A

ATTACHMENT A

EVIDENTIARY TABLE: "LIST OF MISBRANDED DENTAL DEVICES"

Attachment A

List of Misbranded Dental Devices

	Source (Device Distributer)	Invoice Date	Type of Device	Device Lot Number	Device Manufacturing Location	Device Package Insert Removed	Device Removed from Original Package	Device Package Opened and Resealed	Removed Language Indicating the Device was not Packaged or Intended for Sale in the US or Canada from Device Outer Package	Removed "Not For Sale in the US or Canada" from Device Label	Device Lot # Removed	Bates Number of Photographs
1	Chicago Dental Supply	2/23/06	Herculite XRV Unidose Enamel A1	5-1109	Scafati* (unregistered)				X			000005 - 000007
2	Chicago Dental Supply	2/23/06	Herculite XRV Syringe Enamel A3	Unknown	DMC (registered)	X	X			X	X	000008 - 000012
3	Chicago Dental Supply	2/23/06	Temp Bond Regular	5-1312	Scafati* (unregistered)				X			000013 - 000015
4	Chicago Dental Supply	12/8/05	Herculite XRV Syringe Enamel A3	408141	DMC (registered)		X					000016A - 000017
5	Chicago Dental Supply	11/3/05	Herculite XRV Syringe Enamel A3	305853	DMC (registered)		X			X		000018 - 000021
6	Chicago Dental Supply	12/8/05	Temp Bond Regular	4-1313	Scafati* (unregistered)				X			000022 - 000024
7	Chicago Dental Supply	1/12/06	Temp Bond Regular	4-1313	Scafati* (unregistered)				X			000025 - 000027
8	Chicago Dental Supply	11/3/05	Herculite XRV Unidose Enamel A1	4-1314	Scafati* (unregistered)		X					000028 - 000030
9	Chicago Dental Supply	1/12/06	Herculite XRV Unidose Enamel A1	4-1314	Scafati* (unregistered)		X					000031 - 000033
10	Chicago Dental Supply	12/8/05	Herculite XRV Unidose Enamel A1	416350	DMC (registered)		X			X		000034 - 000036
11	Chicago Dental Supply	11/3/05	Temp Bond Regular	4-1264	Scafati* (unregistered)				X			000037 - 000039
12	Chicago Dental Supply	1/12/06	Optibond Solo Plus Bottle Refill	4-1309	Scafati* (unregistered)	X	X			X		000040 - 000043
13	Chicago Dental Supply	1/12/06	Herculite XRV Unidose Enamel A2	5-1038	Scafati* (unregistered)							000044 - 000046
14	Chicago Dental Supply	2/23/06	Herculite XRV Unidose Enamel A2	5-1038	Scafati* (unregistered)				X			000047 - 000049
15	Chicago Dental Supply	11/3/05	Optibond Solo Plus Bottle Refill	4-1265	Scafati* (unregistered)		X			X		000050 - 000053
16	Chicago Dental Supply	12/8/05	Optibond Solo Plus Bottle Refill	4-1265	Scafati* (unregistered)		X			X		000054 - 000057
17	Chicago Dental Supply	11/3/05	Herculite XRV Unidose Enamel A2	4-1261	Scafati* (unregistered)		X					000058 - 000060
18	Chicago Dental Supply	12/8/05	Herculite XRV Unidose Enamel A2	4-1261	Scafati* (unregistered)		X					000061 - 000063

* This device is also not listed with the FDA as being manufactured in this facility. Information contained in this chart accurately reflects the facts during the time period addressed in this Citizen Petition.

