CENTER FOR DRUG EVALUATION AND RESEARCH

SPECIAL INTEREST TOPIC

TITLE: GLP - Quarterly Compliance Report

DATE: As of December 31, 1996

GOOD LABORATORY PRACTICE
QUARTERLY COMPLIANCE REPORT

BIORESEARCH MONITORING PROGRAM 7348.808
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF COMPLIANCE
DIVISION OF SCIENTIFIC INVESTIGATIONS
INSPECTION UPDATE AS OF 12-31-96

I. During the period June 20, 1979 (the effective date of the Good Laboratory Practice regulations) through December 31, 1996, 1458 GLP inspections have been scheduled by the Office of Compliance, Division of Scientific Investigations.

1395 have been received to date

WASHOUTS (WO)	124
CANCELLED (C)	98
PENDING (PEND)	2
CLASSIFIED	1171
NAI	589
VAI*	16
VAI**	76
VAI-1	29
VAI-2	269
VAI-3	131
OAI	61

VAI* = Classified prior to 10/01/81
VAI** = Classified after 01/01/94

II. A. Of the 1171 nonclinical laboratories classified, the following percent of laboratories had:

	% OF 1171
1. No observed deficiencies	22
2. Only minor deficiencies	17
3. An FDA-483 Inspectional Observations Issued	53
4. Miscellaneous	8

B. The percent of labs deficient in meeting one or **more(*)** of the requirements of 11 major GLP provisions are as follows:

(*) A single laboratory may have multiple deficiencies which would consequently be recorded in each respective GLP category.

SUBPART/CATEGORY	% OF 1171
1. REFUSALS	1
2. PERSONNEL/MANAGEMENT/STUDY DIRECTOR	30
3. QAU OPERATIONS	23
4. ANIMAL/TESTING FACILITIES	9
5. EQUIPMENT MAINTENANCE/CALIBRATION	26
6. SOPs	36
7. ANIMAL CARE	16
8. TEST & CONTROL ARTICLES	18
9. PROTOCOL & CONDUCT	33
10. FINAL REPORT	23
11. RECORDS	15

These data are shown in Table 1 and is further broken down into lab types i.e., sponsor, contract, university, foreign & government.

III. The following is a list of assignments & EIR's classified for fiscal years beginning with the 4th Quarter '79.

	WO	C	#EIs PEND	CLASS	NAI	VAI*	VAI**	VAI-1	VAI-2	VAI-3	OAI
FY '79	0	0	0	6	3	2	-	-	-	-	1
4th Qtr FY '80	12	9	0	54	45	9	-	-	-	-	0
FY '81 thru 9/30/81	6	4	0	49	44	5	-	-	-	-	0
FY '81 rec'd as of 10/1/81	0	1	0	9	2	-	-	2	3	2	0
FY '82	6	6	0	59	17	-	-	12	13	15	2
FY '83	9	2	0	59	20	-	-	2	21	15	1
FY '84	2	0	0	81	44	-	-	1	17	16	3
FY '85	5	1	0	69	19	-	-	3	32	14	1
FY '86	7	2	0	82	39	-	-	0	26	14	3
FY '87	11	6	0	91	47	-	-	0	26	10	8
FY '88	21	4	0	73	32	-	-	2	24	14	1
FY '89	5	3	0	90	46	-	-	1	30	10	3
FY '90	7	1	0	61	32	-	-	3	15	4	7
FY '91	5	4	0	73	39	-	1	1	18	3	11
FY '92	5	6	0	90	45	-	3	2	26	7	7
FY '93	7	10	0	89	37	-	21	0	18	7	6
FY '94	7	27	0	67	34	-	26	-	-	-	7
FY '95	5	9	0	48	30	-	18	-	-	-	0
FY '96	4	3	1	21	14	-	7	-	-	-	0
FY'97	0	0	1	0	0	-	0	-	-	-	0
TOTAL	124	98	2	1171	589	16	76	29	269	131	61

VAI* = Classified prior to 10/01/81
VAI** = Classified after 01/01/94

The significant deviations from the 11 major GLP provisions for each Fiscal Year (beginning with the 4th Quarter '79) are indicated in Tables 2 through 19 respectively.

IV. At the beginning of Fiscal Year 1988 on October 5, 1987, the Good Laboratory Practice (GLP) regulations were significantly revised. The FDA modified the requirements for the Quality Assurance Units's (QAU) operations. Specifically, the requirements that the QAU inspect each phase of a study at periodic intervals according to set schedules was changed. The alterations permits the QAU to identify critical study phases and to set QA inspection schedules so that studies can be inspected "...at intervals adequate to assure the integrity of the study...".

Table 20 compares the GLP noncompliance rates for the cumulative fiscal years of FY'79 through FY'87 versus FY'88 through FY'96.

The section "Personnel, Management, and Study Director" shows a significant increase (up 11%) in noncompliance. This is due to many of the cited raw data deficiencies being categorized as violations of part 58.33(b) under the responsibility of the study director; i.e., "The study director shall assure that: All experimental data, including observations of unanticipated responses of the test system are accurately recorded and verified."

Because of the continuing increase in deviations cited for part 58.33, testing facility management should make periodic assessments of the **ADEQUACY** and **EFFECTIVENESS** of their study director's role, duties, and responsibilities. As such, testing facility management needs to establish adequate and detailed SOPs describing methods used to make such an assessment. For example, testing facility management needs to periodically review and assess the effectiveness of the procedures by which they assure themselves that any deviations from the GLP regulations (as reported by the QAU) are communicated to the study director, and that corrective actions are taken and documented. Further, the question of "How does the study director ensure that all experimental data are accurately recorded and verified?" needs to be answered and assessed for effectiveness by the testing facility management.

We are convinced that too many study directors are not fulfilling their obligations as set forth by the GLP regulations and/or by the facility management. Emphasis needs to be placed on the study director as being the individual responsible for the overall conduct of a study. That is, he/she is responsible for the overall technical conduct of a study, as well as for the interpretation, analysis, documentation, and reporting of results, and represents the single point of study control.

The field will be directed to focus on assessing the study director's role and determining management's efforts to evaluate the study director's functions and responsibilities.

V. Of the 1171 nonclinical laboratories classified, 576 labs required correspondence in the form of Post Inspection (PI), Notice of Adverse Finding (NAF), Rejection of Study, or Warning Letters.

	PI	NAF	REJECTION	WARNING-1	WARNING-2
SPONSOR	173	34	7	1	2
CONTRACT	196	56	24	5	4
UNIVERSITY	10	13	19	1	0
FOREIGN	24	1	0	0	0
GOVERNMENT	3	2	1	0	0
TOTAL	406	106	51	7	6

As of January 1994, the scheme for classifying EIRs was changed. In order to continue tracking letters in which nonclinical laboratory studies are being rejected, this office will separate our "Warning" letters by recording them as noted below:

WARNING-1 = WARNING LETTER ISSUED FOR VARIOUS GLP DEVIATIONS BUT NO STUDIES WERE REJECTED.

WARNING-2 = WARNING LETTER ISSUED **AND** STUDIES WERE REJECTED.

Ty Fujiwara

1. *CUMULATIVE ... 06-20-79 through 12-31-96*

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR (492) [1]	4	123	76	24	100	149	58	74	139	96	41
CONTRACT (557)	4	182	148	58	161	218	97	106	195	131	95
UNIVERSITY (67)	0	26	31	15	18	32	19	20	37	25	23
FOREIGN (48)	0	12	12	9	20	12	10	12	12	10	8
GOVERNMENT (7)	0	4	4	1	4	5	2	4	6	3	4
TOTAL (1171)	8 (1) [2]	347 (30)	271 (23)	107 (9)	303 (26)	416 (36)	186 (16)	216 (18)	389 (33)	265 (23)	171 (15)

[1] (n) = number of labs

[2] (n) = % of labs

2. FY '79 - 4th QTR

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR(1)[1]	0	0	1	0	0	1	0	1	0	1	0
CONTRACT(4)	0	0	1	0	0	3	0	1	2	3	3
UNIVERSITY(0)	-	-	-	-	-	-	-	-	-	-	-
FOREIGN(1)	0	0	1	1	0	1	1	1	1	0	1
TOTAL(6)	0 (0)[2]	0 (0)	3 (50)	1 (17)	0 (0)	5 (83)	1 (17)	3 (50)	3 (50)	4 (67)	4 (67)

[1](n) = number of labs

[2](n) = % of labs

3. FY '80

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR(13)[1]	1	0	4	0	0	5	1	3	8	5	2
CONTRACT(32)	2	4	5	5	5	10	6	6	9	9	4
UNIVERSITY(4)	0	0	3	1	1	2	1	1	3	1	2
FOREIGN(5)	0	0	1	0	1	0	1	1	2	5	0
TOTAL(54)	3 (6)[2]	4 (7)	13 (24)	6 (11)	7 (13)	17 (31)	9 (17)	11 (20)	22 (41)	20 (37)	8 (15)

[1](n) = number of labs

[2](n) = % of labs

4. FY'81

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES,	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR (31)[1]	1	2	8	3	4	14	4	4	10	8	2
CONTRACT (27)	1	6	13	10	8	14	7	7	13	8	8
UNIVERSITY (0)	-	-	-	-	-	-	-	-	-	-	-
FOREIGN (0)	-	-	-	-	-	-	-	-	-	-	-
TOTAL (58)	2 (3)[2]	8 (14)	21 (36)	13 (22)	12 (21)	28 (48)	11 (19)	11 (19)	23 (40)	16 (28)	10 (17)

[1](n) = number of labs

[2](n) = % of labs

5. FY'82

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR (22)[1]	0	1	3	0	3	9	0	2	8	7	2
CONTRACT (25)	0	6	9	3	8	13	4	4	10	7	5
UNIVERSITY (9)	0	3	5	3	3	7	4	4	7	4	4
FOREIGN (0)	-	-	-	-	-	-	-	-	-	-	-
GOVERNMENT (3)	0	2	2	1	1	2	2	3	3	2	2
TOTAL (59)	0 (0)[2]	12 (20)	19 (32)	7 (12)	15 (25)	31 (53)	10 (17)	13 (22)	28 (47)	20 (34)	13 (22)

[1](n) = number of labs

[2](n) = % of labs

6. FY'83

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR (33)[1]	2	9	6	4	6	13	5	8	14	12	6
CONTRACT (21)	0	8	9	3	9	12	6	7	10	8	4
UNIVERSITY (0)	-	-	-	-	-	-	-	-	-	-	-
FOREIGN (5)	0	1	1	0	0	1	2	1	2	1	0
GOVERNMENT (0)	-	-	-	-	-	-	-	-	-	-	-
TOTAL (59)	2 (3)[2]	18 (31)	16 (27)	7 (12)	15 (25)	26 (44)	13 (22)	16 (27)	26 (44)	21 (36)	10 (17)

[1](n) = number of labs

[2](n) = % of labs

7. FY'84

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR(37)[1]	0	9	6	3	9	13	5	5	13	6	1
CONTRACT(35)	0	10	9	0	10	13	7	3	14	7	7
UNIVERSITY(7)	0	2	3	1	3	4	2	3	5	4	2
FOREIGN(2)	0	0	0	0	0	0	0	0	0	0	0
GOVERNMENT(0)	-	-	-	-	-	-	-	-	-	-	-
TOTAL(81)	0 (0)[2]	21 (26)	18 (22)	4 (5)	22 (27)	30 (37)	14 (17)	11 (14)	32 (40)	17 (21)	10 (12)

[1](n) = number of labs

[2](n) = % of labs

8. FY'85

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provision

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR(32)[1]	0	11	5	1	9	11	2	2	8	9	4
CONTRACT(28)	0	11	12	3	9	16	5	6	14	11	8
UNIVERSITY(7)	0	2	2	1	1	2	2	3	3	3	4
FOREIGN(2)	0	0	0	0	0	0	0	0	0	0	0
GOVERNMENT(0)	-	-	-	-	-	-	-	-	-	-	-
TOTAL(69)	0 (0)[2]	24 (35)	19 (28)	5 (7)	19 (28)	29 (42)	9 (13)	11 (16)	25 (36)	23 (33)	16 (23)

[1](n) = number of labs

[2](n) = % of labs

9. FY'86

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR (34)[1]	0	5	2	3	4	9	2	4	9	7	1
CONTRACT (41)	0	13	10	4	10	16	8	10	18	8	8
UNIVERSITY (5)	0	4	4	2	3	4	3	2	5	3	2
FOREIGN (2)	0	0	1	1	1	1	1	1	1	0	1
GOVERNMENT (0)	-	-	-	-	-	-	-	-	-	-	-
TOTAL (82)	0 (0)[2]	22 (27)	17 (21)	10 (12)	18 (22)	30 (37)	14 (17)	17 (21)	33 (40)	18 (22)	12 (15)

[1](n) = number of labs

[2](n) = % of labs

10. FY'87

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR(43)[1]	0	7	9	2	8	13	8	6	13	6	5
CONTRACT(39)	0	13	9	6	12	20	10	10	16	11	9
UNIVERSITY(8)	0	3	3	2	2	3	1	2	3	2	1
FOREIGN(1)	0	0	0	0	0	0	0	0	0	0	0
GOVERNMENT(0)	-	-	-	-	-	-	-	-	-	-	-
TOTAL(91)	0 (0)[2]	23 (25)	21 (23)	10 (11)	22 (24)	36 (40)	19 (21)	18 (20)	32 (35)	19 (21)	15 (16)

[1](n) = number of labs

[2](n) = % of labs

11. FY'88

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR(31)[1]	0	11	9	1	7	9	7	9	12	5	4
CONTRACT(37)	0	14	13	4	10	13	4	8	12	5	6
UNIVERSITY(4)	0	2	1	0	0	2	0	0	1	0	1
FOREIGN(0)	-	-	-	-	-	-	-	-	-	-	-
GOVERNMENT(1)	0	0	1	0	1	1	0	0	1	0	0
TOTAL(73)	0 (0)[2]	27 (37)	24 (33)	5 (7)	18 (25)	25 (34)	11 (15)	17 (23)	26 (36)	10 (14)	11 (15)

[1](n) = number of labs

[2](n) = % of labs

12. FY'89

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisio

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR (40)[1]	0	9	5	3	6	10	7	5	10	3	4
CONTRACT (42)	0	11	10	4	11	13	7	5	10	8	2
UNIVERSITY (3)	0	3	2	0	1	0	1	0	2	2	1
FOREIGN (5)	0	1	3	2	2	2	2	2	2	2	2
GOVERNMENT (0)	-	-	-	-	-	-	-	-	-	-	-
TOTAL (90)	0 (0)[2]	24 (27)	20 (22)	9 (10)	20 (22)	25 (28)	17 (19)	12 (13)	24 (27)	15 (17)	9 (10)

[1](n) = number of labs

[2](n) = % of labs

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR(28)[1]	0	7	2	1	1	3	1	2	5	2	2
CONTRACT(29)	0	10	6	1	6	9	5	6	13	6	3
UNIVERSITY(3)	0	2	1	1	0	2	2	0	2	1	2
FOREIGN(0)	-	-	-	-	-	-	-	-	-	-	-
GOVERNMENT(1)	0	1	0	0	1	1	0	0	1	0	1
TOTAL(61)	0 (0)[2]	20 (33)	9 (15)	3 (5)	8 (13)	15 (25)	8 (13)	8 (13)	21 (34)	9 (15)	8 (13)

[1](n) = number of labs

[2](n) = % of labs

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR (30)[1]	0	10	2	1	6	10	2	8	7	4	2
CONTRACT (35)	0	11	6	3	7	7	5	5	10	7	2
UNIVERSITY (6)	0	3	4	2	3	4	2	3	3	3	3
FOREIGN (1)	0	1	1	0	1	1	1	1	1	0	1
GOVERNMENT (1)	0	1	1	0	1	1	0	1	1	1	1
TOTAL (73)	0 (0)[2]	26 (36)	14 (19)	6 (8)	18 (25)	23 (32)	10 (14)	18 (25)	22 (30)	15 (21)	9 (12)

[1](n) = number of labs

[2](n) = % of labs

15. FY'92

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR (38)[1]	0	20	4	0	16	12	6	5	9	9	2
CONTRACT (46)	1	17	8	5	13	16	8	8	12	10	8
UNIVERSITY (2)	0	1	1	1	1	1	0	1	1	1	1
FOREIGN (4)	0	0	0	0	0	0	0	0	0	0	0
GOVERNMENT (0)	-	-	-	-	-	-	-	-	-	-	-
TOTAL (90)	1 (1)[2]	38 (42)	13 (14)	6 (7)	30 (33)	29 (32)	14 (16)	14 (16)	22 (24)	20 (22)	11 (12)

[1](n) = number of labs

[2](n) = % of labs

16. FY'93

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR(35)[1]	0	8	6	1	12	8	6	5	7	5	2
CONTRACT(34)	0	16	9	4	18	13	5	8	12	7	6
UNIVERSITY(6)	0	0	1	0	0	0	1	1	1	1	0
FOREIGN(14)	0	8	3	4	12	5	2	5	3	1	2
GOVERNMENT(0)	-	-	-	-	-	-	-	-	-	-	-
TOTAL(89)	0 (0)[2]	32 (36)	19 (21)	9 (10)	42 (47)	26 (29)	14 (16)	19 (21)	23 (26,)	14 (16)	10 (11)

[1](n) = number of labs

[2](n) = % of labs

17. FY'94

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR(19)[1]	0	10	4	1	5	6	1	3	6	4	2
CONTRACT(41)	0	15	13	2	13	17	5	5	12	8	8
UNIVERSITY(3)	0	1	1	1	0	1	0	0	1	0	0
FOREIGN(3)	0	0	1	1	1	0	0	0	0	0	0
GOVERNMENT(1)	0	0	0	0	0	0	0	0	0	0	0
TOTAL(67)	0 (0)[2]	26 (39)	19 (28)	5 (7)	19 (28)	24 (36)	6 (9)	8 (12)	19 (28)	12 (18)	10 (15)

[1](n) = number of labs

[2](n) = % of labs

18. FY'95

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR (14)[1]	0	4	0	0	3	2	0	2	0	3	0
CONTRACT (31)	0	14	5	1	7	9	5	5	7	7	3
UNIVERSITY (0)	-	-	-	-	-	-	-	-	-	-	-
FOREIGN (3)	0	1	0	0	2	1	0	0	0	1	1
GOVERNMENT (0)	-	-	-	-	-	-	-	-	-	-	-
TOTAL (48)	0 (0)[2]	19 (40)	5 (10)	1 (2)	12 (25)	12 (25)	5 (10)	7 (15)	7 (15)	11 (23)	4 (8)

[1](n) = number of labs

[2](n) = % of labs

FY'96 as of 12-31-96

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

LAB TYPE	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
SPONSOR(11)[1]	0	0	0	0	1	1	1	0	0	0	0
CONTRACT(10)	0	3	1	0	5	4	0	2	1	1	1
UNIVERSITY(0)	-	-	-	-	-	-	-	-	-	-	-
FOREIGN(0)	-	-	-	-	-	-	-	-	-	-	-
GOVERNMENT(0)	-	-	-	-	-	-	-	-	-	-	-
TOTAL(21)	0 (0)[2]	3 (14)	1 (5)	0 (0)	6 (29)	5 (24)	1 (5)	2 (10)	1 (5)	1 (5)	1 (5)

[1](n) = number of labs

[2](n) = % of labs

TABLE 20

SIGNIFICANT DEVIATIONS: Number of labs deficient in meeting one or more of the requirements of 11 major GLP provisions

	FISCAL YEAR	REFUSALS	PERSONNEL MANAGEMENT STUDY DIRECTOR	QAU & OPERATIONS	FACILITIES ANIMAL/TESTING	EQUIPMENT MAINTENANCE/CALIBRA.	STANDARD OPERATING PROCEDURES	ANIMAL CARE	TEST & CONTROL ARTICLES	PROTOCOL & CONDUCT	FINAL REPORT	RECORDS
A.	CUMULATIVE: 4th QTR/79-FY'87 (559)[1]	7 (1)[2]	132 (24)	147 (26)	63 (11)	130 (23)	232 (42)	100 (18)	111 (20)	224 (40)	158 (28)	98 (18)
B.	CUMULATIVE: FY'88 - *FY'96* (612)	*1* (0.2)	*215* (35)	*124* (20)	*44* (7)	*173* (28)	*184* (30)	*86* (14)	*105* (17)	*165* (27)	*107* (17)	*73* (12)
	A vs. B Change in % of labs	*-0.8*	*+11*	*-6*	*-4*	*+5*	*-12*	*-4*	*-3*	*-13*	*-11*	*-6*

[1](n) = number of labs

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* In process of CDER Nomenclature Standards Committee review.

