.65 (e) revised 3718
507.69 (a)(1) revised 3718
507.105 Eff. date pending in part **56337**
Regulation at 80 FR 56145 eff. date confirmed in part **74354**
507.110 Eff. date pending in part **56337**
Regulation at 80 FR 56145 eff. date confirmed in part **74354**
507.130 Eff. date pending in part **56337**
Regulation at 80 FR 56145 eff. date confirmed in part **74354**
507.135 Eff. date pending in part **56337**
507.175 Eff. date pending in part **56337**
Regulation at 80 FR 56145 eff. date confirmed in part **74354**
510.600 (c)(1) table and (2) table amended ... **18775, 34278, 61295, 73104, 76386**
(c)(1) table and (2) table amended 3324
514 Authority citation revised **31733**
514.1 (b)(9) revised **31733**
516.1318 Removed 3324
520 Drug application approvals withdrawn **76387**
520.43 (c)(2) revised **18775**
520.48 (b) revised **34278**
520.88g (c)(2)(i) amended **34278**
520.154a Heading revised; (d)(1)(ii), (2)(i)(A), (ii)(A), (3)(ii) and (4)(ii) amended **34278**
520.304 (b)(3) amended **34278**
(b)(2) amended **61296**
520.441 (b)(4) amended **18775**
520.446 (b)(1) amended **76386**
520.804 (c)(i), (ii) and (iii) redesignated as (c)(1), (2) and (3) **34278**
520.905a (a) and (e)(4)(i) revised; (e)(4)(iii) amended; (e)(5) added **76386**
520.1156 Added **18775**
520.1315 (c)(1) revised **53459**
520.1367 (b)(2) amended **53459**
520.1443 (b) amended **18776**
520.1447 (b) amended **18776**
520.1510 Heading and (b) revised; (d)(1)(ii)(B) amended **18776**
520.1660d (a)(4) revised **34278**
520.1855 (b) amended **34278**
(c)(1) revised **53459**
520.2043 (b)(2) amended **76386**
520.2158 (b) amended **18776**
(d)(1) and (2) revised; (d)(3) added **61296**
520.2218 (d)(1)(i)(A), (B), (2)(i)(A) and (B) revised **34278**
520.2261b (d)(4)(iii) amended **61296**
520.2598 (a) amended **53460**
520.2640 (e)(2)(iii) and (3)(iii) amended **34278**
522 Drug application approval withdrawn **18777**
522.167 Added **18776**
522.230 (b) amended **18776**
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**
(b)(2) and (d)(1)(i) revised; (b)(3) added **76386**
522.812 (b)(3) added **18776**
(b)(2) revised **61296**
522.955 (a), (b), (d)(1) heading, (i) introductory text, (C), (ii) introductory text and (C) revised **61296**
(b)(2) amended **76386**
522.1004 Removed **18776**
522.1073 Removed **34278**
522.1075 Removed **34278**
522.1077 Revised **34279**
522.1145 (e)(2)(i) amended **34279**
522.1289 (a) amended **61297**
522.2005 (b)(2) revised; (b)(3) removed **18776**
522.2075 Added **61297**
522.2470 (b) revised **34279**
522.2483 (b) revised **34279**
524.154 (a)(1), (2) and (b)(2) revised **61297**
524.957 Added **76387**
524.1044a Revised **18776**
524.1450 (a), (b) and (d) revised; (e) removed **53460**
524.1484g (a) and (b) revised **61297**
526.313 (d)(1)(ii) revised **34279**
528.1070 (b) amended **34279**
528.1092 Added **73104**
529.1186 (b) amended **18776**
529.1350 (b) amended **18776**
529.2150 (b) amended **18776**
556.60 Removed **78970**
556.68 Added **61297**