Attachment A

List of Misbranded Dental Devices

	Source (Device Distributer)	Invoice Date	Type of Device	Device Lot Number	Device Manufacturing Location	Device Package Insert Removed	Device Removed from Original Package	Device Package Opened and Resealed	Removed Language Indicating the Device was not Packaged or Intended for Sale in the US or Canada from Device Outer Package	Removed "Not For Sale in the US or Canada" from Device Label	Device Lot # Removed	Bates Number of Photographs
19	Chicago Dental Supply	12/8/05	Herculite XRV Syringe Enamel A2	4-1328	Scafati* (unregistered)		X			X		000064 - 000066
20	Chicago Dental Supply	1/12/06	Herculite XRV Syringe Enamel A2	4-1328	Scafati* (unregistered)		X			X		000067 - 000069
21	Chicago Dental Supply	2/23/06	Herculite XRV Syringe Enamel A2	4-1328	Scafati* (unregistered)		X			X		000070 - 000072
22	Ethical Dental Supplies	9/19/05	Herculite XRV Unidose Enamel A1	4-1275	Scafati* (unregistered)				X			000073 - 000075
23	Ethical Dental Supplies	8/15/05	Optibond Solo Plus Bottle Refill	5-1026	Scafati* (unregistered)							000076 - 000078
24	Ethical Dental Supplies	7/12/05	Herculite XRV Unidose Enamel A1	4-1261	Scafati* (unregistered)				X			000079 - 000081
25	Ethical Dental Supplies	8/15/05	Herculite XRV Unidose Enamel A1	4-1261	Scafati* (unregistered)				X			000082 - 000084
26	Ethical Dental Supplies	8/15/05	Herculite XRV Syringe Enamel A2	Unknown	DMC (registered)	X	X				X	000085 - 000087
27	Ethical Dental Supplies	7/12/05	Herculite XRV Unidose Enamel A2	4-1274	Scafati* (unregistered)				X			000088 - 000090
28	Ethical Dental Supplies	7/12/05	Optibond Solo Plus Bottle Refill	5-1024	Scafati* (unregistered)							000091 - 000093
29	Ethical Dental Supplies	7/12/05	Herculite XRV Syringe Enamel A2	Unknown	DMC (registered)	X	X				X	000094 - 000096
30	Ethical Dental Supplies	12/8/05	Optibond Solo Plus Bottle Refill	5-1136	Scafati* (unregistered)				X			000097 - 000099
31	Ethical Dental Supplies	7/12/05	Temp Bond Regular	4-1313	Scafati* (unregistered)				X			000100 - 000102
32	Ethical Dental Supplies	8/15/05	Temp Bond Regular	4-1313	Scafati* (unregistered)				X			000103 - 000105
33	International Dental Supply	12/8/05	Temp Bond Regular	4-1313	Scafati* (unregistered)				X			000106 - 000108
34	International Dental Supply	12/8/05	Optibond Solo Plus Bottle Refill	5-1136	Scafati* (unregistered)				X			000109 - 000111
35	International Dental Supply	11/3/05	Optibond Solo Plus Bottle Refill	5-1137	Scafati* (unregistered)				X			000112 - 000114
36	International Dental Supply	8/12/05	Herculite XRV Unidose Enamel A1	Unknown	DMC (registered)						X	000115 - 000117

* This device is also not listed with the FDA as being manufactured in this facility. Information contained in this chart accurately reflects the facts during the time period addressed in this Citizen Petition.

Attachment A

List of Misbranded Dental Devices

	Source (Device Distributer)	Invoice Date	Type of Device	Device Lot Number	Device Manufacturing Location	Device Package Insert Removed	Device Removed from Original Package	Device Package Opened and Resealed	Removed Language Indicating the Device was not Packaged or Intended for Sale in the US or Canada from Device Outer Package	Removed "Not For Sale in the US or Canada" from Device Label	Device Lot # Removed	Bates Number of Photographs
37	International Dental Supply	8/12/05	Herculite XRV Unidose Enamel A2	Unknown	DMC (registered)						X	000118 - 000120
38	International Dental Supply	8/12/05	Herculite XRV Syringe Enamel A3	4-1265	Scafati* (unregistered)							000121 - 000123
39	International Dental Supply	12/8/05	Herculite XRV Unidose Enamel A2	5-1038	Scafati* (unregistered)							000124 - 000126
40	International Dental Supply	12/8/05	Herculite XRV Unidose Enamel A1	416350	DMC (registered)		X			X		000127 - 000129
41	International Dental Supply	8/12/05	Herculite XRV Syringe Enamel A2	4-1280	Scafati* (unregistered)							000130 - 000132
42	International Dental Supply	11/3/05	Herculite XRV Syringe Enamel A2	4-1280	Scafati* (unregistered)							000133 - 000135
43	International Dental Supply	12/8/05	Herculite XRV Syringe Enamel A2	4-1280	Scafati* (unregistered)							000136 - 000138
44	Omni Dental Supply	11/3/05	Optibond Solo Plus Bottle Refill	5-1136	Scafati* (unregistered)			X	X	X		000139 - 000141
45	Omni Dental Supply	2/23/06	Optibond Solo Plus Bottle Refill	5-1311	Scafati* (unregistered)			X	X	X		000142 - 000144
46	Omni Dental Supply	2/23/06	Herculite XRV Unidose Enamel A1	5-1335	Scafati* (unregistered)				X			000145 - 000147
47	Omni Dental Supply	2/23/06	Herculite XRV Unidose Enamel A2	5-1279	Scafati* (unregistered)				X			000148 - 000150
48	Omni Dental Supply	1/12/06	Herculite XRV Unidose Enamel A2	5-1187	Scafati* (unregistered)				X			000151 - 000153
49	Omni Dental Supply	9/16/05	Herculite XRV Syringe Enamel A3	409009	DMC (registered)			X		X		000154 - 000157
50	Omni Dental Supply	7/11/05	Temp Bond Regular	4-1313	Scafati* (unregistered)				X			000158 - 000160
51	Omni Dental Supply	9/16/05	Herculite XRV Syringe Enamel A2	429062	DMC (registered)			X		X		000161 - 000164
52	Omni Dental Supply	7/11/05	Herculite XRV Syringe Enamel A2	416413	DMC (registered)			X		X	X	000165 - 000167
53	Omni Dental Supply	7/11/05	Herculite XRV Unidose Enamel A1	4-1314	Scafati* (unregistered)				X			000168 - 000170
54	Omni Dental Supply	7/11/05	Herculite XRV Syringe Enamel A3	408140	DMC (registered)			X		X		000171 - 000173

