5-12 SUMMARY OF REGISTRATION AND LISTING HUMAN PHARMACEUTICALS

SUMMARY OF REGISTRATION AND LISTING REQUIREMENTS FOR THE MANUFACTURE OR DISTRIBUTION OF HUMAN PHARMACEUTICALS			
TYPE OF FIRM	**REGISTRATION STATUS**	**LISTING STATUS**	**FACTS CODE**
Manufacturer [including homeopathic & controlled drugs]	yes	yes	M
Contract Manufacturer	yes	yes	M
Own Label Distributor	no	yes	L
Wholesale Distributor (no manufacturing or distribution under own name and label)	no	no	W-*
Own Label Repacker	yes	yes	R
Own Label Relabeler [including recirculizer]	yes	yes	Y
Contract Relabeler	yes	yes	Y
Contract Testing Laboratory [dosage forms & active ingredient release]	yes	no	C
Contract Testing Lab [doing non-release tests]	no	no	C
Contract Sub-Manufacturer	yes	yes	M
IND Manufacturer [Clinical Drugs]	no	no	M
NDA and ANDA Manufacturer	yes	yes	M
Sponsor/Monitors/Clinical Investigator	no	no	4, 5, 6, 7
Contract Sterilizer	yes	yes	0
Fulfillment Packager [adding substantive labeling]	yes	yes	Y
Mail Order House [adding insubstantial labeling]	no	no	D
Printing House	no	no	None
Medical Gas Transfiller	yes	yes	MG
First Aid/Rescue Squad [transfilling for own use]	no	no	MG
Medical Gas Transfiller [operating out of a van]	yes	yes	MG
Contract Assembler	yes	no	M
Active Drug Substance Manufacturer	yes	yes	M
Excipient Drug Manufacturer	no	no	M
Manufacturer of Research Drugs	no	no	M
Drug Importer	no	no	A
Foreign Drug Manufacturer	yes	yes	M
Methadone Clinic	no	no	T
Retail Pharmacy	no	no	D
Salvage Operation	yes	no	X
Biopharmaceutical Clinical Facility	no	no	2
Outsourcing Facility	yes	no	OF

*Includes W, WA, WF, WR, and/or WZ

5-13 SUBSTANTIALLY EQUIVALENT MEDICAL DEVICES

	Operation	Submit 510(k)	Register	List	COMPLY W/GMP
1.	Manufacture and distribute device	YES: 807.81(a)	YES 807.20(a)	YES 807.20(a)	YES
2.	Contract manufacturer who commercially distributes device for specifications developer	NO: 807.81(a)	YES if domestic: 807.20(a)(2), YES if foreign 807.40(a)	YES if domestic 807.20(a)(2), YES if foreign 807.40(a)	YES
3a.	Contract manufacturer who meets the definition of finished device manufacturer per 21 CFR 820.3(l).	NO	YES 807.20(a)(2)	YES 807.20(a)(2)	YES
3b.	Contract manufacturer who does not meet the definition of finished device manufacturer per 21 CFR 820.3(l) (e.g., component manufacturer, subassembler)	NO	NO	NO	NO
4.	Manufacturer modifies device or new intended use and distribute	NO: preamble no. 17 & 18 FR 8/23/77 YES: 807.81(a)(3) with signif. change in device or use	YES 807.20(a)	YES 807.20(a)	YES
5.	Located in US and distribute US made device. No specification initiation (domestic distributor)	NO: 807:85(b)	NO: 510(g)(4) of act, 807.20(c)	NO 807.20(c)	NO
6.	Specification initiator and distribute only	YES: 807.81(a)	YES: 807.20(a)(1)	YES: 807.20(a)(1)	YES: 820.181, etc.
7.	Specification consultant only; no distribution	NO	NO:	NO	NO
8	Relabeler or repacker: change labeling or packaging in manner other than adding own name	YES	YES: 807.20 (a)(3)	YES. 807.20(a)(3)	YES 820.3(w), 820.3(o) and Preamble Comment 28, FR 52610
9.	Relabeler or repacker: distribute under own name	NO: 807.85(b): no change to device or existing labeling and another person has a cleared premarket notification application	NO	NO	NO
10.	Kit assembler using prelabeled & prepackaged devices only	NO: no change in device or existing labeling other than adding dist. name & address 807.81(a)(3)	YES: 807.20(a)	YES: 807.20(a)	YES
11.	Kit assembler changes intended use (801.4) of prepackaged/prelabeled devices	YES: 807.81(a)	YES: 807.20(a)(3)	YES: 807.20(a)(3)	YES: 820.120, 820.130, etc.
12.	Kit assembler changes prepackaged/prelabeled devices	NO: if no significant change to labeling or device: otherwise YES: 807.81(a)(3)(i)	YES: 807.20(a)(3)	YES: 807.20(a)(3)	YES
13.	Manuf. Accessory, component and package & label for health purpose to end user.	YES: 807.81(a)	YES: 807.20(a)(6)	YES: 807.20(a)(6)	YES
14.	Manuf. Components & dist. Only to finished device mfr.	NO: 807.81(a)	NO: 807.65(a)	NO	Use as guide: 820.1
15.	Contract mfr. Of subassembly or component (see no. 13, accessory)	NO	NO	NO	Primary mfr. must see that GMP is met 21 CFR 820.50
16.	Contract packager or labeler	NO	YES	YES	Yes 820.2(a)(1) 820.3(o)
17.	Contract Sterilizer	NO	YES if domestic 807.20(a)(2), YES if foreign 807.40(a)	YES if domestic 807.20(a)(2), YES if foreign 807.40(a)	YES
18.	Manufacture custom device (domestic or foreign)	NO: 807.85(a)(1)&(2)	YES 807.20(a)	YES 807.20(a)	YES: also see 520(b); 520(f)
19.	U.S. Establishment who manufactures for export only	NO	YES 807.20(a) and 807.25(g)(5)	YES 807.20(a) and 807.25(g)(5)	YES
20.	Foreign manufacturers and all foreign establishments	YES: 807.81	YES, 807.40(a)	YES 807.40(a)	YES
21.	Initial distributor/importer of device	YES: 807.81(a) or 807.85(b) unless 510(k) has been filed by foreign manufacturer or another init. Dist	YES: 807.20(a)(5)	NO:Must identify foreign manufacturer(s) or device(s) imported)	YES: 807.3(d), 820.198, 820.100, 820.200, etc.
22.	Installer-mfr.'s agent	NO	NO	NO	YES: 820.170
23.	Installer-user	NO	NO	NO	NO: for x-ray see 1020.30(d) report
24.	Device being investigated under ide	Exempt: 812.1(a)	NO	NO: 807.40(c)	Exempt per 812.1(a), except for Design Control per 820.30
25.	Mfr. Buys manufacturing rights for device (see no. 4)	NO: preamble 18 FR 8-23-77 only if same type of manuf. equip. is used and no signif. change to device	YES: 807.20(a)	YES 807.40(a)	YES
26.	Reprocessor of single use device	YES	YES: 807.20(a)(4)	YES: 807.20(a)(4)	YES
27.	Foreign exporter of device (device manufactured in foreign country)	YES: (original manufacturer's 510(k) maybe used)	YES: 807.40 (a)	YES: 807.40 (a)	YES 820.1(a)(2) YES