AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

CHANGES APRIL 3, 2000 THROUGH JANUARY 31, 2001

TITLE 21—FOOD AND DRUGS

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

5.20 (b), (c), (e), (f) and (g) revised; (i) redesignated as (j); new (i) added **34960**
5.22 (a)(1), (2), (3), (6), (7), (10)(ii), (11)(ii), (12)(ii), (b)(1), (2), (3) and new (d) revised; (c) redesignated as (d); new (c) added **34961**
5.23 (a)(1), (2), (4) and (d) revised **34961**
5.25 (a)(7) and (c) revised **34962**
5.27 Revised **34962**
5.30 (c)(1) revised **34962**
5.32 Revised **34962**
5.34 (a) revised **34962**
5.58 (a) introductory text and (b) introductory text revised **34962**
5.81 Revised **34962**
5.200 Revised **19830**
5.210 Revised **19832**
5.215 Revised **19832**
7.1 Amended **56476**
7.40—7.59 (Subpart C) Heading revised **56476**
7.40 (a) amended **56476**
10 Authority citation revised **25440**
10.20 (j)(1)(v) amended **56477**
10.30 (i)(6) amended 6467
10.33 (k)(6) amended 6467
10.35 (h)(6) amended 6468
10.40 (g)(7) amended 6468
10.45 (d) amended **56477**
10.65 Revised 6468
10.85 (d)(5) removed **56477**
10.90 (b) amended **56477**
10.100 Revised 6468
10.115 Added **56477**
13 Authority citation revised **25440**
14 Authority citation revised **25440**
Authority citation revised 1259
14.20 (e) removed 6469
14.27 (b)(3) amended **56479**
14.33 (c) amended **56479**
14.75 (a)(1) revised; eff. 5–23–01 1259
15 Authority citation revised **25440**
16.5 (a)(4) added; eff. 9–4–01 ..... **76110**
16.60 (a)(3) amended 6469
19.10 (c) amended **56479**
25 Effective date confirmation **60359**
25.20 (i) revised **30355**
25.30 (h) amended **56479**
25.32 (i), (j), (k), (q) and (r) revised **30355**
50.3 (b)(11) correctly removed; CFR correction **81739**
56.102 (b)(10) and (11) revised **52302**
71.1 (a) and (c) amended; (j) added (effective date pending) **51762**
71.20 (a)(3) added **51762**
73 Comment period extension **59717**
Technical correction **60253**
73.185 Added **41584**
73.355 Added **41587**
73.2995 Added **48377**
(c) corrected **75158**
74 Effective date confirmed **58221**
74.3602 (b)(2)(i) revised; (b)(2)(iv) added **46344**
101 Stay of compliance **58346**
Compliance date established **69666**
Authority citation revised **76110**
101.9 (b)(7)(vi) amended **56479**
101.17 Heading and (h) added; eff. 9–4–01 ..... **76111**
101.71 (a), (c) and (e) removed; (b) and (d) redesignated as (a) and (b) **58918**
101.79 (c)(2)(i)(G) removed; (c)(2)(i)(H) redesignated as (c)(2)(i)(G) **58918**
101.83 Added **54717**
(c)(2)(ii)(A)(*2*), (e)(1)(i), (ii), (2)(i) and (ii) corrected **70466**
107.270 Amended **56479**
110.80 (a)(3) and (4) amended **56479**
114.100 (a) amended **56479**
115 Added; eff. 6–4–01 ..... **76112**
120 Added; eff. 1–22–02 6197
170.35 (c)(3) through (6) redesignated as (c)(4) through (7); new (c)(3) added **51762**
170.39 (h) amended **56479**
171.1 (a) and (c) amended; (n) added (effective date pending) **51763**
171.100 (b) redesignated as (c); new (b) added **51763**
172.120 (b)(1) table amended **48378**
172.135 (b)(1) table amended **48379**
172.841 (c) revised **64605, 79719**
172.846 (c)(9) added **60859**
173 Technical correction **45522**
173.300 (a) revised **34587**
173.370 Added **70660**