* This device is also not listed with the FDA as being manufactured in this facility. Information contained in this chart accurately reflects the facts during the time period addressed in this Citizen Petition.

Attachment A

List of Misbranded Dental Devices

	Source (Device Distributer)	Invoice Date	Type of Device	Device Lot Number	Device Manufacturing Location	Device Package Insert Removed	Device Removed from Original Package	Device Package Opened and Resealed	Removed Language Indicating the Device was not Packaged or Intended for Sale in the US or Canada from Device Outer Package	Removed "Not For Sale in the US or Canada" from Device Label	Device Lot # Removed	Bates Number of Photographs
55	Omni Dental Supply	7/11/05	Herculite XRV Unidose Enamel A2	4-1274	Scafati* (unregistered)				X			000174 - 000176
56	Omni Dental Supply	1/12/06	Herculite XRV Syringe Enamel A3	429063	DMC (registered)			X		X		000177 - 000180
57	Omni Dental Supply	9/16/05	Optibond Solo Plus Bottle Refill	4-1349	Scafati* (unregistered)			X	X	X		000181 - 000184
58	Omni Dental Supply	11/3/05	Herculite XRV Unidose Enamel A1	425410	DMC (registered)			X		X		000185 - 000187
59	Omni Dental Supply	1/12/06	Optibond Solo Plus Bottle Refill	5-1252	Scafati* (unregistered)			X	X	X		000188 - 000191
60	Omni Dental Supply	1/12/06	Temp Bond Regular	5-1298	Scafati* (unregistered)				X			000192 - 000194
61	Omni Dental Supply	2/23/06	Temp Bond Regular	5-1298	Scafati* (unregistered)				X			000195 - 000197
62	PA Dental Supplies	1/12/06	Herculite XRV Syringe Enamel A3	5-1237	Scafati* (unregistered)							000198 - 000200
63	PA Dental Supplies	11/4/05	Herculite XRV Unidose Enamel A1	5-1109	Scafati* (unregistered)							000201 - 000203
64	PA Dental Supplies	11/4/05	Herculite XRV Unidose Enamel A2	4-1331	Scafati* (unregistered)							000204 - 000206
65	PA Dental Supplies	11/4/05	Herculite XRV Syringe Enamel A2	4-1287	Scafati* (unregistered)							000207 - 000209
66	PA Dental Supplies	1/12/06	Herculite XRV Unidose Enamel A1	5-1258	Scafati* (unregistered)							000210 - 000212
67	PA Dental Supplies	1/12/06	Herculite XRV Unidose Enamel A2	5-1187	Scafati* (unregistered)							000213 - 000215

* This device is also not listed with the FDA as being manufactured in this facility. Information contained in this chart accurately reflects the facts during the time period addressed in this Citizen Petition.