

Validated End-User	Eligible Items (By ECCN)	Eligible Destination
Semiconductor Manufacturing International Corporation.	1C350.c.3; 1C350.d.7; 2B006.b.1; 2B230; 2B350.d.2; 2B350.g.3; 2B350.i.4; 3B001.a; 3B001.b; 3B001.c; 3B001.d; 3B001.e; 3B001.f; 3C001; 3C002; 3C004; 5B002; 5E002 (limited to "technology" according to the General Technology Note for the "production" of integrated circuits controlled by ECCN 5A002 that has been successfully reviewed under the encryption review process specified in §§ 740.17.b.2 or 740.17.b.3 and 742.15 of the EAR).	National Semiconductor Hong Kong Limited, Shenzhen Representative Office, Room 1709 Di Wang Commercial Centre, Shung Hing Square, 5002 Shenna Road East, Shenzhen, China 518008. Semiconductor Manufacturing International (Shanghai) Corporation, 18 Zhang Jiang Rd., Pudong New Area, Shanghai, China 201203. Semiconductor Manufacturing International (Tianjin) Corporation, 19 Xing Hua Avenue, Xi Qing Economic Development Area, Tianjin, China 300385. Semiconductor Manufacturing International (Beijing) Corporation, No. 18 Wen Chang Road, Beijing Economic-Technological Development Area, Beijing, China 100176. Semiconductor Manufacturing International (Chengdu) Corporation, Assembly and Testing (AT2) Facility, 8-8 Kexin Road, Export Processing Zone (West Area), Chengdu, China 611731. Cension Semiconductor Manufacturing Corporation, 3/F, 8-1 Kexin Road, Export Processing Zone (West Area), Chengdu, China 611731.
Shanghai Hua Hong NEC Electronics Company, Ltd.	1C350.c.3; 1C350.d.7; 2B230; 2B350.d.2 2B350.g.3 2B350.i.4; 3B001.c.2; 3C002; 3C004.	Headquarters and Fab. 1 of HHNEC, No. 1188 Chuan Qiao Rd., Pu Dong, Shanghai, China 201206. Fab. 2 of HHNEC, No. 668 Guo Shou Jing Rd., Zhang Jiang High Tech Park, Pu Dong, Shanghai, China 201203.

Dated: October 16, 2007.

Christopher A. Padilla,

Assistant Secretary for Export Administration.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

19 CFR Chapter I

[CBP Dec. 07-82]

Technical Corrections Regarding the Organizational Structure of U.S. Customs and Border Protection

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: This document amends the U.S. Customs and Border Protection (CBP) regulations to reflect changes in the organizational structure of CBP resulting from the establishment of the new Office of International Trade, as well as the nomenclature changes effected by the transfer in 2003 of CBP to the Department of Homeland Security

and the subsequent renaming of the U.S. Customs Service as CBP.

DATES: October 19, 2007.

FOR FURTHER INFORMATION CONTACT:

Jacinto P. Juarez, Jr., Regulations and Rulings, Office of International Trade, (202) 572-8752, or Michelle Garcia, Regulations and Rulings, Office of International Trade, (202) 572-8745.

SUPPLEMENTARY INFORMATION:

Background

On November 25, 2002, the President signed the Homeland Security Act of 2002, 6 U.S.C. 101 *et seq.*, Public Law 107-296, (the "HSA"), establishing the Department of Homeland Security ("DHS"). Pursuant to section 403(1) of the HSA (6 U.S.C. 203(1)), the United States Customs Service was transferred from the Department of the Treasury to DHS effective March 1, 2003. Under section 1502 of the HSA, the Customs Service was renamed as the "Bureau of Customs and Border Protection". Subsequently, on April 23, 2007, a notice was published in the **Federal Register** (72 FR 20131) informing the public that DHS had changed the name of the Bureau of Customs and Border Protection to "U.S. Customs and Border Protection" effective March 31, 2007.

The HSA reserved customs revenue functions to the Department of the Treasury. Treasury Department Order

No. 100-16 delegated general authority vested in the Secretary of the Treasury over customs revenue functions (with certain specified exceptions) to the Secretary of Homeland Security.