The CDER Data Standards Manual is published by the Division of Database Management, Office of Management. If you would like an additional copy, or if you would like to propose an addition or modification to an existing data standard, please contact Mr. William A. Hess, the Center Lexicographer, at HFD-93, 1901 Chapman Avenue, Rockville, MD 20857 - (Telephone 301-443-3910; Fax 301-443-1326; Internet HESS@FDACD.SSW.DHHS.GOV).

FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

STAFF MANUAL GUIDE
TRANSMITTAL NUMBER 91-1

February 11, 1991

MATERIAL TRANSMITTED

Staff Manual Guide CDER 4010.3.1 - Nomenclature Standards Committee

FILING INSTRUCTIONS AND EXPLANATION OF CHANGES

REMOVE	INSERT	EXPLANATION
CDB 4010.3.1 TN 86-26 07/11/86	CDER 4010.3.1	This guide describes current guidelines, procedures and responsibilities for the Nomenclature Standards Committee.

PEN AND INK CHANGES: Table of Contents CDER 4000 - Entry 4010.3.1 - Line out title, TN No., date and enter new title, TN No., date. Table of Contents for Chapters CDER 4000 - Entry 4010.3.1 - Line out title, TN No., date and enter new title, TN No., date.

Post receipt of this Guide Transmittal Number in the CDER Checklist and destroy this Transmittal.

John R. Treacy

Chief
Management Systems and Analysis Branch

DISTRIBUTION:

NOMENCLATURE STANDARDS COMMITTEE

1. PURPOSE This guide describes current guidelines, procedures, and responsibilities for the Nomenclature Standards Committee.

2. REFERENCE Staff Manual Guide BD 4010.3, "Establishment of Bureau of Drugs Information Systems Users Committee."

3. POLICY Nomenclature control is essential to the successful operation of individual information systems and to assuring the compatibility of numerous information systems within CDER.

   To achieve this, a Center-level, Nomenclature Standards Committee is established. This Committee will establish policy (not regulatory), coordinate its implementation and will monitor to assure compliance with this policy.

4. AUTHORITY The Committee advises the Director, Division of Drug Information Resources and Director, Office of Management (OM), on all matters concerning the standards of nomenclature in the Center by means of the minutes of the meetings and reports generated by the Committee. Any items requiring immediate attention are communicated by the Chairperson directly. The Center Lexicographer shall serve as the final point of approval for policies and standards pertaining to nomenclature, with the concurrence and signatory authority of the Director, OM.

5. MEMBERSHIP

   a. Committee.

      (1) In addition to the Chairperson, membership shall be comprised of at least eight Center managers or their designees. Such membership is open to Center managers and others reliant upon automated data files who have an interest in nomenclature standards. Upon request to the Chairperson, members may be seated from other FDA components, such as the Office of Regulatory Resource Management, Office of Regulatory Affairs. At least one member of the Committee shall represent each

of the following CDER components: a Review Division of the Office of Drug Evaluation I; the Pilot Drug Evaluation Staff, or a Review Division of the Office of Drug Evaluation II; the Division of Drug Information Resources, OM; Division of Information Systems Design, OM; the Division of Management and Budget, OM; Division of Epidemiology and Surveillance, Office of Epidemiology and Biostatistics; Division of Drug Quality Evaluation, Office of Compliance; and the Division of Generic Drugs, Office of Generic Drugs. These members shall serve as a forum for policy development pertaining to the standardization of nomenclature in the Center.

(2) Members should be thoroughly knowledgeable about their area's nomenclature needs and operations and responsible for representing the requirements of their respective files.

(3) The Center Lexicographer serves as the Chairperson and will appoint an Executive Secretary.

b. Subcommittee(s)

Members of the Subcommittee(s) are appointed by the Chairperson with the recommendations of the Committee membership. They serve as the functional complement of the Committee by assisting in the implementation of Committee policy.

c. Alternates.

Alternate members for the Committee are to be specifically designated by each member. Only one alternate is to be permitted for each member and that person should be knowledgeable in the information service requirements of their functional area.

d. Vacancies.

Continued representation from involved Center user areas is essential and replacement of members are encouraged to provide continuity for the completion of ongoing projects.

6. OFFICERS

a. The Center's Lexicographer, Division of Drug Information Resources, holds the position of Committee Chairperson. The Committee Chairperson appoints the Chairperson(s) of the Subcommittee(s) and is responsible for arranging the time, place, agenda, and minutes of the meetings. The Center Lexicographer also represents the Center at Agency level activities on terminology standardization issues as a member of the Information Management Council Data Standards Subcommittee.

b. The Committee Chairperson appoints the Executive Secretaries of both the Committee and Subcommittee(s).

7. ADVISORS AND CONSULTANTS. Advisors and consultants may serve on the Committee and Subcommittee(s) at the discretion of the full Committee to serve as a resource in resolving issues that are beyond the scope of the membership.

8. PROCEDURES

a. Committee meetings shall be open to all interested Agency personnel.

b. The Committee and Subcommittee(s) will meet as needed for the purposes of policy and goal development.

c. Membership of the Committee and Subcommittee(s) is dependent upon the project or mission the Committee is undertaking at the time. Therefore, membership may change as missions are completed and new ones are initiated.

d. Reports will be prepared and distributed describing the intentions, methods, and plans of the Committee as well as the membership's consenting and dissenting viewpoints on salient issues and policy. The reports will be used to gain concurrence by the membership and Director, OM on issues and policy.

9. RESPONSIBILITIES

a. The Chairperson will establish Subcommittees or ad hoc Committees, as may be required, to address specific nomenclature development and/or implementation issues.

b. The Committee will review all manual and automated dictionaries currently available in the Center; develop policy and guidelines for the preparation of new nomenclature dictionaries which are compatible with all Center data files; and make recommendations regarding nomenclature standardization within the Center. The Committee serves as the arbitration body in the maintenance of existing nomenclature tables in order to ensure compatibility, consistency, and quality of all terminology. The Director of OM, Director of the Division of Drug Information Resources and the Director of the Division of Information Systems Design will serve as an appeals board, to which appeals may be sought from decisions of the Committee.

10. EFFECTIVE DATE. This guide is effective upon receipt.

CDER DATA STANDARDS MANUAL

CDER Policy:

CENTER-WIDE THESAURI, DICTIONARIES, AND TABLES. It is in the Center's interest to make all Center-wide thesauri, dictionaries, and tables available to all reviewers, managers, and consumer safety officers on a query-only basis. This will be achieved by allowing these individuals access through the COMIS main menu under the 'SPECIALIZED USERS' selection. This policy is effective immediately.

CDER Approval Date: September 14, 1993.

CDER DATA STANDARDS MANUAL

CDER Policy:

IMPLEMENTATION OF CDER DATA STANDARDS. All systems in operation at the time of adoption of a data standard must incorporate the standard during the next major system modification or as the needs of the Center dictate, whichever occurs first.

CDER Approval Date: November 5, 1991.

CDER DATA STANDARDS MANUAL

CDER Policy:

METRIC SYSTEM AND POTENCY EXPRESSION. Whenever possible, CDER should use the metric system to express potency. Potencies of 10^{-2} or less should be expressed as the next lowest value (e.g., 0.01 GM would become 10 MG), and potencies of 10^{3} or greater should be expressed as the next highest value (e.g., 1000 MG would become 1 GM).

CDER Approval Date: June 14, 1994.

CDER DATA STANDARDS MANUAL

CDER Policy:

Policy for Use of Drug Name Terms. Appropriate terms shall be used when referring to the different types of drug names, as defined below. This includes, but is not limited to, the mention of these terms in the Code of Federal Regulations, databases, outgoing correspondence, and on the Internet/Intranet. Of particular concern is the improper usage of the term "Trade Name" where the term "Proprietary Name" is often meant.

Term Definitions:

Brand Name: (See Proprietary Name) A word, name, symbol, etc., especially one legally registered as a trademark, used by a manufacturer to identify its products distinctively from others of the same type.

Chemical Name: The name generated using the nomenclature conventions of the International Union of Pure and Applied Chemistry (IUPAC). Several correct names may be formulated using these rules but ordinarily the accepted chemical name will be the name listed by the Chemical Abstracts Service (CAS) and is conveniently located in the USAN dictionary.

Compendial Name: The name of an article for which a monograph is provided in an official compendia (e.g., United States Pharmacopeia, National Formulary, or Homeopathic Pharmacopeia) recognized by the Food, Drug, and Cosmetic Act. An article may be an official substance or official preparation.

Drug: As defined under the Federal Food, Drug, and Cosmetic Act, as amended (section 201(g)), applies to both drug substances and drug products.

Established Name: The designated FDA Official name, the Compendial name, the USAN Council name or the common or usual name (section 502(e)(3) of the Act and 21 CFR 299.4). Ordinarily, the established name of a drug will be the compendial name. However, FDA may designate an established name in cases where a monograph does not exist.

Generic Name: An official or unofficial designation by which a drug is commonly available, unprotected by a trademark.

INN Name: The International Nonproprietary Name designated by the World Health Organization (WHO). Usually the USAN and INN name are identical. WHO only assigns names to active drug moieties.

Nonproprietary Name: A name unprotected by trademark rights that is entirely in the public domain. It may be used without restriction by the public at large, both lay and professional.

Official: The word "official" as used in the United States Pharmacopeia, is synonymous with "Pharmacopeial", with "USP", and with "compendial."

Official Name: The name designated under the provisions of section 508(a) of the Federal Food, Drug, and Cosmetic Act.

Official Preparation: A drug product, a nutritional supplement or a finished device.

Official Substance: An active drug entity, a recognized nutrient, or a pharmaceutic ingredient for which the USP monograph title includes no indication of the nature of the finished form.

Proprietary Name: The exclusive name of a drug substance or drug product owned by a company under trademark law regardless of registration status with the PTO.

Trademark: The words, names, slogans, pictures or symbols that are used to identify the source of a particular company's drug or technology.

Tradename: The words, names, slogans, pictures or symbols that are used to identify a company. In common usage, tradename is often used inappropriately for brand name and trademark.

USAN Name: The Official nonproprietary name published in the USP Dictionary of USAN and International Drug Names[A] by the United States Adopted names Council.

CDER Approval Date: November 8, 1996.

CDER DATA STANDARDS MANUAL

CDER Policy:

VALID VALUES. It is in the Center's interest to restrict the number of sets of valid values for each data element, even though there may be multiple sets of valid values specified in the Federal Information Processing Standards (FIPS), or at the Agency level. An example of this is the set of numeric values coexisting with the set of alphabetic values for the FIPS postal state codes (CDER recognizes only the alphabetic set of values in this case). When multiple sets of values exist, the selection of only one set of valid values for the Center will be a function of the CDER Nomenclature Standards Committee.

CDER Approval Date: November 10, 1992.

CDER DATA STANDARDS MANUAL

FDA Data Element Number: None.

CDER Data Element Number: C-DRG-00201

Data Element Name: Dosage Form.

Description. This standard provides for all drug dosage forms.

Source. COMIS Reference table (which is used by the Drug Product Reference File to generate Approved Drug Products with Therapeutic Equivalence Evaluations (aka "The Orange Book")), and the Drug Registration and Listing Database.

Relationship.

FDA Specifications: None.

CDER Specifications. Dosage Form shall consist of an alphabetic term which has a maximum length restricted to 240 characters, with the comma and hyphen being the only punctuation permissible. Codes representing these dosage forms shall consist of three digits.

FDA Approved Date: None.

CDER Approved Date: April 14, 1992.

FDA Revised Date.

CDER Revised Dates: January 12, 1993; October 11, 1994; January 10, 1995; December 12, 1996; November 8, 1996

Data Values.

Name	Definition	Code
AEROSOL	A product that is packaged under pressure and contains therapeutically active ingredients that are released upon activation of an appropriate valve system; it is intended for topical application to the skin as well as local application into the nose (nasal aerosols), mouth (lingual aerosols), or lungs (inhalation aerosols).	246
AEROSOL, FOAM	An emulsion containing one or more active ingredients, surfactants, aqueous or nonaqueous liquids, and the propellants; if the propellant is in the internal (discontinuous) phase (i.e., of the oil-in-water type), a stable foam is discharged, and if the propellant is in the external (continuous) phase (i.e., of the water-in-oil type), a spray or a quick-breaking foam is discharged.	800
AEROSOL, METERED	An aerosol dosage form consisting of metered dose valves which allow for the delivery of a uniform quantity of spray upon each activation.	339

AEROSOL, POWDER	A product that is packaged under pressure and contains therapeutically active ingredients, in the form of a powder, that are released upon activation of an appropriate valve system.	801
AEROSOL, SPRAY	An aerosol product which utilizes a compressed gas as the propellant to provide the force necessary to expel the product as a wet spray; it is applicable to solutions of medicinal agents in aqueous solvents.	247
BAR, CHEWABLE	A solid dosage form usually in the form of a rectangle that is meant to be chewed.	347
BEAD	A solid dosage form in the shape of a small ball.	317
BEAD, IMPLANT, EXTENDED RELEASE	A small sterile solid mass consisting of a highly purified drug intended for implantation in the body which would allow at least a two-fold reduction in dosing frequency as compared to that drug presented as a conventional dosage form.	802
BLOCK	Solid dosage form, usually in the shape of a square or rectangle.	803
CAPSULE	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container or "shell" made from a suitable form of gelatin.	600
CAPSULE, COATED	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container or "shell" made from a suitable form of gelatin; additionally, the capsule is covered in a designated coating.	602
CAPSULE, COATED, EXTENDED RELEASE	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container or "shell" made from a suitable form of gelatin; additionally, the capsule is covered in a designated coating, and which releases a drug (or drugs) in such a manner to allow at least a two-fold reduction in dosing frequency as compared to that drug (or drugs) presented as a conventional dosage form.	611
CAPSULE, COATED PELLETS	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container or "shell" made from a suitable form of gelatin; the drug itself is in the form of granules to which varying amounts of coating have been applied.	603
CAPSULE, DELAYED RELEASE	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container made from a suitable form of gelatin, and which releases a drug (or drugs) at a time other than promptly after administration. Enteric-coated articles are delayed release dosage forms.	620
CAPSULE, DELAYED RELEASE PELLETS	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container or "shell" made from a suitable form of gelatin; the drug itself is in the form of granules to which enteric coating has been applied, thus delaying release of the drug until its passage into the intestines.	621
CAPSULE, EXTENDED RELEASE	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container made from a suitable form of gelatin, and which releases a drug (or drugs) in such a manner to allow at least a two-fold reduction in dosing frequency as compared to that drug (or drugs) presented as a conventional dosage form.	610

CAPSULE, FILM COATED, EXTENDED RELEASE	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container or "shell" made from a suitable form of gelatin; additionally, the capsule is covered in a designated film coating, and which releases a drug (or drugs) in such a manner to allow at least a two-fold reduction in dosing frequency as compared to that drug (or drugs) presented as a conventional dosage form.	612
CAPSULE, GELATIN COATED	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container made from a suitable form of gelatin; through a banding process, the capsule is coated with additional layers of gelatin so as to form a complete seal.	605
CAPSULE, LIQUID FILLED	A solid dosage form in which the drug is enclosed within a soluble, gelatin shell which is plasticized by the addition of a polyol, such as sorbitol or glycerin, and is therefore of a somewhat thicker consistency than that of a hard shell capsule; typically, the active ingredients are dissolved or suspended in a liquid vehicle.	606
CEMENT	A substance that serves to produce solid union between two surfaces.	252
CIGARETTE	A narrow tube of cut tobacco (or other similar material) enclosed in paper and designed for smoking.	253
CONE	A solid dosage form bounded by a circular base and the surface formed by line segments joining every point of the boundary of the base to a common vertex. A cone (usually containing antibiotics) is normally placed below the gingiva after a dental extraction.	049
CORE, EXTENDED RELEASE	An ocular system placed in the eye from which the drug diffuses through a membrane at a constant rate over a specified period.	804
CREAM	A semisolid dosage form containing one or more drug substances dissolved or dispersed in a suitable base; more recently, the term has been restricted to products consisting of oil-in-water emulsions or aqueous microcrystalline dispersions of long chain fatty acids or alcohols that are water washable and more cosmetically and aesthetically acceptable.	805
CRYSTAL	A naturally produced angular solid of definite form in which the ultimate units from which it is built up are systematically arranged; they are usually evenly spaced on a regular space lattice.	051
CULTURE	The propagation of microorganisms or of living tissue cells in special medial conducive to their growth.	281
DENTIFRICE	A preparation composed of an inorganic abrasive, detergent, humectant, binder, and flavoring agent, intended to clean and polish the teeth. A dentifrice may be either a paste or a powder, but not a gel.	282

DENTIFRICE/GEL	A combination of a dentifrice (a preparation composed of an inorganic abrasive, detergent, humectant, binder, and flavoring agent, intended to clean and polish the teeth), and a gel (a semisolid system which consists of suspensions made up of either small inorganic particles or large organic molecules interpenetrated by a liquid) and which is used with a toothbrush for the purpose of cleaning and polishing the teeth.	806
DIAPHRAGM	A device usually dome-shaped, worn during copulation over the cervical mouth for prevention of conception or infection.	255
DISC	A circular plate-like organ or structure.	256
DOUCHE	A liquid preparation, intended for the irrigative cleansing of the vagina, that is prepared from powders, liquid solutions, or liquid concentrates and contains one or more chemical substances dissolved in a suitable solvent or mutually miscible solvents.	838
DRESSING	The application of various materials for protecting a wound.	285
ELIXIR	A clear, pleasantly flavored, sweetened hydroalcoholic liquid containing dissolved medicinal agents; it is intended for oral use.	807
EMULSION	A two-phase system in which one liquid is dispersed throughout another liquid in the form of small droplets.	052
ENEMA	A rectal preparation for therapeutic, diagnostic, or nutritive purposes.	286
EXTRACT	A concentrated preparation of vegetable or animal drugs obtained by removal of the active constituents of the respective drugs with a suitable menstrua, evaporation of all or nearly all of the solvent, and adjustment of the residual masses or powders to the prescribed standards.	287
FILM	A thin layer or coating.	061
FILM, EXTENDED RELEASE	A drug delivery system in the form of a film that releases the drug over an extended period in such a way as to maintain constant drug levels in the blood or target tissue.	310
FILM, SOLUBLE	A thin layer or coating which is susceptible to being dissolved when in contact with a liquid.	063
GAS	Any elastic aeriform fluid in which the molecules are separated from one another and have free paths.	064
GEL	A semisolid system consisting of either suspensions made up of small inorganic particles or large organic molecules interpenetrated by a liquid.	066
GEL, JELLY	A class of gels—semisolid systems which consist of suspensions made up of either small inorganic particles or large organic molecules interpenetrated by a liquid—in which the structural coherent matrix contains a high portion of liquid, usually water.	072
GENERATOR	An apparatus for the formation of vapor or gas from a liquid or solid by heat or chemical action. The term GENERATOR also applies to radioactive columns from which radionuclides are provided.	289