NOTE: **Boldface page numbers indicate 2000 changes.**

CHANGES APRIL 3, 2000 THROUGH JANUARY 31, 2001

175.105 (c)(5) table amended **20728**
175.300 (b)(3)(viii)(*b*) amended **21312**
(b)(3)(xxxiii) amended **37041**
175.320 (b)(3) table amended **37041**
176.170 (a)(5) table amended **20728**
(b)(2) table amended **34081**
(a)(5) table amended **36786**
176.180 (b)(2) table amended **36787**
176.300 (c) table amended **40497, 70789**
177.1210 (b)(5) table 1 amended **26745**
(b)(5) table amended **52908**
177.2600 (c)(4)(i) amended **68890**
178.2010 (b) table amended ... **26129, 26746, 38426, 41875**
178.3297 (e) table amended 6469
178.3725 Table amended **52909**
179.26 (b) table amended **45281, 64607**
179.39 (a) and (b) table revised **71057**
179 Technical correction **76005**
200.51 Added; eff. 5–27–02 ..... **34089**
201 Compliance date extention **38191**
201.66 (c)(5)(ii)(C) revised; eff. 5–16–02 ..... **46867**
(c)(5)(ii)(C) revised; eff. 5–17–02 ..... **48904**
201.323 Regulation at 65 FR 4110 eff. date delayed to 1–26–03 7864
203 Hearing **56480**
203.3 Regulation at 64 FR 67757 effective delayed in part to 10–01–01 ..... **25639**
203.50 Regulation at 64 FR 67761 effective date delayed to 10–01–01 ..... **25639**
205 Hearing **56480**
207 Authority citation revised 5466
207.20 Heading revised, eff. 4–4–01; (f) added, eff. 1–21–03 5466
211.194 (a)(2) amended **18889**
291 Removed 4090
310.500 (e) amended **56479**
310.545 Regulation at 64 FR 27687 effective date delayed through 12–31–03 ..... **36319**
(d)(31) revised **36324**
(a)(15)(ii) reinstated in part **48902**
(a)(15) heading, (i) heading and (ii) revised; eff. 5–17–02 ..... **48905**
(d)(2) correctly added; CFR correction **81739**
312.3 (b) corrected; CFR correction **81739**
312.23 (a)(8) amended **56479**
312.42 (b)(1)(v) added; (b)(2)(i) revised **34971**
312.145 Revised **56479**
314 Authority citation revised **64617**
Corrected; CFR correction **81739**
314.50 Introductory text amended **56479**
314.70 (a) amended **56479**
314.81 (b)(2) introductory text and (vii) revised; (b)(2)(viii) and (ix) added **64617**
314.94 Introductory text amended **56479**
314.105 (c) amended **56479**
314.107 (e)(1) through (2)(iii) removed; (e)(2)(iv) redesignated as (e); new (e) heading revised; interim **43235**
314.420 (c) amended **56479**
314.430 (f)(6) amended 1832
314.445 Revised **56480**
316.50 Revised **56480**
330 Compliance date extention **38191**
331 Compliance date extention **38191**
333.250 (b)(1)(i) introductory text, (2)(i) introductory text and (ii) revised; eff. 5–16–02 ..... **52305**
341 Compliance date extention **38191**
341.74 (c)(5)(iii) through (vii) added; (d)(2)(i), (ii), (iv) and (v) revised; eff. 5–16–02 ..... **46867**
344.3 (c) and (d) added; eff. 5–17–02 ..... **48905**
344.10 Heading revised; eff. 5–17–02 ..... **48905**
344.12 Added; eff. 5–17–02 ..... **48905**
344.50 Heading revised; (e) removed; eff. 5–17–02 ..... **48905**
344.52 Added; eff. 5–17–02 ..... **48905**
346 Compliance date extention **38191**
349.75 (c)(2) revised; (c)(5) added; eff. 5–16–02 ..... **38428**
352 Regulation at 64 FR 27687 effective date delayed through 12–31–03 ..... **36319**
355 Compliance date extention **38191**
358 Compliance date extention **38191**
369 Compliance date extention **38191**
500.80 (a) amended **56480**
510.300 (a)(4) amended **76929**
510.600 (c)(1) table and (2) table amended ..... **20729—20731, 25642, 36615, 36787, 45876, 54147, 55461, 60097, 60585, 69865**
(c)(1) table and (2) table amended 7578
514.1 (d)(1)(ii) revised **47669**