Section 402 of Title IV of the Security and Accountability for Every Port Act of 2006 ("SAFE Port Act"), Public Law 109-347, established a new Office of International Trade (OT) to be headed by an Assistant Commissioner within U.S. Customs and Border Protection (CBP). Section 402(d)(2)(A) and (B) of the SAFE Port Act specifically authorized the Commissioner of CBP to transfer the assets, functions, and personnel of the Office of Strategic Trade (OST) and the Office of Regulations and Rulings (ORR) to OT. Pursuant to his authority under section 402(d)(2)(C), the Commissioner authorized the transfer of certain assets, functions, or personnel within the Office of Field Operations (OFO) to the OT.

Prior to the establishment of OT on October 15, 2006, the functions of trade policy and program development were split among three offices within CBP: the Office of Strategic Trade, the Office of Regulations and Rulings, and the Office of Field Operations. The OT consolidates the trade policy, program development, and compliance measurement functions of CBP into one

office without creating dual reporting mechanisms or overlapping and redundant management structures.

The OT includes all functions and staff from the former Office of Strategic Trade (OST) and the former Office of Regulations and Rulings (ORR), as well as designated national program managers and specialists, national analysis specialists from OFO Headquarters and the national account managers currently stationed at ports of entry.

The OT is responsible for the following functions:

(1) Providing national strategic direction to facilitate legitimate trade while protecting the American economy from unfair trade practices.

(2) Directing national enforcement responses through effective targeting of goods crossing the border as well as strict, swift punitive actions against companies participating in predatory trade practices.

(3) Coordinating with international partners to ensure effective enforcement of textile admissibility issues as well as the enforcement of free trade agreement eligibility.

(4) Cooperating with other U.S. agencies and like-minded foreign governments to achieve effective enforcement of intellectual property rights.

(5) Maintaining effective internal controls over the revenue process.

(6) Coordinating with other government agencies and international partners to identify risks to detect and prevent contaminated agricultural or food products from harming the American public or the nation's economy.

(7) Promoting trade facilitation and partnership with the importing community and trade associations by streamlining the flow of legitimate shipments and fostering corporate self-governance as a means of achieving compliance with trade laws and regulations.

(8) Managing a risk-based audit program to respond to allegations of commercial fraud and to conduct

corporate reviews of internal controls to ensure importers comply with trade laws and regulations.

(9) Providing legal tools to promote facilitation and compliance with customs, trade and border security requirements through: the issuance of all CBP regulations, legally binding rulings and decisions, informed compliance publications and structured programs for external CBP training and outreach on international trade laws and CBP regulations.

This document sets forth amendments to the CBP regulations (19 CFR chapter I) to reflect the new CBP organizational structure resulting from the creation of the Office of International Trade, as well as the transfer of the former U.S. Customs Service to DHS and the subsequent renaming of the Customs Service to CBP.

The amendments set forth in this document include the removal of certain provisions within part 171 of the CBP regulations (specifically, paragraphs (b) and (c) of § 171.62 and § 171.63) relating principally to the role of the Department of the Treasury in the consideration of supplemental petitions for relief from fines, penalties, and forfeitures. These provisions are no longer necessary or appropriate due to the transfer of CBP to DHS, the delegation of authority over certain customs revenue functions from the Department of the Treasury to the DHS, and the delegation of certain authorities from DHS to CBP as set forth in Delegation Number 7010.3 dated May 11, 2006.

The CBP regulations contain a significant number of references to offices that either no longer exist or have a different functional context. The changes set forth in this document to correct these references are non-substantive and relate to internal agency organization matters.

Inapplicability of Notice and Delayed Effective Date

Because the technical corrections set forth in this document merely conform to the Homeland Security Act of 2002

and section 402 of the SAFE Port Act, CBP finds that good cause exists for dispensing with notice and public procedure as unnecessary under 5 U.S.C. 553(b)(B). In addition, these amendments concern matters relating to agency organization and personnel which are not subject to prior notice and comment procedures pursuant to 5 U.S.C. 553(a)(2) and (b)(A). For these same reasons, pursuant to 5 U.S.C. 553(d)(3), CBP finds that good cause exists for dispensing with the requirement for a delayed effective date.

Regulatory Flexibility Act

Because this document is not subject to the notice and public procedure requirements of 5 U.S.C. 553, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*)

Executive Order 12866

These amendments do not meet the criteria for a "significant regulatory action" as specified in E.O. 12866.

Signing Authority

This document is limited to technical corrections of CBP regulations. Accordingly, it is being signed under the authority of 19 CFR 0.1(b)(1).

List of Subjects in 19 CFR Part 171

Administrative practice and procedure, Customs duties and inspection, Law enforcement, Penalties, Seizures and forfeitures.