GLOBULE	Also called pellets or pilules, are made of pure sucrose, lactose, or other polysaccharides. They are formed into small globular masses of various sizes, and are medicated by placing them in a vial and adding the liquid drug attenuation in the proportion not less than one percent (v/w). After shaking, the medicated globules are dried at temperatures not to exceed 40 degrees Centigrade.	308
GRAFT	A slip of skin or of other tissue for implantation.	290
GRANULE	A small particle or grain.	078
GRANULE, EFFERVESCENT	A small particle or grain containing a medicinal agent in a dry mixture usually composed of sodium bicarbonate, citric acid, and tartaric acid which, when in contact with water, has the capability to release gas, resulting in effervescence.	080
GRANULE, DELAYED RELEASE	A small medicinal particle or grain to which an enteric or other coating has been applied, thus delaying release of the drug until its passage into the intestines.	820
GRANULE, FOR SOLUTION	A small medicinal particle or grain made available in its more stable dry form, to be reconstituted with solvent just before dispensing; the granules are so prepared to contain not only the medicinal agent, but the colorants, flavorants, and any other desired pharmaceutic ingredient. (Dorland's Illustrated Medical Dictionary, 24th Ed.; INTRODUCTION TO PHARMACEUTICAL DOSAGE FORMS, 4th Ed.)	309
GRANULE, FOR SUSPENSION	A small medicinal particle or grain made available in its more stable dry form, to be reconstituted with solvent just before dispensing to form a suspension; the granules are so prepared to contain not only the medicinal agent, but the colorants, flavorants, and any other desired pharmaceutic ingredient.	819
GRANULE, FOR SUSPENSION, EXTENDED RELEASE	A small medicinal particle or grain made available in its more stable dry form, to be reconstituted with solvent just before dispensing to form a suspension; the extended release system achieves slow release of the drug over an extended period of time and maintains constant drug levels in the blood or target tissue.	811
GUM	A mucilaginous excretion from various plants.	084
GUM, RESIN	Natural mixture of gum and resin, usually obtained as exudations from plants.	087
GUM, CHEWING	A sweetened and flavored insoluble plastic material of various shapes which when chewed, releases a drug substance into the oral cavity.	085
IMPLANT	A material containing drug intended to be inserted securely or deeply in a living site for growth, slow release, or formation of an organic union.	715
INHALANT	A special class of inhalations consisting of a drug or combination of drugs, that by virtue of their high vapor pressure, can be carried by an air current into the nasal passage where they exert their effect; the container from which the inhalant generally is administered is known as an inhaler.	293

INJECTION	A sterile preparation intended for parenteral use; five distinct classes of injections exist as defined by the USP	700
INJECTION, EMULSION	An emulsion, a two-phase system in which one liquid is dispersed throughout another liquid in the form of small droplets, consisting of a sterile, pyrogen-free preparation intended to be administered parenterally.	701
INJECTION, SUSPENSION, EXTENDED RELEASE	A sterile preparation intended for parenteral use which has been formulated in a manner to allow at least a twofold reduction in dosing frequency as compared to that drug presented as a conventional dosage form (e.g., as a solution or a prompt drug-releasing, conventional solid dosage form).	711
INJECTION, POWDER, FOR SOLUTION	A sterile preparation intended for reconstitution to form a solution for parenteral use.	702
INJECTION, POWDER, FOR SUSPENSION	A sterile preparation intended for reconstitution to form a suspension for parenteral use.	703
INJECTION, POWDER, FOR SUSPENSION, EXTENDED RELEASE	A sterile freeze dried preparation intended for reconstitution to form a suspension for parenteral use which has been formulated in a manner to allow at least a twofold reduction in dosing frequency as compared to that drug presented as a conventional dosage form (e.g., as a solution).	710
INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	A dosage form intended for the solution prepared by lyophilization ("freeze drying"), a process which involves the removal of water from products in the frozen state at extremely low pressures; this is intended for subsequent addition of liquid to create a solution that conforms in all respects to the requirements for Injections; .	705
INJECTION, POWDER, LYOPHILIZED, FOR LIPOSOMAL SUSPENSION	A sterile freeze dried preparation intended for reconstitution for parenteral use which has been formulated in a manner that would allow liposomes to be formed upon reconstitution.	713
INJECTION, POWDER, LYOPHILIZED, FOR SUSPENSION, EXTENDED RELEASE	A sterile freeze dried preparation intended for reconstitution for parenteral use which has been formulated in a manner to allow at least a twofold reduction in dosing frequency as compared to that drug presented as a conventional dosage form (e.g., as a solution).	712
INJECTION, POWDER, LYOPHILIZED, FOR SUSPENSION	A liquid preparation, intended for parenteral use, that contains solids suspended in a suitable fluid medium and conforms in all respects to the requirements for Sterile Suspensions; the medicinal agents intended for the suspension are prepared by lyophilization ("freeze drying"), a process which involves the removal of water from products in the frozen state at extremely low pressures.	706
INJECTION, SOLUTION	A liquid preparation containing one or more drug substances dissolved in a suitable solvent or mixture of mutually miscible solvents that is suitable for injection.	708

INJECTION, SOLUTION, CONCENTRATE	A sterile preparation for parenteral use which, upon the addition of suitable solvents, yields a solution conforming in all respects to the requirements for Injections.	709
INJECTION, SUSPENSION	A liquid preparation, suitable for injection, which consists of solid particles dispersed throughout a liquid phase in which the particles are not soluble. It can also consist of an oil phase dispersed throughout an aqueous phase, or vice-versa.	704
INJECTION, SUSPENSION, LIPOSOMAL	A liquid preparation, suitable for injection, which consists of an oil phase dispersed throughout an aqueous phase in such a manner that liposomes are formed.	714
INSERT, EXTENDED RELEASE	A specially formulated and shaped solid preparation (e.g., ring, tablet, or stick) intended to be placed in the vagina by special inserters, where the medication is released, generally for localized effects; the extended release system is designed to allow at least a two-fold reduction in dosing frequency.	812
INTRAUTERINE DEVICE	A device inserted and left in the uterus to prevent effective conception.	260
IRRIGANT	A sterile solution intended to bathe or flush open wounds or body cavities; they're used topically, never parenterally.	830
KIT	A packaged collection of related material.	261
LINER, DENTAL	A material applied to the inside of the dental cavity, for protection or insulation of the surface.	316
LINIMENT	A solution or mixture of various substances in oil, alcoholic solutions of soap, or emulsions intended for external application.	298
LIPSTICK	A waxy solid, usually colored cosmetic, in stick form for the lips.	265
LIQUID	A state of substance that is an intermediate one entered into as matter goes from solid to gas; liquids are also intermediate in that they have neither the orderliness of a crystal nor the randomness of a gas. (Note: This term should not be used to describe solutions, only pure chemicals in their liquid state.)	299
LOLLIPOP	A medicated lozenge on the end of a stick intended for oral administration.	266
LOTION	"The term lotion" has been used to categorize many topical suspensions, solutions and emulsions intended for application to the skin.	300
LOZENGE	A solid preparation containing one or more medicaments, usually in a flavored, sweetened base which is intended to dissolve or disintegrate slowly in the mouth.	831
MOUTHWASH	An aqueous solution which is most often used for its deodorant, refreshing, or antiseptic effect.	332

Topical Products	There are a variety of topical dosage forms available for dermatologic, ophthalmic, otic, rectal, and vaginal administration, including solutions, creams, ointments, gels, lotions, pastes, sprays, and suppositories. Even though different topical dosage forms may contain the same active ingredient and potency, these dosage forms are not considered pharmaceutically equivalent. Therefore, they are not considered therapeutically equivalent. All solutions and DESI drug products containing the same active ingredient in the same topical dosage form for which a waiver of *in vivo* bioequivalence has been granted and for which chemistry and manufacturing processes are adequate, are considered therapeutically equivalent and coded **AT**. Pharmaceutically equivalent topical products that raise questions of bioequivalence including all post-1962 topical drug products are coded **AB** when supported by adequate bioequivalence data, and **BT** in the absence of such data.	**AT**
Extended-release dosage forms (capsules, injectables and tablets)	An extended-release dosage form is defined by the official compendia as one that allows at least a twofold reduction in dosing frequency as compared to that drug presented as a conventional dosage form (e.g., as a solution or a prompt drug-releasing, conventional solid dosage form). Although bioavailability studies have been conducted on these dosage forms, they are subject to bioavailability differences, primarily because firms developing extended-release products for the same active ingredient rarely employ the same formulation approach. FDA, therefore, does not consider different extended-release dosage forms containing the same active ingredient in equal strength to be therapeutically equivalent unless equivalence between individual products in both rate and extent has been specifically demonstrated through appropriate bioequivalence studies. Extended-release products for which such bioequivalence data have not been submitted are coded **BC**, while those for which such data are available have been coded **AB**.	**BC**
Active ingredients and dosage forms with documented bioequivalence problems	The **BD** code denotes products containing active ingredients with known bioequivalence problems and for which adequate studies have not been submitted to FDA demonstrating bioequivalence. Where studies showing bioequivalence have been submitted, the product has been coded **AB**.	**BD**

Delayed-release oral dosage forms	A delayed-release dosage form is defined by the official compendia as one that releases a drug (or drugs) at a time other than promptly after administration. Enteric-coated articles are delayed-release dosage forms. Drug products in delayed-release dosage forms containing the same active ingredients are subject to significant differences in absorption. Unless otherwise specifically noted, the Agency considers different delayed-release products containing the same active ingredients as presenting a potential bioequivalence problem and codes these products BE in the absence of *in vivo* studies showing bioequivalence. If adequate *in vivo* studies have demonstrated the bioequivalence of specific delayed-release products, such products are coded AB.	BE
Products in aerosol-nebulizer drug delivery systems	This code applies to drug solutions or powders that are marketed only as a component of, or as compatible with, a specific drug delivery system. There may, for example, be significant differences in the dose of drug and particle size delivered by different products of this type. Therefore, the Agency does not consider different metered aerosol dosage forms containing the same active ingredient(s) in equal strengths to be therapeutically equivalent unless the drug products meet an appropriate bioequivalence standard.	BN

Active ingredients and dosage forms with potential bioequivalence problems	FDA's bioequivalence regulations (21 CFR 320.33) contain criteria and procedures for determining whether a specific active ingredient in a specific dosage form has a potential for causing a bioequivalence problem. It is FDA's policy to consider an ingredient meeting these criteria as having a potential bioequivalence problem even in the absence of positive data demonstrating inequivalence. Pharmaceutically equivalent products containing these ingredients in oral dosage forms are coded **BP** until adequate *in vivo* bioequivalence data are submitted.	BP
	Injectable suspensions containing an active ingredient suspended in an aqueous or oleaginous vehicle have also been coded **BP**. Injectable suspensions are subject to bioequivalence problems because differences in particle size, polymorphic structure of the suspended active ingredient, or the suspension formulation can significantly affect the rate of release and absorption. FDA does not consider pharmaceutical equivalents of these products bioequivalent without adequate evidence of bioequivalence.	
Suppositories or enemas that deliver drugs for systemic absorption	The absorption of active ingredients from suppositories or enemas that are intended to have a systemic affect (as distinct from suppositories administered for local effect) can vary significantly from product to product. Therefore, FDA considers pharmaceutically equivalent systemic suppositories or enemas bioequivalent only if *in vivo* evidence of bioequivalence is available. In those cases where *in vivo* evidence is available, the product is coded **AB**. If such evidence is not available, the products are coded **BR**.	BR
Products having drug standard deficiencies	If the drug standards for an active ingredient in a particular dosage form are found by FDA to be deficient so as to prevent an FDA evaluation of either pharmaceutical or therapeutic equivalence, all drug products containing that active ingredient in that dosage form are coded **BS**. For example, if the standards permit a wide variation in pharmacologically active components of the active ingredient such that pharmaceutical equivalence is in question, all products containing that active ingredient in that dosage form are coded **BS**.	BS

Topical products with bioequivalence issues	This code applies mainly to post-1962 dermatologic, ophthalmic, otic, rectal, and vaginal products for topical administration, including creams, ointments, gels, lotions, pastes, and sprays, as well as suppositories not intended for systemic drug absorption. Topical products evaluated as having acceptable clinical performance, but that are not bioequivalent to other pharmaceutically equivalent products or that lack sufficient evidence of bioequivalence will be coded BT.	BT
Drug products for which the data are insufficient to determine therapeutic equivalence	The code BX is assigned to specific drug products for which the data that have been reviewed by the Agency are insufficient to determine therapeutic equivalence under the policies stated in this document. In these situations, the drug products are presumed to be therapeutically inequivalent until the Agency has determined that there is adequate information to make a full evaluation of therapeutic equivalence.	BX

CDER DATA STANDARDS MANUAL

FDA Data Element Number.

CDER Data Element Number. C-GEN-10208

Data Element Name. Application Number

Description. Application Number is the number associated with the primary category of official submission that is received by the Center.

Source. Various Oracle tables, including COMIS Reference Table.

Relationship. See Application Type.

FDA Specifications. None.

CDER Specifications. Application Number is represented by numeric text of six character in length, with leading zeros and without punctuation.

FDA Approved Date.

CDER Approved Date. March 14, 1995

FDA Revised Date.

CDER Revised Date.

Data Values. Literal.

CDER DATA STANDARDS MANUAL

FDA Data Element Number.

CDER Data Element Number. C-GEN-10207

Data Element Name. Application Type

Description. Application Type is the primary category of official submission that is received by the Center.

Source. Various Oracle tables, including COMIS Reference Table.

Relationship. See Application Number.

FDA Specifications. None.

CDER Specifications. Application Type is represented by alphunumeric text of one character in length.

FDA Approved Date.

CDER Approved Date. March 14, 1995

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Code
Device Classification 513(G) (CDRH)	C
New Device Application in Form 5's and Form 6's (CDRH)	F
Premarket Notification Submission 510(K)	K
Product Development Protocol	Z
Reclassification Petition	R
Drug Master File	D
Investigational Device Exemption 520(G) (CDRH)	G
Investigational Device Exemption 520(L)	L
Investigational New Drug Exemption (CBER)	B
Investigational New Drug Exemption (CDER)	I
New Drug Application (CBER)	X
New Drug Application (CDER)	N
Premarket Approval Application	P

CDER DATA STANDARDS MANUAL

FDA Data Element Number. GEN-0002

CDER Data Element Number. C-GEN-0002

Data Element Name. Calendar Date - Format 2.

Description. This standard provides format specifications for representing the day, month, and the year as identified by the Gregorian Calendar.

Source. U.S. Department of Commerce, National Institute for Standards and Technology; Federal Information Processing Standards.

Relationship.

FDA Specifications. Calendar Date - Format 2 is represented by alphanumeric text of nine (9) or eleven (11) characters in the format DD-MMM-(YY)YY where:

DD represents day of month (01, 02, ..., 31);
MMM represents month of year (JAN, FEB, ..., DEC); and
(YY)YY represents year of century ((19)00, (19)01, ..., (20)00).

(The repesentation for year can be expressed in two or four digits depending on a particular systems requirements.

CDER Specifications. All systems should attempt to convert to the four digit year (instead of the two-digit year) because of the nearing of the end of the current century.

FDA Approved Date. July 14, 1988.

CDER Approved Date. November 5, 1991.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
Literal	Date represented the day, the month, and the year by the Gregorian Calendar.	

CDER DATA STANDARDS MANUAL

FDA Data Element Number.

CDER Data Element Number. C-GEN-10301

Data Element Name. Educational Level

Description. This standard specifies various human educational levels. It is for the highest level of education attained.

Source. FDA Standardized Nomenclature Program

Relationship. Person Given Name (GEN-00201), Person Surname (GEN-00203), Person Family Rank (GEN-00204), Person Middle Name (GEN-00202).

FDA Specifications. None.

CDER Specifications. Educational level terminology will consist of alphanumeric text with a maximum length of 60 characters. Corresponding codes shall be represented alphanumerically with one character. Valid abbreviations from the list below are mandatory.

FDA Approved Date.

CDER Approved Date. February 13, 1996

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
Less Than High School Diploma	Literal	1
Correspondence School Diploma	Literal	7
Completed One Semester of College	Literal	8
Currently in High School	Literal	9
Adult Education Diploma	Literal	B
Occupational Program Certificate	Literal	C
Associate Degree	Literal	D
Test-Based Equivalency Diploma	Literal	E
Overseas General Education Degree	Literal	F
Professional Nursing Diploma	Literal	G
Home Study Diploma	Literal	H
High School Certificate of Attendance	Literal	J
Baccalaureate Degree	Literal	K
High School Diploma	Literal	L

Masters Degree	Literal	N
Post Masters Degree	Literal	R
High School Senior	Literal	S
Doctorate Degree	Literal	U
First Professional Degree	Literal	W

CDER DATA STANDARDS MANUAL

FDA Data Element Number. GEN-00005

CDER Data Element Number. C-GEN-00005

Data Element Name. Fiscal Year.

Description. This standard represents a twelve (12) month accounting year as specified by the U.S. Congress for the Federal Government. As of the approval date of this standard, a fiscal year runs from October 1 of a calendar year through September 30 of the following calendar year. Fiscal year is usually abbreviated as FY.

Source. U.S. Congress.

Relationship.

FDA Specifications. Fiscal Year is represented by a four (4) digit number. The format for FY is YYYY.

CDER Specifications. No further specifications.

FDA Approved Date. October 12, 1989.

CDER Approved Date. November 5, 1991.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
Literal	Number representing a Federal Government twelve month accounting year.	N/A

CDER DATA STANDARDS MANUAL

FDA Data Element Number.

CDER Data Element Number. C-GEN-10209

Data Element Name. Gender

Description. Gender refers to the sex of a species.

Source. ISO 5218, and Webster's New Collegiate Dictionary

Relationship.

FDA Specifications. Gender shall consist of alphabetic terms with a maximum of 15 characters in length. Codes representing these terms shall consist of one numeral.

CDER Specifications. No further specifications.

FDA Approved Date. This data element is pending approval as an FDA Demographics Data Element.

CDER Approved Date. September 12, 1995.

FDA Revised Data.

CDER Revised Date.

Data Values.

Name	Definition	Code
Not Known	Literal	0
Male	Literal	1
Female	Literal	2
Not Specified	Literal	9

CDER DATA STANDARDS MANUAL

FDA Data Element Number.

CDER Data Element Number. C-GEN-10212

Data Element Name. Height

Description. Height is the distance from the bottom to the top of something standing upright.

Source. ASTM; Webster's New Collegiate Dictionary

Relationship. Weight.

FDA Specifications. Height shall consist of alphanumeric entries of a maximum of 10 characters in length. Unless otherwise specified in the field, the default value shall always be in centimeters.

CDER Specifications. No further specifications.

FDA Approved Date. This data element is pernding approval as an FDA Demographics Data Element.

CDER Approved Date. September 12, 1995.

FDA Revised Date.