NOTE: **Boldface page numbers indicate 2000 changes.**

CHANGES APRIL 3, 2000 THROUGH JANUARY 31, 2001

TITLE 21 Chapter I—Con.

(d)(2) amended **56480**
(b)(9) added **76929**
520.1192 (a) and (b) revised; (c) redesignated as (d); new (c) added **70661**
520.1195 (b) amended 7579
520.1197 (d)(2) amended **45876**
520.1390 Added **20730**
520.1485 (b) amended **45877, 53581**
520.1510 Added **70662**
520.1720b (b) amended **20731**
520.2122 (b)(1) amended **45877**
522.390 (b) amended **45877**
522.540 (d)(2)(i) and (e)(2) amended **45877**
522.778 (b) amended **45878**
522.1044 (b)(4) amended **45877**
522.1125 (d)(1) and (2) amended **20732**
522.1183 (e)(1) amended **45877**
522.1222a (c) amended **45878**
522.1244 (b) amended **61090**
522.1662a (i)(2) amended **45877**
522.1680 (b) amended **45877**
522.1696a Revised 711
522.1696b Revised 712
522.2120 (b) amended **45877**
522.2477 (b), (d)(1)(i)(A), (B), (C), (ii), (2)(i), (ii) and (3)(i) revised **26748**
(b) amended; (d)(1)(i)(D) added; (d)(2)(i) and (ii) revised **45879**
(b) amended; (d)(3)(i) revised **70663**
524.802 Added **66620**
524.1005 (b)(1) and (c)(3) revised; (c)(2)(iii) removed **41588**
524.1044h Added 712
524.1195 Added 7578
524.1376 (c)(2) amended **50913**
524.1451 (d)(2) and (3) amended **36617**
524.2098 (d)(2) amended **45282**
526.365 (d)(3) amended **20733**
526.1810 Heading and (d)(3) amended **61091**
556.70 Revised **70791**
556.275 Revised **20733**
(b)(1)(ii) and (3)(ii) added **41588**
(b)(3) redesignated as (b)(4); new (b)(3) added **50914**
556.426 Revised **36617**
(b) revised **76930**
556.515 Revised **61091**
556.592 Added **70791**
558.3 (b)(1)(ii) revised; (b)(6) through (11) added **76929**
558.6 Added **76929**
558.76 (d)(3)(xxii) added **41589**
(d)(3)(v) through (xvii) redesignated as (d)(3)(vi) through (xviii); new (d)(3)(v) added **50134**
(d)(3) revised **50915**
(d)(1) table amended **54411**
558.78 (d)(3) revised **55894**
558.95 (d)(4)(ii) amended **20734**
(d)(5) introductory text and (i) through (iv) revised **50134**
(d)(5)(iii) and (iv) redesignated as (d)(5)(iv) and (v); new (d)(5)(iii) added **53582**
(a)(4) amended **54148**
558.128 (d)(1)(xii) table amended **45882**
558.195 (d) table amended **66620, 82913**
(d) table amended 1833
558.198 (d) revised **50134**
558.258 (c) redesignated as (d); (d)(1)(vi) and (vii) added **41589**
(d)(1) through (4) redesignated as (d)(2) through (5); new (d)(1) added **50914**
558.265 (c)(1)(viii) and (3)(ii) added **45712**
558.355 (d)(6), (f)(3)(x)(*a*) and (*c*) revised **45880**
(f)(1)(xxviii), (2)(v) and (vi) added **53582**
(f)(4)(ii) and (iii) redesignated as (f)(4)(i)(*a*) and (*b*); new (f)(4)(ii) and (iii) added **53583**
(f)(4)(iv) added **54412**
(f)(7) added **82913**
(f)(7) amended 1834
558.363 (a)(7) and (d)(1)(x) added **55894**
(d)(1)(xi) added **65271**
558.364 (d) table amended **45881**
558.460 (b) amended **45880**
558.485 (a)(29) added **66621**
558.515 (c) and (d) revised **50915**
558.530 (a) and (d)(5) revised; (d)(6) removed **45712**
558.550 (a)(2), (d)(1)(xv)(*c*) and (xvi)(*c*) amended; (a)(3) removed; (d)(3)(i), (ii), and (iii) redesignated as (d)(3)(i)(A), (B) and (C); (d)(1)(xviii), (xix), new (3)(ii) and new (iii) added **41876**
(d)(3)(iv) added **45523**
(d)(3)(ii), (iii) and (iv) redesignated as (d)(3)(iv), (vi) and