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558 Authority citation revised **31733**
Policy statement **58602**
Drug application approvals withdrawn **61298, 76387, 78970**
558.3 (b)(1)(ii), (6), (7), (9) and (11) revised; (b)(12) added **31733**
558.4 (d) table amended **61297, 78970**
558.6 Revised **31733**
(b)(5) and (c) introductory text corrected **35841**
558.68 Added **61297**
(c)(1) revised **76387**
558.76 (d)(3)(xiii) removed **78970**
(b), (c) and (d) redesignated as (c), (d) and (e); new (b) added; heading, (a) and new (e)(1) revised **79474**
558.95 (d)(4)(ii) table amended **53460**
558.128 (b)(2), (e)(1) table, (2) table, (3) table, (iv) and (4) table amended **18776**
558.261 (c)(1) and (2) revised **76387**
558.369 Removed **78970**
558.460 (a) and (b) revised **61298**
558.500 (e)(1)(ii), (iii), (iv), (2)(iv), (ix), (x) and (xiii) amended **61298**
558.618 (e)(2)(i) amended **61298**
(c)(1) revised **76387**
558.625 (b)(5) removed; (b)(6) redesignated as new (b)(5) **76387**
558.630 (b)(2) amended **76387**
558.665 (e)(9) added **18776**
(d)(2) and (e) revised **53460**
573.490 Added **35569**
578.3 Amended **75804**
578.87 (b)(4) amended **75804**
578.103 (a)(4) through (17) redesignated as (a)(5) through (18); new (a)(4) added **75804**
579.12 Amended **56356**
600 Regulation at 79 FR 33090 eff. date delayed **30151**
Authority citation revised **38939**
600.2 (a), (c)(1) and (2) amended **18091**
Regulation at 79 FR 33090 eff. date delayed **30151**
600.11 (f)(6) amended **18092**
600.14 (e)(1) revised **18092**
600.22 (e) amended **18092**
600.80 Regulation at 79 FR 33090 eff. date delayed **30151**
600.81 Regulation at 79 FR 33091 eff. date delayed **30151**
600.82 Added **38939**
600.90 Regulation at 79 FR 33092 eff. date delayed **30151**
601.2 (a) amended **18092**
(c)(1) amended **37974**
601.12 (f)(4) amended **18092**
601.15 Amended **18092**
601.22 Amended **37974**
601.28 Introductory text amended **18092**
601.29 (b) amended **18092**
601.70 (d) amended **18092**
606.3 (a) and (c) revised **29894**
606.40 (a)(1) amended **29895**
606.100 (b) introductory text and (20) revised; (b)(1) amended; (b)(21) and (22) added **29895**
(b)(19) introductory text amended **80651**
606.110 (a) and (b) amended **29895**
606.121 (c)(11), (12), (h)(2), (3) and (i)(5) amended **29895**
606.122 (e) amended **29895**
606.145 Added **29895**
606.160 (b)(1)(ix), (x), (xi) and (e) revised **29895**
(b)(1)(viii) amended **80651**
606.170 (b) amended **18092**
601.171 (e) revised **18092**
607.7 (b) and (c) amended **18092**
607.22 (a) amended **18092**
607.37 Revised **18092**
610.2 (a) and (b) amended **18093**
610.11 (g)(2) amended **18093**
Removed **37974**
610.11a Removed **37974**
610.15 (a)(3) amended **18093**
610.39—610.48 (Subpart E) Heading revised **29896**
610.39 Added **29896**
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**
610.41 (a) introductory text, (2) through (5) and (b) amended; (a)(1) revised **29897**
610.42 (a) amended **29897**
610.44 (a)(1) and (2) amended **29897**
610.46 (a)(2), (3), (4), (b)(2) and (3) amended **29897**

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610.47 (a)(2), (3), (4), (b)(2) and (3) amended **29897**
610.48 Removed **80651**
630 Heading revised **29898**
630.1—630.3 (Subpart A) Added **29898**
630.5—630.35 (Subpart B) Added **29898**
630.40 (Subpart C) Subpart and heading added **29898**
630.6 Redesignated as 630.40 ..... **29898**
630.40 Redesignated from 630.10; Heading revised; (a), (b) introductory text, (1), (3), (c), (d)(1) introductory text, (i) and (iii) amended **29898**
640.3 Removed **29904**
640.4 (a) removed; (e) amended **29904**
640.5 Introductory text and (f) amended; (a) removed **29904**
640.12 Revised **29904**
640.14 Amended **29904**
640.21 Revised **29904**
640.22 (c) revised **29904**
640.23 (a) amended **29904**
640.27 Removed **29904**
640.31 Revised **29904**
640.32 (b) amended **29905**
640.33 (a) amended **29905**
640.51 Revised **29905**
640.52 (b) amended **29905**
640.53 (a) amended **29905**
640.61 Removed **29905**
640.62 Removed **29905**
640.63 Removed **29905**
640.64 (a) removed **29905**
640.65 (b)(1)(i), (ii), (2)(iii) and (iv) amended; (b)(2)(i) revised **29905**
640.66 Amended **29905**
640.67 Amended **29905**
640.69 (e) and (f) added **29905**
640.71 (a) introductory text and (b)(1) amended; (a)(1) through (4) removed **29905**
640.72 (a)(2), (3) and (4) revised **29905**
640.120 Revised **29906**
640.125—640.130 (Subpart M) Added **29906**
660.3 Amended **18093**
660.6 (a)(2) and (c) heading amended **18093**
660.22 (b) amended **18093**
660.31 Revised **29906**
660.36 (a) introductory text, (b) and (c) amended **18093**
660.46 (a)(2) introductory text amended **18093**
660.52 Amended **18093**
680.1 (b)(2)(iii), (3)(iv) and (c) amended **18093**
680.3 (b) removed **37974**
801.55 (b)(1) amended **18093**
807.90 (a)(2) amended **18094**
812.19 (a)(2) amended **18094**
814.20 (h)(2) amended **18094**
814.104 (d)(2) amended **18094**
820.1 (a)(1) amended **29906**
822.8 Amended **18094**
866.3130 Added **51939**
866.3365 Added **30154**
866.3860 Added **46192**
866.3990 Added **67314**
866.5940 Added **65630**
870.1415 Added **63673**
870.4360 Revised **32311**
870.5700 Added **58606**
870.5910 Added **49896**
872.5560 Added **72586**
874.3315 Added 3324
874.5900 Added **46194**
876.2050 Added **72900**
876.5025 Added **30355**
Republished **35843**
876.5140 Added **18309**
876.5930 Added **30933**
878.4670 Added **46486**
880.6600 Added **72588**
882.1470 Added **49138**
884.5980 Added 361
(c) added 369
884.6165 Added 379
886.5905 Added **57092**
890.3110 (b) revised **72590**
890.3480 Revised (republished) **25229**
890.5290 (a)(1) and (b) revised; (c) removed **61302**
895.30 (c) revised **31300**
1020.32 (b)(4)(ii)(A) revised **19532**
Regulation at 80 FR 19532 eff. date confirmed **43320**
1271.22 (b)(1), (3), (c)(1) and (2) amended **18094**
1271.37 Revised **18094**
1271.350 (a)(5) amended; (b)(3) revised **18095**