CDER Revised Date.

Data Values. There are no pre-defined values.

CDER DATA STANDARDS MANUAL

FDA Data Element Number.

CDER Data Element Number. C-GEN-10211

Data Element Name. Marital Status

Description. Marital Status is the legal status of a person in relation to his/her marriage, or lack thereof.

Source. ASTM

Relationship.

FDA Specifications. Marital status shall consist of alphanumeric terms with a maximum of 15 characters in length, with alphanumeric codes representing these terms of 1 character in length.

CDER Specifications. No further specifications.

FDA Approved Date. This data element is pending approval as an FDA Demographics Data Element.

CDER Approved Date. September 12, 1995.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
Married	Literal	M
Never Married	Literal	S
Separated	Literal	A
Widowed	Literal	W
Divorced	Literal	D
Undetermined	Literal	U

CDER DATA STANDARDS MANUAL

FDA Data Element Number. GEN-00204

CDER Data Element Number. C-GEN-00204

Data Element Name. Person Family Rank.

Description. This standard defines a person's family rank following their surname.

Source. Data Standards Committee, FDA.

Relationship. Person Given Name (GEN-00201), Person Middle Name (GEN-00202), Person Surname (GEN-00203).

FDA Specifications. Person Family Rank is represented by an alphanumeric code consisting of three (3) characters.

CDER Specifications. No further specifications.

FDA Approved Date. October 12, 1989.

CDER Approved Date. February 11, 1992.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
Junior	Distinguishes the son from the father with the same name.	JR
Senior	Denotes the older of two persons having the same name.	SR
Second	Second occurrence of a name within a family; not in consecutive generations.	II
Third	Third occurrence of a name within a family.	III
Fourth	Fourth occurrence of a name within a family.	IV
Fifth	Fifth occurrence of a name within a family.	V

CDER DATA STANDARDS MANUAL

FDA Data Element Number. GEN-00201

CDER Data Element Number. C-GEN-00201

Data Element Name. Person Given Name.

Description. This standard represents a name that usually precedes the middle name and the surname. Person Given Name is commonly referred to as a first name.

Source. Data Standards Committee, FDA.

Relationship. Person Middle Name (GEN-00202), Person Surname (GEN-00203), Person Family Rank (GEN-00204).

FDA Specifications. Person Given Name is represented by variable length alphanumeric text consisting of a maximum of fifteen (15) characters.

CDER Specifications. No further specifications.

FDA Approved Date. October 12, 1989.

CDER Approved Date. February 11, 1992

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
Literal	A person's given name or first name.	N/A

CDER DATA STANDARDS MANUAL

FDA Data Element Number. GEN-00202

CDER Data Element Number. C-GEN-00202

Data Element Name. *Person Middle Name.*

Description. This standard provides specifications for representing a person's middle name. This name is usually located between the given name and the surname.

Source. Data Standards Committee, FDA.

Relationship. Person Given Name (GEN-00201), Person Surname (GEN-00203), Person Family Rank (GEN-00204).

FDA Specifications. Person Middle Name is represented by variable length alphanumeric text consisting of a maximum fifteen (15) characters.

CDER Specifications. No further specifications.

FDA Approved Date. October 12, 1989.

CDER Approved Date. February 11, 1992.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
Literal	A person's middle name.	N/A

CDER DATA STANDARDS MANUAL

FDA Data Element Number. GEN-00203

CDER Data Element Number. C-GEN-00203

Data Element Name. Person Surname.

Description. This standard represents a person's family name or last name.

Source. Data Standards Committee, FDA.

Relationship. Person Given Name (GEN-00201), Person Middle Name (GEN-00202), Person Family Rank (GEN-00204).

FDA Specifications. Person Surname is represented by variable text alphanumeric text consisting of a maximum of twenty-five (25) characters.

CDER Specifications. No further specifications.

FDA Approved Date. October 12, 1989.

CDER Approved Date. February 11, 1992.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
Literal	A person's family name or last name.	N/A

CDER DATA STANDARDS MANUAL

FDA Data Element Number:

CDER Data Element Number: C-GEN-10210

Data Element Name. Race.

Description. An ethnic stock or division of mankind.

Source. ASTM/E1384, and Dorland's Illustrated Medical Dictionary, 24th Edition

Relationship. Ethnic Origin.

FDA Specifications. Ethnic Origin shall consist of an alphanumeric term of indefinite length. There are no codes associated with these terms.

CDER Specifications: No further specifications.

FDA Approved Date. Pending Approval as an FDA Demographics Data Element.

CDER Approved Date: September 12, 1995; November 8, 1996.

FDA Revised Date:

CDER Revised Date:

Data Values.

Name	Definition	Code
American Indian- Alaska Native	Literal	A
Asian	Literal	B
White	Literal	C
Black	Literal	D
Other	Literal	E

CDER DATA STANDARDS MANUAL

FDA Data Element Number.

CDER Data Element Number. C-GEN-10201

Data Element Name. Sponsor/Applicant Name

Description. This standard represents 1)The name or designation under which a company transacts business; 2)The name or designation under which an institution, hospital, or agency (federal and private) transacts business or provides patient care; and 3)The Person Surname, the Person Given Name (or first initial), the Person Middle Name (or its first initial), and the Person Family Rank, followed by valid professional degrees under which an individual transacts business or provides patient care.

Source. Nomenclature Standards Committee, CDER

Relationship. Person Given Name (GEN-00201), Person Surname (GEN-00203), Person Family Rank (GEN-00204), Firm Name (ORG-00101).

FDA Specifications. None.

CDER Specifications. Sponsor/Applicant is represented by variable length alphanumeric text consisting of a maximum of two-hundred forty (240) characters. Punctuation will be limited to hyphenated Person Surnames, and virgules (e.g., in A/S and C/O). Hyphens in firm names will be replaced by a space. Text before and after an apostrophe will be concatonated. Valid abbreviations from the list below are mandatory.

FDA Approved Date.

CDER Approved Date. April 13, 1993

FDA Revised Date.

CDER Revised Date. April 14, 1994

Data Values.

Name	Definition	Code
ASSOCIATES	Literal	ASSOC
ASSOCIATION	Literal	ASSN
ATTENTION	Literal	ATTN
CARE OF	Literal	C/O
COLLEGE	Literal	COLL
COMPANY	Literal	CO
CORPORATION	Literal	CORP
DEPARTMENT	Literal	DEPT
DIVISION	Literal	DIV
DOCTOR OF DENTAL MEDICINE	Literal	DMD
DOCTOR OF DENTAL SURGERY	Literal	DDS
DOCTOR OF MEDICINE	Literal	MD
DOCTOR OF OPTOMETRY	Literal	OD

DOCTOR OF OSTEOPATHY	Literal	DO
DOCTOR OF PHARMACY	Literal	PHARMD
DOCTOR OF PHILOSOPHY	Literal	PHD
DOCTOR OF VETRINARY MEDICINE	Literal	DVM
FOUNDATION	Literal	FDN
HOSPITAL	Literal	HOSP
INCORPORATED	Literal	INC
LIMITED	Literal	LTD
MEDICAL CENTER	Literal	MEDCTR
RESEARCH CENTER	Literal	RESCTR
SAINT	Literal	ST
SCHOOL	Literal	SCH
SUBSIDIARY	Literal	SUB
UNIVERSITY	Literal	UNIV
UNLIMITED	Literal	UNLTD

CDER DATA STANDARDS MANUAL

FDA Data Element Number. None.

CDER Data Element Number. C-GEN-10202

Data Element Name. Telephone Area Code.

Description. This standard provides format specifications for representing the telephone area code for the United States, Canada, and the Carribean nations of Anguilla, Antigua, Barbuda, Bahamas, Barbados, British Virgin Islands, Cayman Islands, Dominica, Dominican Republic, Grenada, Jamaica, Montserrat, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and Grenadines, Trinidad and Tobago, Turks and Caicos Islands.

Source. Bell Atlantic directory.

Relationship. See Telephone Number, Format 1.

FDA Specifications. None.

CDER Specifications. Telephone Area Code is represented by numeric text of three characters. There shall be no punctuation (including no parentheses surrounding the code).

FDA Approved Date.

CDER Approved Date. January 10, 1995.

FDA Revised Date.

CDER Revised Date.

Data Values. See the current telephone book listing of area codes for values. Actual values have not been presented in this standard because area code geographic boundaries are defined by the telephone systems according to each city, and sometimes further defined by unnamed sections within each city. In addition, there are some area codes that cover two countries plus a territory (e.g., 809 for all Carribean nations and Puerto Rico); Oracle tables cannot store more than one code for each country. Finally, area codes frequently split with only regional notification. These idiosyncracies would make the actual maintenance of a verifiable area code list extremely tedious and time consuming.

CDER DATA STANDARDS MANUAL

FDA Data Element Number. None.

CDER Data Element Number. C-GEN-10206

Data Element Name. Telephone City Code.

Description. This standard provides format specifications for representing the telephone city code for all foreign countries, excluding the Bahamas, Bermuda, and Canada. These codes are normally accessed after the telephone country code is accessed, but before the telephone number is accessed. They may necessitate consulting a foreign telephone operator.

Source.

Relationship. See Telephone Country Code, and Telephone Number, Format 2.

FDA Specifications. None.

CDER Specifications. Telephone City Code is represented by numeric text of up to three characters. There shall be no punctuation (including no parentheses surrounding the code).

FDA Approved Date. None.

CDER Approved Date. January 10, 1995.

FDA Revised Date.

CDER Revised Date.

Data Values. Since the establishment of the telephone city code is made by the local telephone company of the country to which calls are being made, there may not be a distinct numeric relationship for each city (e.g., Dhaka, Bangladesh and Brussels, Belgium both have a telephone city code of 2). It is suggested that a foreign telephone operator be consulted for specific telephone city codes.

CDER DATA STANDARDS MANUAL

FDA Data Element Number. None.

CDER Data Element Number. C-GEN-10203

Data Element Name. Telephone Country Code.

Description. This standard provides format specifications for representing the telephone country code for all foreign countries, excluding Canada and the Caribean nations of Anguilla, Antigua, Barbuda, Bahamas, Barbados, British Virgin Islands, Cayman Islands, Dominica, Dominican Republic, Grenada, Jamaica, Montserrat, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and Grenadines, Trinidad and Tobago, Turks and Caicos Islands.

Some codes are not available (N/A) for some of the more obscure countries (e.g., Clipperton Island) and countries deemed hostile to the United States (e.g., North Korea). This may necessitate consulting directory assistance.

Certain nations that have recently gained independence (e.g., Russia) may temporarily share their country code with their predecessor nation (e.g., USSR).

Source.

Relationship. See Telephone City Code, and Telephone Number, Format 2.

FDA Specifications. None.

CDER Specifications. Telephone Country Code is represented by numeric text of up to three characters. There shall be no punctuation (including no parentheses surrounding the code).

FDA Approved Date. None.

CDER Approved Date. January 10, 1995.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
AFGHANISTAN	Literal	N/A
ALBANIA	Literal	355
ALGERIA	Literal	213
AMERICAN SAMOA	Literal	684
ANDORA	Literal	33
ANGOLA	Literal	244

ANTARCTICA	Literal	672
ARGENTINA	Literal	54
ARMENIA	Literal	7
ARUBA	Literal	297
ASCENSION ISLAND	Literal	247
ASHMORE AND CARTIER ISLANDS	Literal	N/A
AUSTRALIA	Literal	61
AUSTRIA	Literal	43
AZERBAIJAN	Literal	7
BAHRAIN	Literal	973
BANGLADESH	Literal	880
BASSAS DA INDIA	Literal	N/A
BELARUS	Literal	7
BELGIUM	Literal	32
BELIZE	Literal	501
BENIN	Literal	229
BHUTAN	Literal	975
BOLIVIA	Literal	591
BOSNIA-HERZEGOVINA	Literal	387
BOTSWANA	Literal	267
BOUVET ISLAND	Literal	N/A
BRAZIL	Literal	55
BRITISH INDIAN OCEAN TERRITORIES	Literal	N/A
BRUNEI	Literal	673
BULGARIA	Literal	359
BURKINA FASO	Literal	226
BURUNDI	Literal	257
CAMEROON	Literal	237
CAPE VERDE	Literal	238
CENTRAL AFRICAN REPUBLIC	Literal	236
CHAD	Literal	235
CHILE	Literal	56
CHINA	Literal	86
CHRISTMAS ISLAND	Literal	672
CLIPPERTON ISLAND	Literal	N/A
COCOS (KEELING) ISLANDS	Literal	N/A
COLOMBIA	Literal	57
COMOROS	Literal	269
CONGO	Literal	242
COOK ISLAND	Literal	682
CORAL SEA ISLANDS	Literal	N/A
COSTA RICA	Literal	506
COTE D'IVOIRE	Literal	225
CROATIA	Literal	385
CUBA	Literal	N/A
CYPRUS	Literal	357
CZECH REPUBLIC	Literal	42
DENMARK	Literal	45
DIEGO GARCIA	Literal	246
DJIBOUTI	Literal	253
ECUADOR	Literal	593
EGYPT	Literal	20
EL SALVADOR	Literal	503
EQUATORIAL GUINEA	Literal	240
ERITREA	Literal	291
ESTONIA	Literal	372
ETHIOPIA	Literal	251
EUROPA ISLAND	Literal	N/A
FALKLAND ISLANDS	Literal	500
FAROE ISLANDS	Literal	298
FIJI	Literal	679
FINLAND	Literal	358
FRANCE	Literal	33
FRENCH GUIANA	Literal	594
FRENCH POLYNESIA	Literal	689
GABON	Literal	241

GAMBIA	Literal	220
GAZA STRIP	Literal	N/A
GEORGIA	Literal	7
GERMANY	Literal	49
GHANA	Literal	233
GIBRALTAR	Literal	350
GLORIOSO ISLANDS	Literal	N/A
GREECE	Literal	30
GREENLAND	Literal	299
GUADELOUPE	Literal	590
GUAM	Literal	671
GUATEMALA	Literal	502
GUERNSEY	Literal	N/A
GUINEA	Literal	224
GUINEA-BISSAU	Literal	245
GUYANA	Literal	592
HAITI	Literal	509
HEARD ISLAND AND MCDONALD ISLANDS	Literal	N/A
HONDURAS	Literal	504
HONG KONG	Literal	852
HOWLAND ISLAND	Literal	N/A
HUNGARY	Literal	36
ICELAND	Literal	354
INDIA	Literal	91
INDONESIA	Literal	62
IRAN	Literal	98
IRAQ	Literal	964
IRELAND (SOUTHERN ONLY)	Literal	353
ISRAEL	Literal	972
ITALY	Literal	39
JAN MAYEN	Literal	N/A
JAPAN	Literal	81
JERSEY	Literal	N/A
JORDAN	Literal	962
JUAN DE NOVA ISLAND	Literal	N/A
KAMPUCHEA	Literal	855
KAZAKHSTAN	Literal	7
KENYA	Literal	254
KIRIBATI	Literal	686
KOREA, NORTH	Literal	N/A
KOREA, SOUTH	Literal	82
KUWAIT	Literal	965
KYRGYZSTAN	Literal	7
LAOS	Literal	856
LATVIA	Literal	371
LEBANON	Literal	961
LESOTHO	Literal	266
LIBERIA	Literal	231
LIBYA	Literal	218
LIECHTENSTEIN	Literal	41
LITHUANIA	Literal	370
LUXEMBOURG	Literal	352
MACAU	Literal	853
MACEDONIA	Literal	389
MADAGASCAR	Literal	261
MALAWI	Literal	265
MALAYSIA	Literal	60
MALDIVES	Literal	960
MALI	Literal	223
MALTA	Literal	356
MAN, ISLE OF	Literal	N/A
MARTINIQUE	Literal	596
MAURITANIA	Literal	222
MAURITIUS	Literal	230
MAYOTTE	Literal	269
MEXICO	Literal	52

MICRONESIA	Literal	691
MOLDOVA	Literal	373
MONACO	Literal	33
MONGOLIA	Literal	976
MONTENEGRO	Literal	N/A
MOROCCO	Literal	212
MOZAMBIQUE	Literal	258
MYANMAR	Literal	95
NAMIBIA	Literal	264
NAURA	Literal	674
NEPAL	Literal	977
NETHERLANDS	Literal	31
NETHERLANDS ANTILLES	Literal	599
NEW CALEDONIA	Literal	687
NEW ZEALAND	Literal	64
NICARAGUA	Literal	505
NIGER	Literal	227
NIGERIA	Literal	234
NIUE	Literal	683
NORFOLK ISLAND	Literal	672
NORWAY	Literal	47
OMAN	Literal	968
PAKISTAN	Literal	92
PALAU	Literal	680
PANAMA	Literal	507
PAPUA NEW GUINEA	Literal	675
PARACEL ISLANDS	Literal	N/A
PARAGUAY	Literal	595
PERU	Literal	51
PHILIPPINES	Literal	63
PITCAIRN ISLANDS	Literal	N/A
POLAND	Literal	48
PORTUGAL	Literal	351
QATAR	Literal	974
REUNION	Literal	262
ROMANIA	Literal	40
RUSSIA	Literal	7
RWANDA	Literal	250
SAINT HELENA	Literal	290
SAINT PIERRE AND MIQUELON	Literal	508
SAIPAN	Literal	670
SAN MARINO	Literal	378
SAO TOME AND PRINCIPE	Literal	239
SAUDI ARABIA	Literal	966
SENEGAL	Literal	221
SERBIA	Literal	N/A
SEYCHELLES	Literal	248
SIERRA LEONE	Literal	232
SINGAPORE	Literal	65
SLOVAKIA	Literal	42
SLOVENIA	Literal	386
SOLOMON ISLANDS	Literal	677
SOMALIA	Literal	N/A
SOUTH AFRICA	Literal	27
SOUTH GEORGIA/SANDWICH ISLANDS	Literal	N/A
SPAIN	Literal	34
SPRATLY ISLANDS	Literal	N/A
SRI LANKA	Literal	94
SUDAN	Literal	N/A
SURINAME	Literal	597
SVALBARD	Literal	N/A
SWAZILAND	Literal	268
SWEDEN	Literal	46
SWITZERLAND	Literal	41
SYRIA	Literal	963
TAIWAN	Literal	886

TAJIKISTAN	Literal	7
TANZANIA, UNITED REPUBLIC OF	Literal	255
THAILAND	Literal	66
TOGO	Literal	228
TOKELAU	Literal	N/A
TONGA	Literal	676
TROMELIN ISLAND	Literal	N/A
TUNISIA	Literal	216
TURKEY	Literal	90
TURKMENISTAN	Literal	7
TUVALU	Literal	688
UGANDA	Literal	256
UKRAINE	Literal	7
UNITED ARAB EMIRATES	Literal	971
UNITED KINGDOM	Literal	44
UNITED STATES	Literal	1
URUGUAY	Literal	598
UZBEKISTAN	Literal	7
VANUATU	Literal	678
VATICAN CITY	Literal	39
VENEZUELA	Literal	58
VIETNAM	Literal	84
WALLIS AND FUTUNA	Literal	681
WEST BANK	Literal	N/A
WESTERN SAHARA	Literal	N/A
WESTERN SAMOA	Literal	685
YEMEN	Literal	967
ZAIRE	Literal	243
ZAMBIA	Literal	260
ZIMBABWE	Literal	263

CDER DATA STANDARDS MANUAL

FDA Data Element Number. None.

CDER Data Element Number. C-GEN-10204

Data Element Name. Telephone Number, Format 1.