NOTE: **Boldface page numbers indicate 2000 changes.**

CHANGES APRIL 3, 2000 THROUGH JANUARY 31, 2001

(vii); (a)(3), (d)(1)(xx), (xxi), new (3)(ii), (iii) and (v) added **70791**
558.618 (d)(4) removed **76930**
558.625 (a) amended; (f)(2)(v)(*e*) redesignated as (f)(1)(vi)(*e*) **53582**
(f)(2) revised **65271**
(f)(2)(i) through (v) redesignated as (f)(2)(ii) through (vi); new (f)(2)(i) added 1834
558.635 (d)(4) introductory text and (i) through (vii) revised **50135**
573.920 (b) revised; (h) added **35824**
(h) corrected **53167**
600.3 (hh) and (ii) added **66634**
600.14 Revised **66634**
600.21 (a)(2) and (3) amended; eff. 6–11–01 ..... **77499**
600.50 (a) amended; eff. 6–11–01 ..... **77499**
600.51 (a)(3) and (4) amended; eff. 6–11–01 ..... **77499**
601 Authority citation revised **64618**
601.12 (Subpart B) Heading removed **59718**
601.12 Transferred to Subpart C **59718**
601.12—601.28 (Subpart C) Heading revised **59718**
601.15 Redesignated from 601.28 ..... **59718**
601.28 Redesignated as 601.15; new 601.28 added **59718**
(c) amended **64618**
601.29 Added **56480**
601.70 Added **64618**
606.3 (k) and (l) added **66635**
(j) revised 1835
606.151 (b) and (c) revised 1835
606.160 (b)(7)(iii) revised **66635**
606.171 Added **66635**
640.2 (b) revised 1836
640.3 (c)(1) revised 1836
640.4 (g) introductory text, (1), (2), (4) and (5) revised 1836
640.5 Introductory text and (c) revised 1836
640.15 Revised 1836
640.16 (a) revised 1836
640.23 (a) revised 1836
640.24 (b) revised 1836
640.25 (c) introductory text amended 1836
640.34 (a) through (e)(1) revised 1836
640.54 (a)(2) revised 1837
640.56 (c) introductory text amended 1837
640.62 Revised 1837
640.63 (c)(11) revised 1837
640.71 (a) introductory text amended 1837
640.81 (e) amended; (f) revised **52018**
640.102 (e) amended **52018**
660 Authority citation revised **77499**
660.20 (a) amended; eff. 6–11–01 ..... **77499**
700.35 Regulation at 64 FR 27693 effective date delayed through 12–31–03 ..... **36319**
701 Compliance date extention **38191**
720 Heading revised **18889**
801.410 (d)(2) amended **44436**
801.430 (f)(2) amended; note revised **44436**
(e)(1) table revised **62284**
803.14 (b) amended **56480**
807 Authority citation revised 5466
807.20 Heading revised, eff. 4–4–01; (d) added, eff. 1–21–03 5466
808.51 Removed **66636**
808.52 Removed **66636**
808.94 Removed **66636**
809.10 (f) added; eff. 4–9–01 ..... **18234**
809.40 Added; eff. 4–9–01 ..... **18234**
811 Technical correction **51532**
814.20 (g) revised **56480**
820.1 (e) added **66636**
821.50 (a) amended **43690**
860.3 (c)(2) amended **56480**
862.1710 (b) revised **62286**
864.3250 (a) amended; eff. 4–9–01 ..... **18234**
864.3260 Added; eff. 4–9–01 ..... **18234**
866.5785 Added **70307**
868.2450 (c) revised **19834**
868.5115 Added **39099**
(b) corrected **47670**
870.4200 Revised **19319**
872.1745 Added **18235**
872.3980 Added **60099**
876.3350 (c) revised **19658**
876.5280 (c) revised **57731**
Regulation at 65 FR 57713 eff. date corrected to 9–26–00 ..... **64618**
876.5310 Added **18237**
876.5980 (b)(1) revised **76932**
876.5990 Added **48612**
878.4495 Added **19836**
878.5035 Added **20735**
880.5965 Added **37043**
880.5970 Added **37043**
880.6885 Added **36325**