Chapter II—Drug Enforcement Administration, Department of Justice (Parts 1300—1399)

1308 Policy statement **27854, 70658**
Technical correction **70680, 78657**

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1308.11 (h)(24) added **42385**
1308.12 (b)(4) revised..... **54718**
1308.14 (g)(3) added **69864**
1308.22 Table amended; interim **65634, 65637**
1314.101 Regulation at 76 FR 20523 confirmed 3959
1314.102 Regulation at 76 FR 20523 confirmed 3959
1314.103 Regulation at 76 FR 20524 confirmed 3959

Chapter III—Office of National Drug Control Policy (Parts 1400—1499)

1403 Regulation at 79 FR 76106 confirmed..... **57383**
1404 Regulation at 79 FR 76106 confirmed..... **57383**
1405 Regulation at 79 FR 76106 confirmed..... **57383**

Proposed Rules:

1 ..... **19160, 43987, 55802, 57136**
2 ..... **36937**
11 ..... **55564, 57136**
15 ..... **32868, 54256**
16..... **57136**
73..... **22449**
101..... **44302, 44303, 45465, 54446, 55564, 63477, 69905, 71990, 80718** 3751
106..... **57136**
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201 ..... **57756, 74737**
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573 ..... **42069, 48471, 73153**
579..... **57136**
601..... **38145**
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801 ..... **57756, 74737**
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878..... **79493**
880..... **60809**
882..... **81223** 3751
1002..... **79505**
1020..... **19589**
1040..... **79505**
1100 ..... **37555, 51146, 57756, 74737**
1140..... **37555, 51146**
1143..... **37555, 51146**
1271..... **66844, 66845, 66847, 66849, 66850, 81233**
1308..... **27611, 29227, 31521, 48044, 55565, 70650**

TITLE 22—FOREIGN RELATIONS

Chapter I—Department of State (Parts 1—199)

11 Revised..... **64320**
22.1 Regulation at 79 FR 51253 confirmed..... **51466**
Amended; interim **53709**
Correctly amended; eff. date corrected..... **55243**
Table amended..... **72591**
35 Authority citation revised..... **49139**
35.2 (r) revised..... **49139**
41 Authority citation revised..... **69589**
41.102 Revised **69589**
41.113 Revised **67315**
51.3 (b) revised; interim..... **27857**
51.20 (a) revised..... **72592**
51.56 (a) revised..... **72592**
62 Policy statement **48687**
Authority citation revised 4955
62.24 Revised 4955
96.60 Revised..... **50196**
102 Removed **76631**
121.1 Amended..... **37975, 78131**
Amended; eff. 8-30-17 ..... **78131**
126.1 (p) removed **30615**
135 Regulation at 79 FR 76019 confirmed..... **31299**
145 Regulation at 79 FR 76019 confirmed..... **31299**
171.36 (b)(5) and (6) amended 2989
172.2 (a) corrected **30155**

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