Description. This standard provides format specifications for representing the telephone number for the United States, the Bahamas, Bermuda, and Canada.

Source. Bell Atlantic directory.

Relationship. See Telephone Area Code, Format 1.

FDA Specifications. None.

CDER Specifications. Telephone Number, Format 1 is represented by numeric text of seven characters. There shall be no punctuation (including no hyphen between the third and fourth digits).

FDA Approved Date.

CDER Approved Date. January 10, 1995.

FDA Revised Date.

CDER Revised Date.

Data Values. Literal. Letters shall be converted to numbers in the following way:

A, B, and C = 2
D, E, and F = 3
G, H, and I = 4
J, K, and L = 5
M, N, and O = 6
P, R, and S = 7
T, U, and V = 8
W, X, and Y = 9

CDER DATA STANDARDS MANUAL

FDA Data Element Number. None.

CDER Data Element Number. C-GEN-10205

Data Element Name. Telephone Number, Format 2.

Description. This standard provides format specifications for representing the telephone number for all foreign countries, excluding the Bahamas, Bermuda, and Canada.

Source. Bell Atlantic directory.

Relationship. See Country Code and City Code.

FDA Specifications. None.

CDER Specifications. Telephone Number, Format 2 is represented by numeric text of fifteen characters. Punctuation in the form of hyphens and parentheses shall be permitted.

FDA Approved Date.

CDER Approved Date. January 10, 1995.

FDA Revised Date.

CDER Revised Date.

Data Values. Literal. Letters shall be converted to numbers in the following way:

A, B, and C = 2
D, E, and F = 3
G, H, and I = 4
J, K, and L = 5
M, N, and O = 6
P, R, and S = 7
T, U, and V = 8
W, X, and Y = 9

CDER DATA STANDARDS MANUAL

FDA Data Element Number.

CDER Data Element Number. C-GEN-10213

Data Element Name. Weight

Description. Weight is the amount that an object weighs.

Source. ASTM; Webster's New Collegiate Dictionary

Relationship. Height.

FDA Specifications. Weight shall consist of alphanumeric entries of a maximum of 10 characters in length. Unless otherwise specified in the field, the default value shall always be in kilograms.

CDER Specifications. No further specifications.

FDA Approved Date. This data element is pernding approval as an FDA Demographics Data Element.

CDER Approved Date. September 12, 1995.

FDA Revised Date.

CDER Revised Date.

Data Values. There are no pre-defined values.

CDER DATA STANDARDS MANUAL

FDA Data Element Number. GEO-00302

CDER Data Element Number. C-GEO-00302

Data Element Name. City Name.

Description. This standard provides for the city portion of a domestic or foreign address. The Federal Information Processing Standards Publications 55-1 contains a listing of the cities within the United States.

Source. Division of Regulatory Information Systems, Office of Regulatory Resources Management, Office of Regulatory Affairs, FDA.

Relationship. Firm Name (ORG-00101), Street Address (GEO-00301), Foreign State/Province (GEO-00303), Country Name (GEO-00304).

FDA Specifications. City Name is represented by variable length alphanumeric text consisting of a maximum of thirty (30) characters.

CDER Specifications. This field should not contain any non-related information, such as a zip code.

FDA Approved Date. October 12, 1989.

CDER Approved Date. November 5, 1991.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
Literal	City portion of a domestic or foreign address.	N/A

CDER DATA STANDARDS MANUAL

FDA Data Element Number. GEO-00101

CDER Data Element Number. C-GEO-00101

Data Element Name. Countries, Dependencies, and Areas of Special Sovereignty.

Description. This standard provides names and abbreviations for representing countries, dependencies, and areas of special sovereignty as defined in ANSI Z39.27 - 1984, "Structure for the Representation of Names of Countries, Dependencies, and Areas of Special Sovereignty for Information Interchange," of the American National Standards Institute (ANSI).

Source. Federal Information Processing Standards (FIPS) Publication 104.

Relationship.

FDA Specifications. Names of Countries, Dependencies, and Areas of Special Sovereignty are represented by alphabetic text of two (2) characters.

CDER Specifications. a) There have been many changes in the names of countries since the FIPS list was published in 1984 (e.g., East and West Germany have unified). Therefore, this standard needs to be reevaluated on at least a yearly basis. b) FIPS designates a country code for each territory of the United States, which usually has the letter 'Q' as the second character, rather than using the U.S. Postal Service territory codes. Since CDER uses this address data to generate letters, it was felt that CDER needed to deviate from the FIPS data elements in this field when U.S. territories were represented. Thus, we have added the U.S. Postal Service U.S. territory abbreviations to C-GEO-00204, and have deleted the FIPS U.S. territory abbreviations from C-GEO-00101. Further, when a U.S. Postal Service U.S. territory abbreviation is placed in a state field, the country field associated with that record should contain the FIPS abbreviation 'US'. c) When the country is not known, CDER reserves the abbreviation 'XX' where null fields are not allowed.

FDA Approved Date. October 9, 1986.

CDER Approved Date. November 5, 1991.

FDA Revised Date.

CDER Revised Date. February 11, 1992; April 14, 1992; October 11, 1994.

Data Values.

Name	Definition	Code
AFGHANISTAN	Literal	AF
ALBANIA	Literal	AL
ALGERIA	Literal	AG
ANDORA	Literal	AN
ANGOLA	Literal	AO

ANGUILLA	Literal	AV
ANTARCTICA	Literal	AY
ANTIGUA AND BARBUDA	Literal	AC
ARGENTINA	Literal	AR
ARMENIA	Literal	AM
ASHMORE AND CARTIER ISLANDS	Literal	AT
AUSTRALIA	Literal	AS
AUSTRIA	Literal	AU
AZERBAIJAN	Literal	AJ
BAHAMAS	Literal	BF
BAHRAIN	Literal	BA
BANGLADESH	Literal	BG
BARBADOS	Literal	BB
BASSAS DA INDIA	Literal	BS
BELARUS	Literal	BO
BELGIUM	Literal	BE
BELIZE	Literal	BH
BENIN	Literal	BN
BERMUDA	Literal	BD
BHUTAN	Literal	BT
BOLIVIA	Literal	BL
BOSNIA-HERZEGOVINA	Literal	BK
BOTSWANA	Literal	BC
BOUVET ISLAND	Literal	BV
BRAZIL	Literal	BR
BRITISH INDIAN OCEAN TERRITORIES	Literal	IO
BRITISH VIRGIN ISLANDS	Literal	VI
BRUNEI	Literal	BX
BULGARIA	Literal	BU
BURKINA	Literal	UV
BURMA	Literal	BM
BURUNDI	Literal	BY
CAMEROON	Literal	CM
CANADA	Literal	CA
CAPE VERDE	Literal	CV
CAYMAN ISLANDS	Literal	CJ
CENTRAL AFRICAN REPUBLIC	Literal	CT
CHAD	Literal	CD
CHILE	Literal	CI
CHINA	Literal	CH
CHRISTMAS ISLAND	Literal	KT
CLIPPERTON ISLAND	Literal	IP
COCOS (KEELING) ISLANDS	Literal	CK
COLOMBIA	Literal	CO
COMOROS	Literal	CN
CONGO	Literal	CF
COOK ISLAND	Literal	CW
CORAL SEA ISLANDS	Literal	CR
COSTA RICA	Literal	CS
COTE D'IVOIRE	Literal	IV
CROATIA	Literal	HR
CUBA	Literal	CU
CYPRUS	Literal	CY
CZECH REPUBLIC	Literal	EZ
DENMARK	Literal	DA
DJIBOUTI	Literal	DJ
DOMINICA	Literal	DO
DOMINICAN REPUBLIC	Literal	DR
ECUADOR	Literal	EC
EGYPT	Literal	EG
EL SALVADOR	Literal	ES
EQUATORIAL GUINEA	Literal	EK
ERITREA	Literal	ER
ESTONIA	Literal	EN
ETHIOPIA	Literal	ET
EUROPA ISLAND	Literal	EU

FALKLAND ISLANDS	Literal	FK
FIJI	Literal	FJ
FINLAND	Literal	FI
FRANCE	Literal	FR
FRENCH GUIANA	Literal	FG
FRENCH POLYNESIA	Literal	FP
FRENCH SOUTHERN AND ANTARCTIC LANDS	Literal	FS
GABON	Literal	GB
GAMBIA, THE	Literal	GA
GAZA STRIP	Literal	GZ
GEORGIA	Literal	GG
GERMANY	Literal	GM
GHANA	Literal	GH
GIBRALTAR	Literal	GI
GLORIOSO ISLANDS	Literal	GO
GREECE	Literal	GR
GREENLAND	Literal	GL
GRENADA	Literal	GJ
GUADELOUPE	Literal	GP
GUATEMALA	Literal	GT
GUERNSEY	Literal	GK
GUINEA	Literal	GV
GUINEA-BISSAU	Literal	PU
GUYANA	Literal	GY
HAITI	Literal	HA
HEARD ISLAND AND MCDONALD ISLANDS	Literal	HM
HONDURAS	Literal	HO
HONG KONG	Literal	HK
HOWLAND ISLAND	Literal	HQ
HUNGARY	Literal	HU
ICELAND	Literal	IC
INDIA	Literal	IN
INDONESIA	Literal	ID
IRAN	Literal	IR
IRAQ	Literal	IZ
IRELAND (SOUTHERN ONLY)	Literal	EI
ISRAEL	Literal	IS
ITALY	Literal	IT
JAMAICA	Literal	JM
JAN MAYEN	Literal	JN
JAPAN	Literal	JA
JERSEY	Literal	JE
JORDAN	Literal	JO
JUAN DE NOVA ISLAND	Literal	JU
KAMPUCHEA	Literal	CB
KAZAKHSTAN	Literal	KZ
KENYA	Literal	KE
KIRIBATI	Literal	KR
KOREA, NORTH	Literal	KN
KOREA, SOUTH	Literal	KS
KUWAIT	Literal	KU
KYRGYZSTAN	Literal	KG
LAOS	Literal	LA
LATVIA	Literal	LG
LEBANON	Literal	LE
LESOTHO	Literal	LT
LIBERIA	Literal	LT
LIBYA	Literal	LY
LIECHTENSTEIN	Literal	LS
LITHUANIA	Literal	LH
LUXEMBOURG	Literal	LU
MACAU	Literal	MC
MACEDONIA	Literal	MK
MADAGASCAR	Literal	MA
MALAWI	Literal	MI
MALAYSIA	Literal	MY

MALDIVES	Literal	MV
MALI	Literal	ML
MALTA	Literal	MT
MAN, ISLE OF	Literal	IM
MARTINIQUE	Literal	MB
MAURITANIA	Literal	MR
MAURITIUS	Literal	MP
MAYOTTE	Literal	MF
MEXICO	Literal	MX
MOLDOVA	Literal	MD
MONACO	Literal	MN
MONGOLIA	Literal	MG
MONTENEGRO	Literal	MW
MONTSERRAT	Literal	MH
MOROCCO	Literal	MO
MOZAMBIQUE	Literal	MZ
NAMIBIA	Literal	WA
NAURA	Literal	NR
NEPAL	Literal	NP
NETHERLANDS	Literal	NL
NETHERLANDS ANTILLES	Literal	NA
NEW CALENDONIA	Literal	NC
NEW ZEALAND	Literal	NZ
NICARAGUA	Literal	NU
NIGER	Literal	NG
NIGERIA	Literal	NI
NIUE	Literal	NE
NORFOLK ISLAND	Literal	NF
NORWAY	Literal	NO
OMAN	Literal	MU
PAKISTAN	Literal	PK
PANAMA	Literal	PM
PAPUA NEW GUINEA	Literal	PP
PARACEL ISLANDS	Literal	PF
PARAGUAY	Literal	PA
PERU	Literal	PE
PHILIPPINES	Literal	RP
PITCAIRN ISLANDS	Literal	PC
POLAND	Literal	PL
PORTUGAL	Literal	PO
QATAR	Literal	QA
REUNION	Literal	RE
ROMANIA	Literal	RO
RUSSIA	Literal	RS
RWANDA	Literal	RW
SAINT KITTS AND NEVIS	Literal	SC
SAINT HELENA	Literal	SH
SAINT LUCIA	Literal	ST
SAINT PIERRE AND MIQUELON	Literal	SB
SAINT VINCENT AND THE GRENADINES	Literal	VC
SAN MARINO	Literal	SM
SAO TOME AND PRINCIPE	Literal	TP
SAUDI ARABIA	Literal	SA
SENEGAL	Literal	SG
SERBIA	Literal	SR
SEYCHELLES	Literal	SE
SIERRA LEONE	Literal	SL
SINGAPORE	Literal	SN
SLOVAKIA	Literal	LO
SLOVENIA	Literal	SI
SOLOMON ISLANDS	Literal	BP
SOMALIA	Literal	SO
SOUTH AFRICA	Literal	SF
SOUTH GEORGIA/SANDWICH ISLANDS	Literal	SX
SPAIN	Literal	SP
SPRATLY ISLANDS	Literal	PG

SRI LANKA	Literal	CE
SUDAN	Literal	SU
SURINAME	Literal	NS
SVALBARD	Literal	SV
SWAZILAND	Literal	WZ
SWEDEN	Literal	SW
SWITZERLAND	Literal	SZ
SYRIA	Literal	SY
TAIWAN	Literal	TW
TAJIKISTAN	Literal	TI
TANZANIA, UNITED REPUBLIC OF	Literal	TZ
THAILAND	Literal	TH
TOGO	Literal	TO
TOKELAU	Literal	TL
TONGA	Literal	TN
TRINIDAD AND TOBAGO	Literal	TD
TROMELIN ISLAND	Literal	TE
TUNISIA	Literal	TS
TURKEY	Literal	TU
TURKMENISTAN	Literal	TX
TURKS AND CAICOS ISLANDS	Literal	TK
TUVALU	Literal	TV
UGANDA	Literal	UG
UKRAINE	Literal	UP
UNITED ARAB EMIRATES	Literal	TC
UNITED KINGDOM	Literal	UK
UNITED STATES	Literal	US
UNKNOWN COUNTRY	Literal	XX
URUGUAY	Literal	UY
UZBEKISTAN	Literal	UZ
VANUATU	Literal	NH
VATICAN CITY	Literal	VT
VENEZUELA	Literal	VE
VIETNAM	Literal	VM
WALLIS AND FUTUNA	Literal	WF
WEST BANK	Literal	WE
WESTERN SAHARA	Literal	WI
WESTERN SAMAO	Literal	WS
YEMEN	Literal	YM
ZAIRE	Literal	CG
ZAMBIA	Literal	ZA
ZIMBABWE	Literal	ZI

CDER DATA STANDARDS MANUAL

FDA Data Element Number. GEO-00304

CDER Data Element Number. C-GEO-00304

Data Element Name. Country Name.

Description. This standard provides for the country name portion of the address. Countries, Dependencies, and Areas of Special Sovereignty as described in Federal Information Processing Standards Publications 104 are included in this standard.

Source. Division of Regulatory Information Systems, Office of Regulatory Resources Management, Office of Regulatory Affairs, FDA.

Relationship. Firm Name (ORG-00101), Street Address (GEO-00301), City Name (GEO-00302), Foreign State/Province (GEO-00303), Countries Dependencies and Areas of Special Sovereignty (GEO-00101).

FDA Specifications. Country Name is represented by variable length alphanumeric text consisting of a maximum of thirty (30) characters.

CDER Specifications. No further specifications.

FDA Approved Date. October 12, 1989.

CDER Approved Date. November 5, 1991.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
Literal	Country name portion of an address.	N/A

CDER DATA STANDARDS MANUAL

FDA Data Element Number. None.

CDER Data Element Number. C-GEO-00305

Data Element Name. District Office Code.

Description. This standard provides format specifications for representing the FDA District Office code.

Source. FDA Office of Regulatory Affairs.

Relationship.

FDA Specifications. None.

CDER Specifications. District Office Code is represented by alphabetic text of three characters, without punctuation. District Office codes are based upon the US Postal Service zip code (rather than state name because the states of New York and California each have two FDA District Offices).

FDA Approved Date.

CDER Approved Date. January 10, 1995.

FDA Revised Date.

CDER Revised Date.

Data Values.

District Office Name	Definition (Zip Code, State Name)	Code
ATLANTA	27000–28999, NORTH CAROLINA	ATL
	29000–29999, SOUTH CAROLINA	
	30000–31999, GEORGIA	
BALTIMORE	20000–20599, DISTRICT OF COLUMBIA	BLT
	20600–21999, MARYLAND	
	22000–24699, VIRGINIA	
	24700–26899, WEST VIRGINIA	

NEW ENGLAND	01000--02799, MASSACHUSETTS	NWE
	02800--02999, RHODE ISLAND	
	03000--03899, NEW HAMPSHIRE	
	03900--04999, MAINE	
	05000--05999, VERMONT	
	06000--06999, CONNECTICUT	
BUFFALO	10505, 10509, 10512, 10516, 10537, 10541, 10542, 10579, 10910, 10912, 10914, 10915, 10916, 10917, 10918, 10919, 10922, 10925, 10926, 10928, 10930, 10932, 10933, 10940, 10950, 10953, 10958, 10959, 10963, 10969, 10973, 10975, 10979, 10981, 10985, 10987, 10988, 10990, 10992, 10998, and 12000--14999, parts of NEW YORK	BUF
CHICAGO	60000--62999, ILLINOIS CHI	
CINCINNATI	40000--42799, KENTUCKY	CIN
	43000--45899, OHIO	
DALLAS	71600--72999, ARKANSAS	DAL
	73000--74999, OKLAHOMA	
	75000--79999, TEXAS	
DENVER	80000--81619, COLORADO	DEN
	82000--83199, WYOMING	
	84000--84799, UTAH	
	87000--88499, NEW MEXICO	
DETROIT	46000--47999, INDIANA	DET
	48000--49999, MICHIGAN	

KANSAS CITY	50000--52899, IOWA	KAN
	63000--65899, MISSOURI	
	66000--67999, KANSAS	
	68000--69399, NEBRASKA	
LOS ANGELES	85000--86599, ARIZONA	LOS
	90000--93199, 93400--93499, 93510, 93532, 93533, 93534, 93535, 93536, 93537, 93538, 93539, 93543, 93544, 93545, 93550, 93551, 93552, 93553, 93554, 93558, 93562, 93563, parts of CALIFORNIA	
MINNEAPOLIS	53000--54999, WISCONSIN	MIN
	55000--56799, MINNESOTA	
	57000--57799, SOUTH DAKOTA	
	58000--58899, NORTH DAKOTA	
NASHVILLE	35000--36999, ALABAMA	NSH
	37000--38599, TENNESSEE	
NEW ORLEANS	38600--39799, MISSISSIPPI	NOL
	70000--71499, LOUISIANA	
NEW YORK CITY	09000--10499, 10501, 10502, 10503, 10504, 10506, 10507, 10508, 10510, 10511, 10513, 10514, 10515, 10517, 10518--10536, 10538, 10539, 10540, 10543--10578, 10580--10599, 10900, 10901--10909, 10911, 10913, 10920, 10921, 10923, 10924, 10927, 10929, 10931, 10935, 10936, 10937, 10938, 10939, 10941, 10942, 10943, 10944, 10945, 10946, 10947, 10948, 10949, 10951, 10952, 10954, 10955, 10956, 10957, 10960, 10961, 10962, 10964, 10965, 10966, 10967, 10968, 10970, 10971, 10972, 10974, 10976, 10977, 10978, 10980, 10982, 10983, 10984, 10986, 10989, 10991, 10993, 10994, 10995, 10996, 10997, 10999, parts of NEW YORK	NYK
NEW JERSEY	07000--08999, NEW JERSEY	NWJ
FLORIDA	32000--34299, FLORIDA	FLA

PHILADELPHIA	15000--19699, PENNSYLVANIA	PHI
	19700--19999, DELAWARE	
SAN JUAN	00600--00799, PUERTO RICO	SJN
	00800--00899, VIRGIN ISLANDS	
	00900--00999, PUERTO RICO	
SAN FRANCISCO	89000--89899, NEVADA	SAN
	93200--93399, 93500, 93501, 93502, 93503, 93504, 93505, 93506, 93507, 93508, 93509, 93511, 93512, 93513, 93514, 93515, 93516, 93517, 93518, 93519, 93520, 93521, 93522, 93523, 93524, 93525, 93526, 93527, 93528, 93529, 93530, 93531, 93540, 93541, 93542, 93546, 93547, 93548, 93549, 93555, 93556, 93557, 93559, 93560, 93561, 93564, 93565, 93566, 93567, 93568, 93569, 93570, 93571, 93572, 93573, 93574, 93575, 93576, 93577, 93578, 93579, 93580, 93581, 93582, 93583, 93584, 93585, 93586, 93587, 93588, 93589, 93590, 93591, 93592, 93593, 93594, 93595, 93596, 93597, 93598, 93599, 93600--96699, parts of CALIFORNIA	
	96700--96799, AMERICAN SAMOA	
	96800--96899, HAWAII	
	96900--96999, GUAM	
SEATTLE	59000--59999, MONTANA	SEA
	83200--83899, IDAHO	
	87000--97999, OREGON	
	98000--99499, WASHINGTON	
	99500--99999, ALASKA	

CDER DATA STANDARDS MANUAL

FDA Data Element Number. GEO-00303

CDER Data Element Number. C-GEO-00303

Data Element Name. State/Foreign Province.