NOTE: **Boldface page numbers indicate 2000 changes.**

CHANGES APRIL 3, 2000 THROUGH JANUARY 31, 2001

TITLE 21 Chapter I—Con.

880.6890 Added **36326**
884.2050 Revised **41332**
884.5330 Added **31455**
884.5940 (c) revised **19834**
884.5970 Added **47306**
888.1500 Revised **19319**
890.1175 (b) revised **19319**
890.3890 (c) revised **19834**
895.21 (d)(8) amended **43690**
900.12 (e)(5)(iii)(A)(1) and (f)(3) amended **43690**
1240.40—1240.57 (Subpart C) Removed **49908**
1240.45 Transferred to Subpart B **49908**
1270 Regulation at 63 FR 53585 confirmed **51538**
1270.3 (f) revised **51538**
1270.5 (b) revised **51538**
1270.6 (c) added **51538**
1270.7 (c) through (f) redesignated as (d) through (g); new (c) added **51538**
1271 Added, eff. in part 4–4–01 5466
1271.3 (d)(2) added, eff. 1–21–03 5467

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

1300.1 (b)(42) added **44678**
1301 Technical correction **17552**
Supplementary statement **30541**
1301.12 (b)(4) added **44678**
(b)(4) corrected **45829**
1301.77 Added **44678**
(c) corrected **45829**
1304 Technical correction **49484**
1304.03 (g) added **44679**
1306.11 (g) revised; interim **45713**
Regulation at 65 FR 45713 confirmed 2214
1307.12 Revised **44679**
(a) corrected **45829**
1308 Technical correction **17552**
1308.12 (b)(1)(8) through (b)(1)(16) redesignated as (b)(1)(9) through (b)(1)(17); new (b)(1)(8) added **69443**
1308.13 Corrected **17440**
1308.34 Regulation at 65 FR 3126 and 65 FR 5024 confirmed **43694**
1310 Technical correction **48546**
1310.02 (a)(24) added **21647**
(b)(8) revised; (b)(11) added **47316**
1310.04 (f)(2)(ii)(H) and (I) added; (f)(2)(iv) revised **47316**
1310.08 (a) and (b) introductory text revised; (f) through (i) added **47316**
1310.09 (c) added **21647**

Proposed Rules:

1 6502
10 ..... **18934, 21378**
14 1276
16 ..... **26162**
..... 3523
20 ..... **43269**
..... 688
25 ..... **30366**
58 ..... **43269**
101 ..... **41029, 56835, 75887**
111 ..... **17474**
170 ..... **43269**
171 ..... **43269**
174 ..... **43269**
179 ..... **43269**
192 4706
201 ..... **18934, 21378, 56511, 81082**
210 ..... **20774**
211 ..... **20774**
250 ..... **18934, 21378**
290 ..... **18934, 21378**
310 ..... **18934, 21378, 70538**
312 4688
314 ..... **66665**
315 ..... **46674**
329 ..... **18934, 21378**
341 ..... **18934, 21378, 51780**
361 ..... **18934, 21378**
369 ..... **18934, 21378**
514 ..... **51782**
592 4706
601 ..... **46674**
..... 4688
606 ..... **18934, 21378, 69378**
610 ..... **18934, 21378, 69378**
660 ..... **77532**
801 ..... **62317**
807 3523
820 ..... **20774**
821 ..... **24144**
822 ..... **52376**
864 ..... **20933, 70325**
866 ..... **20933, 70325**
868 ..... **20933, 57301, 70325**
870 ..... **20933, 70325**
872 ..... **20933, 70325**
874 ..... **20933, 70325**
876 ..... **20933, 70325**
878 ..... **20933, 70325**
884 ..... **20933, 70325**

NOTE: **Boldface page numbers indicate 2000 changes.**

886 ..... **20933, 70325**
888 ..... **20933, 70325**
890 ..... **50949**
896 ..... **57303**
900 ..... **26162**
1271 ..... **20774, 44485, 77838**
..... 1508
1308 ..... **77328**
1310 ..... **57577**
1313 ..... **63822, 67796**

TITLE 22—FOREIGN RELATIONS

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

22.1 Amended **54150**
Stayed in part to 1–1–01; interim **78093**
40 Authority citation revised **54413**
40.1 (l) through (s) redesignated as (m) through (t); new (l) added **54413**
40.41 (b) revised **78094**
41.2 (i) revised 1034
41.12 Table amended **20904**
41.53 (a)(2) and (b) amended **52306**
41.107 (c)(1) revised **52307**
42.11 Table amended **20904**
42.32 (d)(1)(ii) revised **80745**
42.71 (b) revised **54413**
(b) stayed; (c) added; eff. to 1–1–21; interim **78095**
51.21 (a), heading, (c)(1), (2), (d)(1) and (2) amended **39288**
51.80 Revised **39288**
62 Authority citation revised **20083**
62.90 Added **20083**
123 Authority citation revised **34091**
123.27 Revised; interim **34091**
124.2 (c) added **45283**
125.4 (a) revised; (c) added **45284**
126.1 (a) corrected; CFR correction **81739**
126.6 Revised **45287**
126.9 Revised **45285**
126.14 Added **45285**
146 Added **52865, 52878**
146.105 Amended **52878**
146.605 Added **52879**

Chapter II—Agency for International Development (Parts 200—299)

203.2 (i) added **54790**
229 Added **52865, 52879**
229.105 Amended **52879**
229.605 Added **52879**

Chapter VII—Overseas Private Investment Corporation (Parts 700—799)

706 Revised **64343**

Proposed Rules:

41 1064
51 ..... **60132**
141 ..... **76460**
142 ..... **76460**
143 ..... **76460**
209 ..... **76460**
217 ..... **76460**
218 ..... **76460**
706 ..... **30369**

TITLE 23—HIGHWAYS

Chapter I—Federal Highway Administration, Department of Transportation (Parts 1—999)

140 Authority citation revised **45885**
140.301—140.311 (Subpart C) Removed **45883**
140.701—140.715 (Subpart G) Removed **45885**
450 Policy statement **31803**
645 Nomenclature change **70311**
645.105 Amended **70311**
645.109 (c) revised **70311**
645.113 (f) revised **70311**
645.117 (a)(3) added; (i)(2) revised **70311**
645.119 (c) introductory text revised **70311**
645.207 Amended **70311**
645.209 (j) revised; (m) added **70311**
645.211 Introductory text revised **70312**
645.215 (d) revised **70312**
655 Authority citation revised **78958**
655.401—655.411 (Subpart D) Removed 1453
655.601 (a) revised **78958**
668.103 Amended **25444**
668.105 (j) amended **25444**
668.107 (b) amended **25444**
668.109 (a) introductory text, (b)(6), (8), (c)(2)(i), (iii), (8) and (d) revised **25444**
668.111 Revised **25444**

NOTE: **Boldface page numbers indicate 2000 changes.**