Description. This standard provides for the foreign province, state, or outlying area portion of the address. The Federal Information Processing Standard (5-1) provides names and abbreviation codes for representing the 50 states, Washington, D.C. and the outlying areas, all of which are considered to be "first order subdivisions" of the United States.

Source. Division of Regulatory Information Systems, Office of Regulatory Resources Management, Office of Regulatory Affairs, FDA.

Relationship. Firm Name (ORG-00101), Street Address (GEO-00301), City Name (GEO-00302), Country Name (GEO-00304), Countries Dependencies and Areas of Special Sovereignty (GEO-00101).

FDA Specifications. State/Foreign Province is represented by variable length alphanumeric text consisting of a maximum of thirty (30) characters.

CDER Specifications. No further specifications.

FDA Approved Date. October 12, 1989.

CDER Approved Date. November 5, 1991.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
Literal	Foreign province, state or outlying area portion of the address.	N/A

CDER DATA STANDARDS MANUAL

FDA Data Element Number. GEO-00204

CDER Data Element Number. C-GEO-00204

Data Element Name. States and Outlying Areas of the United States.

Description. This standard provides names, abbreviations and codes for representing the 50 States, the District of Columbia, and the outlying areas of the United States.

Source. Federal Information Processing Standards Publication (FIPS Pub) 5-1.

Relationship. Counties and County Equivalents (GEO-00201); Named Populated Places, Primary County Divisions, and Other Locational Entities of the United States (GEO-00202); Metropolitan Statistical Area (GEO-00203).

FDA Specifications. United States, the District of Columbia, and the outlying areas of the United States are represented by a two (2) digit number, right justified with leading zero.

CDER Specifications. a) FIPS designates a two-digit numeric code for each state and the District of Columbia, instead of using a U.S. Postal Service two-letter abbreviation. Since CDER uses the data in this field to address correspondence, and since the two-digit numeric code is not recognized by the U.S. Postal Service, it was felt that we needed to deviate from FIPS in this regard, and solely employ the U.S. Postal Service two letter abbreviation.
b) As stated in GEO-00101, FIPS designates a country code for each territory of the United States, which usually has the letter 'Q' as the second character, rather than using the U.S. Postal Service territory codes. Since CDER uses this address data to generate letters, it was felt that CDER needed to deviate from the FIPS data elements in this field when U.S. territories were represented. Thus, we have added the U.S. Postal Service U.S. territory abbreviations to C-GEO-00204, and have deleted the FIPS U.S. territory abbreviations from C-GEO-00101. Further, when a U.S. Postal Service U.S. territory abbreviation is placed in a state field, the country field associated with that record should contain the FIPS abbreviation 'US'. c) When the U.S. territory has no known abbreviation, CDER reserves the abbreviation 'XX' where null fields are not allowed. If there is no known two-letter abbreviation, the U.S. territory should be completely spelled out in the ADDR_FORIEGN field.

It was decided that FIPS codes would be specified in this standard monograph as a cross-reference to enable data conversion from non-CDER components.

FDA Approved Date. July 17, 1986.

CDER Approved Date. November 5, 1991.

FDA Revised Date.

CDER Revised Date.

Data Values. (see next two pages)

Name	Definition	CDER Std Postal Alpha State Code	Cross-References FIPS Alpha Country Code	Cross-References FIPS Numeric State Code
ALABAMA	Literal	AL		01
ALASKA	Literal	AK		02
AMERICAN SAMOA	Literal	SA	AQ	60
ARIZONA	Literal	AZ		04
ARKANSAS	Literal	AR		05
BAKER ISLAND	Literal			81
CALIFORNIA	Literal	CA		06
CANAL ZONE	Literal	CZ	PQ	61
CANTON/ENDERBURY ISLANDS	Literal		EQ	62
COLORADO	Literal	CO		08
CONNECTICUT	Literal	CT		09
DELAWARE	Literal	DE		10
DISTRICT OF COLUMBIA	Literal	DC		11
FLORIDA	Literal	FL		12
GEORGIA	Literal	GA		13
GUAM	Literal	GU	GQ	66
HAWAII	Literal	HI		15
HOWLAND ISLAND	Literal			84
IDAHO	Literal	ID		16
ILLINOIS	Literal	IL		17
INDIANA	Literal	IN		18
IOWA	Literal	IA		19
JARVIS ISLAND	Literal			86
JOHNSTON ATOLL	Literal		JQ	67
KANSAS	Literal	KS		20
KENTUCKY	Literal	KY		21
KINGMAN REEF	Literal			89
LOUISIANA	Literal	LA		22
MAINE	Literal	ME		23
MARYLAND	Literal	MD		24
MASSACHUSETTS	Literal	MA		25
MICHIGAN	Literal	MI		26
MIDWAY ISLANDS	Literal		MQ	71
MINNESOTA	Literal	MN		27
MISCELLANEOUS US TERRITORY	Literal	XX		
MISSISSIPPI	Literal	MS		28
MISSOURI	Literal	MO		29
MONTANA	Literal	MT		30
NEBRASKA	Literal	NE		31
NEVADA	Literal	NV		32
NEW HAMPSHIRE	Literal	NH		33
NEW JERSEY	Literal	NJ		34
NEW MEXICO	Literal	NM		35
NEW YORK	Literal	NY		36
NORTH CAROLINA	Literal	NC		37
NORTH DAKOTA	Literal	ND		38
NORTHERN MARIANA ISLANDS	Literal	CM	CQ	69
OHIO	Literal	OH		39
OKLAHOMA	Literal	OK		40
OREGON	Literal	OR		41
PALMYRA ATOLL	Literal			95
PENNSYLVANIA	Literal	PA		42
PUERTO RICO	Literal	PR	RQ	72
RHODE ISLAND	Literal	RI		44
SOUTH CAROLINA	Literal	SC		45
SOUTH DAKOTA	Literal	SD		46
TENNESSEE	Literal	TN		47

Name	Definition	CDER Std Postal Alpha State Code	Cross-References FIPS Alpha Country Code	Cross-References FIPS Numeric State Code
TEXAS	Literal	TX		48
TRUST TERRITORIES PACIFIC	Literal	TT	NQ	75
UTAH	Literal	UT		49
VERMONT	Literal	VT		50
VIRGIN ISLANDS	Literal	VI	VQ	78
VIRGINIA	Literal	VA		51
WAKE ISLAND	Literal		WQ	79
WASHINGTON	Literal	WA		53
WEST VIRGINIA	Literal	WV		54
WISCONSIN	Literal	WI		55
WYOMING	Literal	WY		56

CDER DATA STANDARDS MANUAL

FDA Data Element Number. GEO-00301

CDER Data Element Number. C-GEO-00301

Data Element Name. Street Address.

Description. This standard provides for the street address including building name, post office box, route, etc. Street Address does not include city, state, province, or country.

Source. Division of Regulatory Information Systems, Office of Regulatory Resources Management, Office of Regulatory Affairs, FDA.

Relationship. Firm Name (ORG-00101), City Name (GEO-00302), Foreign State/Province (GEO-00303), Country Name (GEO-00304).

FDA Specifications. Street Address is represented by variable length alphanumeric text consisting of a maximum of forty (40) characters. The punctuation for this field is system specific.

CDER Specifications. a) When possible, building name, room number, post office box, and zip code should be separated into distinct fields. b) See list below for valid mandatory abbreviations (These abbreviations were derived from United States Postal Service valid abbreviations. Since that list was so extensive, the Center restricted abbreviations to 1)Only the more commonly used abbreviations, and 2)Only when the original word contained more than four letters (except ROAD and ROOM, which were too common to omit).) c)Decimal points shall only be used to represent distance from a particular point (e.g., 24.5 KM NORTH OF RT 10) or to represent a fraction in a street address (e.g., 25.5 BROADWAY CT).

FDA Approved Date. October 12, 1989.

CDER Approved Date. November 5, 1991.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
Literal	Street address including building name, post office box, route, etc.	N/A
CDER Valid Values:		
APARTMENT	Literal	APT
AVENUE	Literal	AVE
BOULEVARD	Literal	BLVD
BRANCH	Literal	BR
BUILDING	Literal	BLDG

CIRCLE	Literal	CIR
COURT	Literal	CT
DRIVE	Literal	DR
EXPRESSWAY	Literal	EXPY
EXTENSION	Literal	EXT
HIGHWAY	Literal	HWY
KILOMETER	Literal	KM
MILE	Literal	MI
MOUNT	Literal	MT
MOUNTAIN	Literal	MTN
PARKWAY	Literal	PKY
PLACE	Literal	PL
ROAD	Literal	RD
ROOM	Literal	RM
ROUTE	Literal	RT
RURAL ROUTE	Literal	RR
STREET	Literal	ST
SUITE	Literal	STE
TURNPIKE	Literal	TPKE

CDER DATA STANDARDS MANUAL

FDA Data Element Number. ORG-00101

CDER Data Element Number. C-ORG-00101

Data Element Name. Firm Name.

Description. This standard represents the name or designation under which a company transact business.

Source. Division of Regulatory Information Systems, Office of Regulatory Resources Management, Office of Regulatory Affairs, FDA.

Relationship. Street Address 1 (GEO-00301), City Name (GEO-00302), Foreign State/Province (GEO-00303), Country Name (GEO-00304).

FDA Specifications. Firm Name is represented by variable length alphanumeric text consisting of a maximum of sixty (60) characters.

CDER Specifications. No further specifications. In process of review, 1992.

FDA Approved Date. October 12, 1989.

CDER Approved Date.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
Literal	Name or designation under which a company transacts business.	N/A

POWDER, DENTIFRICE	An intimate mixture of dry, finely divided drugs and/or chemicals that, with the aid of a toothbrush, is used for the purpose of cleaning the accessible surfaces of the teeth. (USP, XXII; Remington's Pharmaceutical Sciences, 17th Ed.)	115
POWDER, FOR SOLUTION	An intimate mixture of dry, finely divided drugs and/or chemicals, which, upon the addition of suitable vehicles, yields a solution.	833
POWDER, FOR SUSPENSION	An intimate mixture of dry, finely divided drugs and/or chemicals, which, upon the addition of suitable vehicles, yields a suspension (a liquid preparation containing the solid particles dispersed in the liquid vehicle).	834
RINSE	A liquid used to cleanse by flushing.	303
SALVE	A thick ointment or cerate (a fat or wax based preparation with a consistency between an ointment and a plaster).	137
SHAMPOO	A liquid soap or detergent used to clean the hair and scalp and is often used as a vehicle for dermatologic agents.	304
SHAMPOO, SUSPENSION	A liquid soap or detergent containing one or more solid, insoluble substances dispersed in a liquid vehicle that is used to clean the hair and scalp and is often used as a vehicle for dermatologic agents.	193
SOAP	Any compound of one or more fatty acids, or their equivalents, with an alkali; soap is detergent and is much employed in liniments, enemas, and in making pills. It is also a mild aperient, antacid and antiseptic.	305
SOLUTION	A liquid preparation that contains one or more chemical substances dissolved, i.e., molecularly dispersed, in a suitable solvent or mixture of mutually miscible solvents.	138
SOLUTION, CONCENTRATE	A liquid preparation (i.e., a substance that flows readily in its natural state) that contains a drug dissolved in a suitable solvent or mixture of mutually miscible solvents; the drug has been strengthened by the evaporation of its nonactive parts.	835
SOLUTION, FOR SLUSH	A solution for the preparation of an iced saline slush, which is administered by irrigation and used to induce regional hypothermia (in conditions such as certain open heart and kidney surgical procedures) by its direct application.	321
SPONGE	An absorbent pad of folded gauze or cotton.	271
SPRAY	A liquid minutely divided as by a jet of air or steam.	272
SPRAY, METERED	An aerosol dosage form consisting of valves which allow the dispensing of a specified quantity of spray.	345
SPRAY, SUSPENSION	A liquid preparation containing solid particles dispersed in a liquid vehicle and in the form of coarse droplets or as finely divided solids to be applied topically, most usually to the nasal-pharyngeal tract or to the skin.	195
STICK	A dosage form prepared in a relatively long and slender often cylindrical form.	273
STRIP	A long narrow piece of material.	274

NOT APPLICABLE	The use of a dosage form term is not relevant or appropriate.	313
OIL	An unctuous, combustible substance which is liquid, or easily liquefiable, on warming, and is soluble in ether but insoluble in water. Such substances, depending on their origin, are classified as animal, mineral, or vegetable oils.	098
OINTMENT	A semisolid preparation intended for external application to the skin or mucous membranes.	101
PACKING	A cord-like material, usually covered by or impregnated with a drug, that is inserted between the tooth enamel and the gingival margin.	839
PASTE	A semisolid dosage form that contains one or more drug substances intended for topical application.	103
PASTE, DENTIFRICE	A substance, in the form a paste, used with a toothbrush for the purpose of cleaning the accessible surfaces of the teeth.	104
PATCH, EXTENDED RELEASE	A transdermal drug delivery system in the form of a patch that releases the drug in such a manner that a two-fold reduction in dosing frequency compared to that drug presented as a conventional dosage form (e.g., a solution or a prompt drug-releasing, conventional solid dosage form).	813
PATCH, EXTENDED RELEASE, ELECTRICALLY CONTROLLED	A transdermal drug delivery system in the form of a patch which is controlled by an electric current that releases the drug in such a manner that a two-fold reduction in dosing frequency compared to that drug presented as a conventional dosage form (e.g., a solution or a prompt drug-releasing, conventional solid dosage form).	814
PELLET	A small sterile solid mass consisting of a highly purified drug (with or without excipients) made by compression or molding; they are intended for implantation in the body (usually subcutaneously) for the purpose of providing continuous release of the drug over long periods of time.	105
PILL	A small, round solid dosage form containing a medicinal agent intended for oral administration.	107
PLASTER	Substance intended for external application made of such materials and of such consistency as to adhere to the skin and attach to a dressing; plasters are intended to afford protection and support and/or to furnish an occlusion and macerating action and to bring medication into close contact with the skin.	108
POULTICE	A soft, moist mass of meal, herbs, seed, etc., usually applied hot in cloth that consists of gruel-like consistency.	109
POWDER	An intimate mixture of dry, finely divided drugs and/or chemicals that may be intended for internal (oral powders) or external (topical powders) use.	110

SUPPOSITORY	A solid body of various weights and shapes, adapted for introduction into the rectal, vaginal, or urethral orifice of the human body; they usually melt, soften, or dissolve at body temperature.	173
SUPPOSITORY, EXTENDED RELEASE	A drug delivery system in the form of a suppository that allows at least a two-fold reduction in dosing frequency.	815
SUSPENSION	A liquid preparation which consists of solid particles dispersed throughout a liquid phase in which the particles are not soluble.	177
SUSPENSION, EXTENDED RELEASE	A liquid preparation consisting of solid particles dispersed throughout a liquid phase in which the particles are not soluble; the suspension has been formulated in a manner to allow at least a twofold reduction in dosing frequency as compared to that drug presented as a conventional dosage form (e.g., as a solution or a prompt drug-releasing, conventional solid dosage form).	816
SUTURE	A strand or fiber used to hold wound edges in apposition during healing.	275
SWAB	A wad of absorbent material usually wound around one end of a small stick and used for applying medication or for removing material from an area.	276
SYRUP	An oral solution containing high concentrations of sucrose or other sugars; the term has also been used to include any other liquid dosage form prepared in a sweet and viscid vehicle, including oral suspensions.	307
TABLET	A solid dosage form containing medicinal substances with or without suitable diluents.	500
TABLET, CHEWABLE	A solid dosage form containing medicinal substances with or without suitable diluents that is intended to be chewed, producing a pleasant tasting residue in the oral cavity that is easily swallowed and does not leave a bitter or unpleasant after-taste.	501
TABLET, COATED	A solid dosage form that contains medicinal substances with or without suitable diluents and is covered with a designated coating.	502
TABLET, DELAYED RELEASE	A solid dosage form which releases a drug (or drugs) at a time other than promptly after administration. Enteric-coated articles are delayed release dosage forms.	520
TABLET, DELAYED RELEASE PARTICLES	A solid dosage form containing a conglomerate of medicinal particles that have been covered with a coating which releases a drug (or drugs) at a time other than promptly after administration. Enteric-coated articles are delayed release dosage forms.	521
TABLET, EFFERVESCENT	A solid dosage form containing, in addition to active ingredients, mixtures of acids (citric acid, tartaric acid) and sodium bicarbonate, which release carbon dioxide when dissolved in water; it is intended to be dissolved or dispersed in water before administration.	503
TABLET, EXTENDED RELEASE	A solid dosage form containing a drug which allows at least a two-fold reduction in dosing frequency as compared to that drug presented in conventional dosage form.	510

TABLET, FILM COATED	A solid dosage form that contains medicinal substances with or without suitable diluents and is coated with a thin layer of a water-insoluble or water-soluble polymer.	504
TABLET, FILM COATED, EXTENDED RELEASE	A solid dosage form that contains medicinal substances with or without suitable diluents and is coated with a thin layer of a water-insoluble or water-soluble polymer; the tablet is formulated in such manner as to make the contained medicament available over an extended period of time following ingestion.	511
TABLET, MULTILAYER	A solid dosage form containing medicinal substances that have been compressed to form a multiple-layered tablet or a tablet-within-a-tablet, the inner tablet being the core and the outer portion being the shell.	505
TABLET, MULTILAYER, EXTENDED RELEASE	A solid dosage form containing medicinal substances that have been compressed to form a multiple-layered tablet or a tablet-within-a-tablet, the inner tablet being the core and the outer portion being the shell, which, additionally, is covered in a designated coating; the tablet is formulated in such manner as to allow at least a two-fold reduction in dosing frequency as compared to that drug presented as a conventional dosage form.	512
TABLET, SOLUBLE	A solid dosage form that contains medicinal substances with or without suitable diluents and possesses the ability to dissolve in fluids.	507
TABLET, SUGAR COATED	A solid dosage form that contains medicinal substances with or without suitable diluents and is coated with a colored or an uncolored water-soluble sugar.	508
TAMPON	A plug made of cotton, sponge, or oakum variously used in surgery to plug the nose, vagina, etc., for the control of hemorrhage or the absorption of secretions.	277
TAPE	A narrow woven fabric, or a narrow extruded synthetic (such as plastic), usually with an adhesive on one or both sides.	278
TINCTURE	An alcoholic or hydroalcoholic solution prepared from vegetable materials or from chemical substances.	837
TROCHE	A discoid-shaped solid containing the medicinal agent in a suitably flavored base; troches are placed in the mouth where they slowly dissolve, liberating the active ingredients.	363
UNASSIGNED	A dosage form has yet to be assigned.	900
WAFER	A thin slice of material containing a medicinal agent.	245

CDER DATA STANDARDS MANUAL

FDA Data Element Number. None.

CDER Data Element Number. C-DRG-00101

Data Element Name. Drug Classification.

Description. This standard provides for a mechanism for classifying all drugs from the Investigational New Drug (IND) stage of development onward.

Source. In process - CDER Drug Classification Subcommittee has reviewed various drug classification databases, and has recommended that USAN and AHFS be the primary candidates to develop this standard. Indication may supersede the need to progress further in the classification area.

Relationship.

FDA Specifications.

CDER Specifications.

FDA Approved Date.

CDER Approved Date.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code

CDER DATA STANDARDS MANUAL

FDA Data Element Number.

CDER Data Element Number. C-ORG-00801

Data Element Name. Exclusivity Code

Description. Exclusivity Code is the code used by the Food and Drug Administration to indicate the type of exclusive marketing rights granted to an NDA holder.

Source. Approved Drug Products with Therapeutic Equivalence Evaluations.

Relationship. See Patent Number and Patent Use Code.

FDA Specifications. None.

CDER Specifications. Exclusivity Code is represented by alphunumeric text of five characters in length, with hyphens as the only punctuation. The letter D in the code refers to a new dosing schedule, the letter I in the code refers to a new indication, and the remainder of the codes are specified herein.

FDA Approved Date.

CDER Approved Date.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
400MG EVERY 12 HOURS FOR THREE DAYS FOR UNCOMPLICATED URINARY TRACT INFECTIONS		D-17
ACUTE TREATMENT OF VARICELLA ZOSTER VIRUS		I-45
ADDITIONAL DOSAGE REGIMEN EQUAL TO HALF OF THE ORIGINAL DOSING REGIMEN		D-25
ADJUNCTIVE THERAPY IN THE MANAGEMENT OF HEART FAILURE		I-92

MIGRAINE HEADACHE PROPHYLAXIS	I-41
MONOTHERAPY USE FOR HYPERTENSION	I-91
NARCOTIC OVERDOSE IN ADULTS	D-9
NARCOTIC OVERDOSE IN CHILDREN	D-10
NEW COMBINATION	NC
NEW CHEMICAL ENTITY	NCE
NEW DOSAGE FORM	NDF
NEW ESTER OF SALT OF AN ACTIVE INGREDIENT	NE
NEW PRODUCT	NP
NEW ROUTE	NR
NEW STRENGTH	NS
ONCE A DAY APPLICATION	D-1
ONCE DAILY DOSING	D-2
ONCE DAILY TREATMENT AS INITIAL THERAPY IN THE TREATMENT OF HYPERTENSION	I-63
ORAL OR RECTAL USE IN CHILDREN FOR THE EXAMINATION OF THE GASTROINTESTINAL TRACT	I-97
ORAL USE IN ADULTS FOR PASS-THROUGH EXAMINATION OF THE GASTROINTESTINAL TRACT	I-34
ORAL USE OF DILUTED OMNIPAQUE INJECTION IN ADULTS FOR CONTRAST ENHANCED COMPUTED TOMOGRAPHY OF THE ABDOMEN	I-33
ORPHAN DRUG EXCLUSIVITY	ODE
PATENT CHALLENGE	PC
PEDIATRIC ANESTHESIA IN CHILDREN 3 YEARS AND OLDER	I-99
PEDIATRIC ANGIOCARDIOGRAPHY	I-48
PEDIATRIC CONTRAST ENHANCEMENT OF COMPUTED TOMOGRAPHIC HEAD IMAGING	I-35
PEDIATRIC EXCRETORY UROGRAPHY	I-52
PEDIATRIC MYELOGRAPHY	I-32
PERIPHERAL VENOGRAPHY (PHLEBOGRAPHY)	I-4

CDER DATA STANDARDS MANUAL

FDA Data Element Number. None.

CDER Data Element Number. C-DRG-00601

Data Element Name. Indications.

Description. This standard provides for all drug indications.

Source. National Library of Medicine's Coach Metathesaurus Browser. This software is available in CDER through the LANMENU using Pathworks, and is located on the X drive. The Metathesaurus preserves the meanings, hierarchal connections, and other relationships between terms present in its source vocabularies, while adding certain basic information about each of its concepts and establishing new relationships between concepts and terms from different source vocabularies. In this way, it allows CDER to determine "best-fit" standardized indication terms for synonymous terms on different labeling (e.g., high blood pressure and hypertension; neoplasm and carcinoma).

Relationship.

FDA Specifications. None.

CDER Specifications. Standard drug indication terms shall consist of a maximum length restricted to 100 characters, with the accompanying code. International Classification of Diseases, Version 9, with Clinical Manifestations (ICD-9-CM) shall be the primary drug indication term, and Systemized Nomenclature of Medicine, Version III (SNOMED-III) shall be the secondary drug indication term. Both classification systems (ICD-9-CM and SNOMED-III) are necessary for those situations where a primary term is too broad (e.g., ICD-9-CM does not define specific microbial infections, while SNOMED-III does).

FDA Approved Date. None.

CDER Approved Date. May 10, 1994.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
Literal, as stated in approved labeling	see UMLS definition	see ICD-9-CM SNOMED-III

FDA Data Element Number. None.

CDER Data Element Number. C-DRG-00401

Data Element Name. Ingredient Name.

Description. This standard provides for all ingredients, both active and inactive. It may also be used for contaminants and similar chemicals not necessarily desirable in the end-product.

Source. CDER Ingredient Dictionary (CDID) is directly linked to DRLS, DDE, and OTC through the CD# to the standard ingredient term. It is indirectly linked to the COMIS system by identifying the ingredients associated with IND's and NDA's.

Relationship. Related terms are the Chemical Abstracts Service Number (CAS NUMBER), and the FDA source document (SOURCE) that the ingredient name was found in.

FDA Specifications. None.

CDER Specifications. Ingredient Name shall consist of an alphanumeric term which has a maximum length restricted to 240 characters. A detailed description of the process of arriving at an ingredient name is found under the data values section. Since the number of entries was so voluminous, it was felt that a description of the process would better serve those interested. Actual data values are not static, and can be determined by contacting DDIR at 301-443-3910.

Codes representing these Ingredient Names shall consist of nine characters (two alpha characters followed by 7 numeric characters). The alpha portion of the code shall be determined by the responsible chemist. The first 6 digits of the numeric portion of the code shall be generated sequentially by computer, with the seventh digit also determined by computer (based upon the last number in the sum of the product of each integer times its numeric location from the right).

Logical flags delineating whether an ingredient name is a preferred term (PT) or a synonym term (SY) are also part of the ingredient name.

FDA Approved Date. None.

CDER Approved Date. April 12, 1994.

FDA Revised Date.

CDER Revised Date.

Data Values. See CDID.

CDID Nomenclature Standards.

1. All ingredients entered into the CDID must be preferred terms. The CDER guidelines for determining preferred names for drugs appear in the CDER Staff Manual Guide.

2. Established Names. Established names are classified according to Section 502 (c) (2) of the Act as follows:

a. Official Name. Section 508 of the FD & C Act, as amended, authorizes the Secretary of Health and Human Services to designate an official name for any drug if it is determined that such an action is necessary or desirable in the interest of usefulness and simplicity.

b. Official Compendium Name. If an official name has not been designated for the drug, and the drug is recognized in an official compendium (U.S. Pharmacopeia, National Formulary, or Homeopathic Pharmacopeia of the U.S.), then the Official title in the compendium is the established name.

c. Common or Usual Name. If a drug has neither an official or compendium name, then the common name for the drug or ingredient is the established name.

3. If a drug contains 2 or more ingredients, the established name must be given for each ingredient.

4. Utility of Established Names. The established name facilitates communication by providing a common designation for identical drugs, or combinations of drugs, available from several sources. It may be used without restrictions imposed by a proprietary trademark.

5. Official Names.

a. The FDA has the final authority to accept or reject any name proposed as an established name, including a USAN.

b. In the official name, the word salt, ester, or other chemical combination in which the drug may exist is generally omitted and only the parent or stem name is given. However, the full name of the drug must be shown in the drug labeling.

c. The official name is the only name of the drug to be used in an official compendium published after such a name has been designated as official.

CDID Format Standards.

The following format standards were established for the CDID above and beyond those dictated by the agency. These were established by the ingredient dictionary subcommittee to have 1) standards that were in compliance with Agency policy, and 2) standards for ingredient nomenclature that were not covered by the agency or USAN.

1. Guidelines for making entries.

a. The preferred order for the name of an inorganic salt and well known salts of simple organic acids is cation-anion.

b. The preferred order for the name of an organic compound is the pharmacologically active portion first, and the salt second.

c. The name of a substance should not indicate the state of hydration, the morphology, the mode of preparation, or the dosage form. These terms are only used when required to prevent ambiguity.

d. Federal law requires that the established name(s) of the active ingredient(s) of the drug appear on the approved product label/labeling and this should conform to USAN standards. When this nomenclature differs, USAN standards should be entered into the Dictionary as the preferred term with the term on the label as the synonym.

2. Name Selection Schema.

a. When possible, selected names will follow USAN convention. The USAN Council chooses each U.S. Adopted Name with the expectation that it will be suitable for subsequent designation as the title of the monograph, should the article be recognized in the Official United States Pharmacopeia or National Formulary, and designation by the FDA as the established name for the article concerned.

b. The following priority selection is followed when choosing a preferred name or a drug or ingredient:

a) Official Name (FDA)
b) Official Compendia Name
c) USAN Name for articles not currently designated "official" or currently recognized in Official Compendia.
d) Common or Usual Name

3. Name Selection Format and Considerations.

a. Elements such as dosage form and route of administration will not be included unless it reflects a standardized formulation that is used as an ingredient in a drug product and is recognized in a USP monograph

as such (ex. Aluminum Hydroxide Gel).

b. To facilitate data retrieval, a minimum of punctuation is utilized.

CDID Rules for Non-USAN Names.

The following rules and standards are utilized if USAN does not have an established name, it is inadequate in its specificity, or is inconsistent in its convention.

1. All established generic ingredient will have a chemical name entered as a synonym. However, if a generic name has numerous salt derivatives, then the chemical name for only one of these salt derivatives will be entered.

2. Chemical names for investigational drugs are entered as a preferred term only when there is no USAN adopted names available.

3. Proprietary names.

   a. Active Ingredients: Proprietary names are generally not entered as preferred terms for active ingredients except as a synonym to serve as a cross reference.

   b. Inactive Ingredients (excipients): Proprietary names are entered as preferred terms for excipients that represent formulations for flavors, colors, etc.

4. Company Drug Code Names for investigational substances are entered as a preferred term only when there is no other reference available (e.g. chemical name).

CDER DATA STANDARDS MANUAL

FDA Data Element Number.

CDER Data Element Number. C-DRG-00803

Data Element Name. Patent Number

Description. Patent Number is the number used by the U.S. Patent Office to specify index a patent on a product, process, use, indication, etc.

Source. U.S. Patent Office and Approved Drug Products with Therapeutic Equivalence Evaluations.

Relationship. See Exclusivity Code and Patent Use.

FDA Specifications. None.

CDER Specifications. Patent Number is represented by alphunumeric text of seven characters in length, with no punctuation.

FDA Approved Date.

CDER Approved Date.

FDA Revised Date.

CDER Revised Date.

Data Values. Literal.

CDER DATA STANDARDS MANUAL

FDA Data Element Number.

CDER Data Element Number. C-DRG-00802

Data Element Name. Patent Use Code

Description. Patent Use Code is the code used by the Food and Drug Administration to specify the "use claims" that protect the approved use of a drug product.

Source. Approved Drug Products with Therapeutic Equivalence Evaluations.

Relationship. See Exclusivity Code and Patent Number.

FDA Specifications. None.

CDER Specifications. Patent Use Code is represented by alphunumeric text of five characters in length, with hyphens as the only punctuation.

FDA Approved Date.

CDER Approved Date.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
A METHOD FOR TREATING ANXIETY IN A HUMAN SUBJECT IN NEED OF SUCH TREATMENT		U-13
A METHOD OF BLOCKING THE UPTAKE OF MONOAMINES BY BRAIN NEURONS IN ANIMALS		U-84
A METHOD OF INDUCING REGRESSION OF LEUKEMIA CELL GROWTH IN A MAMMAL		U-98
A METHOD OF TREATING A PATIENT IN NEED OF MEMORY ENHANCEMENT		U-97
A PROCESS FOR TREATING A PATIENT SUFFERING FROM PARKINSON'S SYNDROME AND IN NEED OF TREATMENT		U-20
ACUTE MYOCARDIAL INFARCTION		U-8

CDER DATA STANDARDS MANUAL

FDA Data Element Number. None.

CDER Data Element Number. C-DRG-00901

Data Element Name. Phase 4 Commitment Category

Description. This standard provides for all Phase 4 study commitment categories. Phase 4 studies are post-marketing studies that are imposed upon a pharmaceutical firm as a condition for drug approval. Defining the various commitment categories of these studies will permit CDER management to determine trend analysis.

Source. CDER Supervisory Project Managers.

Relationship. Phase 4 Fullfilment Category.

FDA Specifications. None.

CDER Specifications. Phase 4 Commitment Category shall consist of an alphabetic term which has a maximum length restricted to 60 characters, with the comma and hyphen being the only punctuation permissible. Codes representing these Phase 4 Commitment Categories shall consist of three digits.

FDA Approved Date. None.

CDER Approved Date. September 12, 1995.

FDA Revised Date.

CDER Revised Date. December 12, 1995; February 13, 1996

Data Values.

Name	Definition	Code
ADE/Toxicity, Specified	A study that focuses upon a specific adverse drug experience or a specific drug toxicity in a defined patient population..	001
ADE/Toxicity, Surveillance	A study where no specific adverse drug experience or specific drug toxicity is being investigated in a defined patient population.	002
Animal Study, Other	Any study where animals instead of humans are used.	003

Bioavailability	A study to determine the extent to which an active ingredient of a drug dosage form become available at the site of drug action or in a biological medium believed to reflect accessibility to a site of action.	004
Bioequivalence	A study to determine whether the pharmacokinetics of a drug product is statistically indistinguishable from that of another drug.product with the same active ingredients.	005
Carcinogencity	A study to determine the propensity of a drug to produce or exacerbate tumors or cancer cells.	006
CMC Method Development or Improvement	A study to determine whether a drug or drug product's chemisty, manufacturing, or controls can be alternatively developed or improved upon.	007
Dissolution	A study to determine the characteristics of how a drug product dissolves.	008
Dose-Proportionality	A study designed to establish whether or not proportionate increases in the dose of a drug product are reflected in proportionate increases in pharmacokinetic parameters (i.e., AUC and C_{MAX}).	009
Drug-Drug Comparison	A study to determine the differences and similarities between drugs.	010
Drug-Drug Interaction	A study to determine how a combination of drugs manifests itself over and above that of any particular drug's known effects, including their pharmacokinetics and pharmacodynamics.	011
Drug-Food Interaction	A study to determine how a combination of drug(s) and food manifests itself over and above that of any particular drug's or food's known effects	012
Efficacy	A study to determine a drug's efficacy.	013
Efficacy, Long-Term	A study to determine a drug's efficacy over a long period of time (generally greater than two years).	014
Efficacy, New Indication	A study to determine a drug's efficacy for an indication other than that for which it was originally or supplementally approved.	015
Impurity Identification	A study to identify impurities in the drug product.	016
Literature Search	A computerized survey of the literature using keywords, hypertext, and fuzzy logic to identify applicable books and journal articles.	017

Mutagenicity	A study to determine whether a drug has the potential or ability to cause a mutation in a gene, tissue, organ, or appendage, usually by conducting microbial, insect, mammalian cell, and whole animal tests..	018
Other	Any study that is not already defined by a phase 4 commitment category.	019
Pharmacokinetics	A study to determine the kinetic mechanisms of exogenous drug absorption, distribution, biotransformation, release, transport, uptake, and elimination as a function of dosage, and extent and rate of metabolic processes. The study may also include measurement of the drug's effect upon the body in relation to the concentration time curve.	020
Reproductive Effects	A study to determine the effect of a drug on reproduction (including, but not necessarily limited to, libido, copulation, ovulation, ovogenesis, and spermatogenesis).	021
Special Population, Ages > 60 years	A study to determine a drug's effect in humans 60 years of age or older.	022
Special Population, Ages < 2 Years	A study to determine a drug's effect in humans less than 2 years of age.	024
Special Population, Ages 2 to 6 Years	A study to determine a drug's effect in humans equal to or between the ages of 2 and 6 years.	027
Special Population, Ages 6 to 12 Years	A study to determine a drug's effect in humans equal to or between the ages of 6 and 12 years	028
Special Population, Female	A study to determine a drug's effect in humans of the female gender.	029
Special Population, Other	A study to determine a drug's effect in humans having a particular characteristic (e.g., G6PD deficiency, AIDS, renal failure).	023
Stability	A study over time to determine the propensity of a drug to undergo a chemical or physical change.	025
Teratogenicity	A study to determine whether a drug can cause physcial defects in a developing embryo.	026

CDER DATA STANDARDS MANUAL

FDA Data Element Number. None.

CDER Data Element Number. C-DRG-00902

Data Element Name. Phase 4 Fulfillment Category

Description. This standard provides for all Phase 4 study fulfillment categories. Phase 4 studies are post-marketing studies that are imposed upon a pharmaceutical firm as a condition for drug approval. Defining the various fulfillment categories for each study will permit CDER management to determine trend analysis.

Source. DHHS Office of Inspector General, "Postmarketing Studies of Prescription Drugs" dated November 1995..

Relationship. Phase 4 Commitment Category

FDA Specifications. None.

CDER Specifications. Phase 4 Category shall consist of an alphabetic term which has a maximum length restricted to 100 characters, with the comma and hyphen being the only punctuation permissible. Codes representing these Phase 4 Fulfillment Categories shall consist of two digits separated by a decimal.

FDA Approved Date. None.

CDER Approved Date. February 13, 1996.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
Study Not Begun, Will Begin in Future	Literal	1.1
Study Not Begun, Company Did Not Agree to Conduct Study	Literal	1.2
Study Not Begun, Company Awaiting Approval of Supplement	Literal	1.3
Study in Progress, Underway	Literal	2.1
Study in Progress, Completed but not Yet Submitted to FDA	Literal	2.2
Study in Progress, Halted	Literal	2.3
Study in Progress, Perpetual	Literal	2.4

Study Submmitted, Accepted by FDA	Literal	3.1
Study Submitted, Not Accepted by FDA	Literal	3.2
Study Submitted, No Determination by FDA	Literal	3.3
Company Released fro Commitment, Drug Not Marketed	Literal	4.1
Company Released from Commitment, Question Answered by Other Studies	Literal	4.2
Company Released from Commitment, reason Unclear	Literal	4.3
Company Released from Commitment, Study Not Feasible	Literal	4.4
Company Released from Commitment, Study Fulfilled	Literal	4.5
Status Unknown, No Information	Literal	5.1

CDER DATA STANDARDS MANUAL

FDA Data Element Number: None.

CDER Data Element Number: C-DRG-00402

Data Element Name: Proprietary Name.

Description. This standard provides for all Proprietary Names.

Source.

Relationship. Related terms include the Center for Drug Evaluation and Research Ingredient Dictionary (CDID) ingredient name.

FDA Specifications. None.

CDER Specifications. Proprietary name shall consist of an alphanumeric term which has a maximum length restricted to 240 characters. Proprietary names are usually approved by a CDER Labeling and Nomenclature Committee, after discussing their acceptability based upon "look alike" and "sound alike" names, and ease of association with the generic name and/or active ingredient name. Occasionally, the CDER Ingredient Dictionary may have a Proprietary name entry and associated CD number for a proprietary mixture of inactive ingredients, but generally speaking, there are no codes necessary for Proprietary names.

FDA Approved Date: None.

CDER Approved Date: November 8, 1996

FDA Revised Date.

CDER Revised Date.

Data Values. Literal.

CDER DATA STANDARDS MANUAL

FDA Data Element Number. None.

CDER Data Element Number. C-DRG-00501

Data Element Name. Potency.

Description. This standard provides for all drug potencies.

Only uppercase Aramaic letters are to be used (i.e., no actual Greek letters, no lowercase Aramaic letters substituted as Greek letters, and no avoirdupois symbols). The following uppercase Aramaic letters may be substituted for actual Greek letters: U for the Greek letter mu, which stands for MICRO.

Oftentimes, a dosage form may coexist with the actual potency term to provide clarification; when this is done, those and only those dosage form abbreviations which are presented in the table below shall be used. Generally, an abbreviation is only made for words of greater than five characters, unless the abbreviation is a widely recognized standard (e.g., GM for GRAM).

Whenever possible, CDER should use the metric system to express potency. Potencies of 10^{-2} or less should be expressed as the next lowest value (e.g., 0.01 GM would become 10 MG), and potencies of 10^{3} or greater should be expressed as the next highest value (e.g., 1000 MG would become 1 GM).

Source. COMIS Reference table (which is used by the Drug Product Reference File to generate Approved Drug Products with Therapeutic Equivalence Evaluations (aka "The Orange Book") and by the Drug Registration and Listing System).

Relationship.

FDA Specifications. None.

CDER Specifications. Standard potency abbreviations shall consist of a maximum length restricted to 240 characters, with the virgule being only punctuation permissible in the abbreviated term itself. Potency abbreviations shall consist of a maximum length of 6 characters with no punctuation.

FDA Approved Data. None.

CDER Approved Data. June 14, 1994

FDA Revised Data.

CDER Revised Data.

Data Values.

Name	Definition	Code
ADJUST PH		ADJ PH
AMPULE		AMPULE
BAG		BAG
BAR		BAR
BOLUS		BOL
BOTTLE		BOT
BOX		BOX
CAN		CAN
CAPSULE		CAP
CAROTID SINUS RYTHYM UNITS		CSRU
CARTRIDGE		CTG
CLINICAL UNITS		CU
COAT		COAT
COUNT		CNT
CONTAINER		CTR
CUBIC CENTIMETER		CU CM
CUBIC INCH		CU IN
CUBIC MILLIMETER		CU MM
CURIE		CI
CYLINDER		CYL
DISK		DISK
DROPS		DROPS
DRUM		DRUM
FEET, CUBIC		CU FT
FEET, SQUARE		SQ FT
FLUID DRAM		FL DR
FLUID OUNCE		FL OZ
GALLON		GAL
GENERATOR		GEN
GRAM		GM
GRAIN		GR
HOMEOPATHIC DILUTION		X
HOUR		HOUR
IMPLANT		IMP
INCH		IN
INHALATION		INH
INTERNATIONAL UNITS		IU
JAR		JAR
KALLIKRIEN INHIBITOR UNIT		KIU
KILOGRAM		KG
KIT		KIT
LITER		L
LOZENGE		LOZ
MICROCURIE		UCI
MICROGRAM		UGM
MICROLITER		UL
MICROMOLE		UMOLE
MICROMOLAR		UMOLAR
MICRON		MCN
MILLICURIE		MCI
MILLIEQUIVALENT		MEQ
MILLIGRAM		MG
MILLILITER		ML
MILLIMETER		MM
MILLIMOLE		MMOLE
MINIM		MINIM
MISCELLANEOUS		MISC
MOLAR		MOLAR
MOLE		MOLE
NANOGRAM		NGM
NANOMOLE		NMOLE
NORMAL		N
NOT APPLICABLE		N/A
OUNCE		OZ
PACKAGE		PKG
PACKET		PKT
PART PER MILLION		PPM
PARTS		PARTS
PATCH		PATCH
PELLET		PEL

PERCENT	%
PERCENT VOLUME/VOLUME	%V/V
PERCENT WEIGHT/VOLUME	%W/V
PERCENT WEIGHT/WEIGHT	%W/W
PINT	PT
POTENCY NOT GIVEN	PNG
POUCH	POUCH
POUND	LB
PRESSOR UNITS	PRU
PROTEIN UNIT	PNU
QUANTITY SUFFICIENT	QS
QUART	QT
SATURATED	SAT
SCOOPFUL	SCP
SPRAY	SPRAY
SQUARE CENTIMETER	SQ CM
SQUARE YARD	SQ YD
STRIP	STRIP
SUPPOSITORY	SUPP
SYRINGE	SYR
TABLET	TAB
TABLESPOON	TBSP
TAMPON	TAMP
TEASPOON	TSP
TEST	TEST
TON	TON
TRACE	TRACE
TROCHE	TRO
TUBE	TUBE
UNASSIGNED	U/A
UNITED STATES PHARMACOPEIA	USP
UNITS	UNITS
VIAL	VIAL
WAFER	WAFER
YARD	YD

CDER DATA STANDARDS MANUAL

FDA Data Element Number. None.

CDER Data Element Number. C-DRG-00301

Data Element Name. Route of Administration.

Description. This standard provides for all routes of administration for drugs.

Source. COMIS Reference table (which is used by the Drug Product Reference File to generate Approved Drug Products with Therapeutic Equivalence Evaluations (aka "The Orange Book")), and the Drug Registration and Listing Database.

Relationship.

FDA Specifications. None.

CDER Specifications. Route of Administration shall consist of an alphabetic term which has a maximum length shall be restricted to 60 characters, with the hyphen and virgule being only punctuation permissible. Codes representing these Routes of Administration shall consist of three digits.

FDA Approved Date. None.

CDER Approved Date. April 14, 1992

FDA Revised Date:

CDER Revised Dates. November 10, 1992; October 11, 1994; November 8, 1996

Data Values.

Name	Definition	Numeric Code
BUCCAL	Pertaining to or directed toward the cheek.	030
CAUDAL BLOCK	An obstruction of a passage or opening directed toward a tail.	029
CONJUNCTIVAL	Pertaining to the conjunctiva, the delicate membrane that lines the eyelids and covers the exposed surface of the eyeball.	068
DENTAL	Pertaining to a tooth or teeth.	038
ELECTRO-OSMOSIS	The diffusion of substance through a membrane in an electric field.	357
ENTERAL	Intestinal.	313
EPIDURAL	Situated upon or over the dura mater.	009
EXTRACORPOREAL	Outside the body.	057
INFILTRATION	A process by which substances pass into tissue spaces or into cells.	361

INHALATION	Drug or solution or suspension of one or more drug substances administered by the nasal or oral respiratory route for local or systemic effect.	018
INHALATION/NASAL	Drug or solution or suspension of one or more drug substances administered by the nasal route for local or systemic effect.	115
INTERSTITIAL	Pertaining to or situated in the interstices of a tissue.	088
INTRA-ABDOMINAL	Within the abdomen.	056
INTRA-AMNIOTIC	Within the amnion.	060
INTRA-ARTERIAL	Within an artery or arteries.	037
INTRA-ARTICULAR	Within a joint.	007
INTRABILIARY	Within the bile, bile ducts or gallbladder.	362
INTRABRONCHIAL	Situated or occurring within a bronchus.	067
INTRABURSAL	Within a bursa.	025
INTRACARDIAC	With the heart.	027
INTRACARTILAGINOUS	Within a cartilage; endochondral.	363
INTRACAVITARY	Within a cavity.	023
INTRACERVICAL	Situated within the canal of the cervix uteri.	051
INTRACORONAL, DENTAL	Administration of a drug within a portion of a tooth which is covered by enamel and which is separated fromthe roots by a slightly constricted region known as the neck.	117
INTRACORONARY	Within the coronary arteries.	119
INTRADERMAL	Within the dermis.	008
INTRADISCAL	Within a disc.	121
INTRADUCTAL	Situated or occurring within the duct of a gland.	123
INTRADUODENAL	Within the duodenum.	047
INTRADURAL	Within or beneath the dura.	052
INTRAEPIDERMAL	Within the epidermis.	127
INTRAESOPHAGEAL	Within the esophagus.	072
INTRAGASTRIC	Situated or occurring within the stomach.	046
INTRAGINGIVAL	Within the gingivae.	307
INTRAILEAL	Within the distal portion of the small intestine, from the jejunum to the cecum.	365
INTRALESIONAL	Occurring within or introduced directly into a localized lesion.	042
INTRALUMINAL	Within the lumen of a tube.	310
INTRALYMPHATIC	Within the lymph.	352
INTRAMUSCULAR	Within the substance of a muscle.	005
INTRAOCULAR	Within the eye.	036
INTRAOVARIAN	Within the ovary.	354
INTRAPERICARDIAL	Within the pericardium.	314
INTRAPERITONEAL	Within the peritoneal cavity.	004
INTRAPLEURAL	Within the pleura.	043
INTRAPROSTATIC	Within the prostate gland.	061
INTRASINAL	Within a sinus.	010
INTRASPINAL	Situated or occurring within the vertebral column.	022
INTRASYNOVIAL	Within the synovial cavity of a joint.	019
INTRATENDINOUS	Within a tendon.	049
INTRATESTICULAR	Within the testicle.	110
INTRATHECAL	Administration into the cerebrospinal fluid at any level of the cerebrospinal axis, including injection into the cerebral ventricles.	103
INTRATHORACIC	Endothoracic.	006
INTRATRACHEAL	Endotracheal.	035
INTRATUBULAR	Within the tubules of an organ.	353
INTRATUMOR	Within a tumor.	030
INTRATYMPANIC	Within the aurus media	366
INTRAUTERINE	Within the uterus.	028
INTRAVASCULAR	Within a vessel or vessels.	021
INTRAVENOUS	Within or into a vein or veins.	002
INTRAVENTRICULAR	Within a ventricle.	048
INTRAVESICAL	Situated within the bladder.	128
INTRAVITREAL	Within the vitreous body of the eye.	311
IONTOPHORESIS	The introduction, by means of the electric current, of ions of soluble salts into the tissues of the body for therapeutic purposes.	055
IRRIGATION	The introduction of a sterile solution intended to bathe or flush open wounds or body cavities.	032

LARYNGEAL	Administered directly upon the larynx.	364
MISCELLANEOUS	Various routes of administration different from those mentioned.	099
NASAL	Pertaining to the nose; administered by way of the nose.	014
NASOGASTRIC	Pertaining to the nose and the stomach; used to describe tubes inserted through the nose to end in the stomach.	071
NERVE BLOCK	The interruption of the passage of impulses through a nerve, as by chemical, mechanical, or electric means.	059
NOT APPLICABLE	Routes of administration are not applicable.	312
OPHTHALMIC	Pertaining to the eye; administered by way of the eye.	012
ORAL	Pertaining to the mouth; administered by way of the mouth.	001
OTIC	Pertaining to the ear; administered by way of the ear.	013
PERCUTANEOUS	Performed through the skin.	113
PERIARTICULAR	About a joint.	045
PERIDURAL	Epidural; especially outside the dura mater of the spinal cord.	050
PERIODONTAL	Situated or occurring around a tooth; pertaining to the periodontium.	040
RECTAL	Pertaining to the rectum.	016
RETROBULBAR	Behind the eyes or behind the eyeball.	034
SOFT TISSUE		109
SUBARACHNOID	Beneath the arachnoid.	066
SUBCONJUNCTIVAL	Situated beneath the conjunctiva.	096
SUBCUTANEOUS	Beneath the skin; hypodermic.	003
SUBLINGUAL	Beneath the tongue.	024
SUBMUCOSAL	Situated beneath the mucous membrane.	053
TOPICAL	Pertaining to a particular spot; local.	011
TRANSDERMAL	Delivery of the drug through the skin to the systemic circulation by diffusion.	358
TRANSMUCOSAL	Passage across the mucosa.	122
TRANSTRACHEAL	Performed by passage through the wall of the trachea.	355
TRANSTYMPANIC	Going across or through the tympanic cavity.	124
UNASSIGNED	Route of administration has not yet been assigned.	400
URETERAL	Used upon the ureter.	112
URETHRAL	Pertaining to the urethra.	017
VAGINAL	Pertaining to the vagina.	015

LARYNGEAL	Administered directly upon the larynx.	364
MISCELLANEOUS	Various routes of administration different from those mentioned.	099
NASAL	Pertaining to the nose; administered by way of the nose.	014
NASOGASTRIC	Pertaining to the nose and the stomach; used to describe tubes inserted through the nose to end in the stomach.	071
NERVE BLOCK	The interruption of the passage of impulses through a nerve, as by chemical, mechanical, or electric means.	059
NOT APPLICABLE	Routes of administration are not applicable.	312
OPHTHALMIC	Pertaining to the eye; administered by way of the eye.	012
ORAL	Pertaining to the mouth; administered by way of the mouth.	001
OTIC	Pertaining to the ear; administered by way of the ear.	013
PERCUTANEOUS	Performed through the skin.	113
PERIARTICULAR	About a joint.	045
PERIDURAL	Epidural; especially outside the dura mater of the spinal cord.	050
PERIODONTAL	Situated or occurring around a tooth; pertaining to the periodontium.	040
RECTAL	Pertaining to the rectum.	016
RETROBULBAR	Behind the pons or behind the eyeball.	034
SOFT TISSUE		109
SUBARACHNOID	Beneath the arachnoid.	066
SUBCONJUNCTIVAL	Situated beneath the conjunctiva.	096
SUBCUTANEOUS	Beneath the skin; hypodermic.	003
SUBLINGUAL	Beneath the tongue.	024
SUBMUCOSAL	Situated beneath the mucous membrane.	053
TOPICAL	Pertaining to a particular spot; local.	011
TRANSDERMAL	Delivery of the drug through the skin to the systemic circulation by diffusion.	358
TRANSMUCOSAL	Passage across the mucosa.	122
TRANSTRACHEAL	Performed by passage through the wall of the trachea.	355
TRANSTYMPANIC	Going across or through the tympanic cavity.	124
UNASSIGNED	Route of administration has not yet been assigned.	400
URETERAL	Used upon the ureter.	112
URETHRAL	Pertaining to the urethra.	017
VAGINAL	Pertaining to the vagina.	015

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CDER DATA STANDARDS MANUAL

FDA Data Element Number. None.

CDER Data Element Number. C-DRG-00701

Data Element Name. Therapeutic Equivalence Code.

Description. This standard provides format specifications for representing the therapeutic equivalence code (TE Code). The TE Code is used in CDER's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, to allow comparisons between different brands of the same drug.

Source. Approved Drug Products with Therapeutic Equivalence Evaluations (aka The Orange Book).

Relationship.

FDA Specifications. None.

CDER Specifications. Therapeutic Equivalence Code is represented by alphabetic text of two characters, without punctuation.

FDA Approved Date.

CDER Approved Date. January 10, 1995.

FDA Revised Date.

CDER Revised Date.

Data Values.

Name	Definition	Code
Products in conventional dosage forms not presenting bioequivalence problems.	Products coded as **AA** contain active ingredients and dosage forms that are not regarded as presenting either actual or potential bioequivalence problems or drug quality or standards issues. However, all oral dosage forms must, nonetheless, meet an appropriate *in vitro* test(s) for approval.	AA

Products meeting necessary bioequivalence requirements.	Products generally will be coded **AB** if a study is submitted demonstrating bioequivalence. Even though drug products of distributors and/or repackagers are not included in the List, they are considered therapeutically equivalent to the application holder's drug product if the application holder's drug product is rated **AB** or is single source in the List. The only instance in which a multisource product will be rated **AB** on the basis of bioavailability rather than bioequivalence is where the innovator product is the only one listed under that drug ingredient heading and has completed an acceptable bioavailability study. However, it does not signify that this product is therapeutically equivalent to the other drugs under the same heading. Drugs coded **AB** under an ingredient heading are considered therapeutically equivalent only to other drugs coded **AB** under that heading.	AB
Solutions and powders for aerosolization	Uncertainty regarding the therapeutic equivalence of aerosolized products arises primarily because of differences in the drug delivery system. Solutions and powders intended for aerosolization that are marketed for use in any of several delivery systems are considered to be pharmaceutically and therapeutically equivalent and are coded **AN**. Those products that are compatible only with a specific delivery system or those products that are packaged in and with a specific delivery system are coded **BN**, unless they have met an appropriate bioequivalence standard because drug products in their respective delivery systems are not necessarily pharmaceutically equivalent to each other and, therefore, are not therapeutically equivalent.	AN
Injectable oil solutions	The absorption of drugs in injectable (parenteral) oil solutions may vary substantially with the type of oil employed as a vehicle and the concentration of the active ingredient. Injectable oil solutions are therefore considered to be pharmaceutically and therapeutically equivalent only when the active ingredient, its concentration, and the type of oil used as a vehicle are all identical.	AO

Injectable aqueous solutions

AP

It should be noted that even though injectable (parenteral) products under a specific listing may be evaluated as therapeutically equivalent, there may be important differences among the products in the general category, *Injectable; Injection*. For example, some injectable products that are rated therapeutically equivalent are labeled for different routes of administration. In addition, some products evaluated as therapeutically equivalent may have different preservatives or no preservatives at all. Injectable products available as dry powders for reconstitution, concentrated sterile solutions for dilution, or sterile solutions ready for injection are all considered to be pharmaceutically and therapeutically equivalent provided they are designed to produce the same concentration prior to injection and are similarly labeled. Consistent with accepted professional practice, it is the responsibility of the prescriber, dispenser, or individual administering the product to be familiar with a product's labeling to assure that it is given only by the route(s) of administration stated in the labeling.

Certain commonly used large volume intravenous products in glass containers are not included on the List (e.g., dextrose injection 5%, dextrose injection 10%, sodium chloride injection 0.9%) since these products are on the market without FDA approval and the FDA has not published conditions for marketing such parenteral products under approved NDAs. When packaged in plastic containers, however, FDA regulations require approved applications prior to marketing. Approval then depends on, among other things, the extent of the available safety data involving the specific plastic component of the product. All large volume parenteral products are manufactured under similar standards, regardless of wether they are packaged in glass or plastic. Thus, FDA has no reason to believe that the packaging container of large volume parenteral drug products that are pharmaceutically equivalent would have any effect on their therapeutic equivalence.