Amendments to CBP Regulations

■ For the reasons given above and under the authority of 19 U.S.C. 66 and 1624, chapter I of the CBP Regulations (19 CFR chapter I) is amended as follows:

CHAPTER I—[AMENDED]

■ 1. For each section indicated in the "Section" column, remove the words indicated in the "Remove" column from wherever they appear in the section, and add, in their place, the words indicated in the "Add" column.

Section	Remove	Add
1. 4.14(c)	Entry Procedures and Carriers Branch	Cargo Security, Carriers & Immigration Branch, Office of International Trade
2. 4.14(c)	Customs Form 301	CBP Form 301
3. 4.14(c)	Customs Headquarters	CBP Headquarters
4. 4.14(c)	Customs	CBP
5. 4.14(f)	Entry Procedures and Carriers Branch	Cargo Security, Carriers & Immigration Branch, Office of International Trade
6. 4.14(f)	Customs Headquarters	CBP Headquarters
7. 4.14(f)	Customs Office of Investigations	U.S. Immigration and Customs Enforcement
8. 4.14(f)	Customs	CBP

Section	Remove	Add
9. 4.14(i)(1)	Customs	CBP
10. 4.14(i)(1)	Entry Procedures and Carriers Branch	Cargo Security, Carriers & Immigration Branch, Office of International Trade
11. 4.14(i)(1)	Customs Headquarters	CBP Headquarters
12. 4.80a(d)	U.S. Customs Service	U.S. Customs and Border Protection
13. 4.80a(d)	Entry Procedures and Carriers Branch	Cargo Security, Carriers & Immigration Branch, Office of International Trade
14. 4.80a(d)	Customs Regulations	CBP Regulations
15. 4.80b(b)	United States Customs Service	U.S. Customs and Border Protection
16. 4.80b(b)	Entry Procedures and Carriers Branch	Cargo Security, Carriers & Immigration Branch, Office of International Trade
17. 10.37	Customs territory	customs territory
18. 10.37	Customs Form	CBP Form
19. 10.37	Commercial Rulings Division, Customs Headquarters	Commercial and Trade Facilitation Division, Office of International Trade, CBP Headquarters
20. 10.37	International Trade Compliance Division, Customs Headquarters	Border Security and Trade Compliance Division, Office of International Trade, CBP Headquarters
21. 10.236(b)—introductory text	Customs	CBP
22. 10.236(b)(1)	Customs Form 450	CBP Form 450
23. 10.236(b)(1)	Office of Field Operations, U.S. Customs Service	Office of International Trade, U.S. Customs and Border Protection
24. 10.256(b)(1)	Customs Form 449	CBP Form 449
25. 10.256(b)(1)	Office of Field Operations, U.S. Customs Service	Office of International Trade, U.S. Customs and Border Protection
26. 10.311(a)	U.S. Customs Service, Regulatory Audit Division	U.S. Customs and Border Protection, Office of International Trade, Regulatory Audit
27. 10.311(a)	Customs Form 355	CBP Form 355
28. 10.311(b)	Regulatory Audit Division	Office of International Trade, Regulatory Audit
29. 10.311(b)	Customs Form 356	CBP Form 356
30. 10.311(b)	U.S. Customs Service, Regulatory Audit Division	U.S. Customs and Border Protection, Office of International Trade, Regulatory Audit
31. 10.311(c)	U.S. Customs Service, Regulatory Audit Division	U.S. Customs and Border Protection, Office of International Trade, Regulatory Audit
32. 10.311(c)	Customs Form 357	CBP Form 357
33. 12.39(b)(4)	Commercial Enforcement, Trade Compliance Division, at Customs Headquarters	Executive Director, Commercial Targeting and Enforcement, Office of International Trade, at CBP Headquarters
34. 12.39(e)(1)	Customs	CBP
35. 12.39(e)(1)	International Trade Compliance Division, U.S. Customs Service	Border Security and Trade Compliance Division, Office of International Trade, U.S. Customs and Border Protection
36. 19.4—heading	Customs and proprietor responsibility and supervision over warehouses	CBP and proprietor responsibility and supervision over warehouses
37. 19.4(b)(8)(iii)	Customs approval	CBP approval
38. 19.4(b)(8)(iii)	Customs Headquarters, Office of Regulations and Rulings	CBP Headquarters, Regulations and Rulings, Office of International Trade
39. 111.1	Office of Field Operations, United States Customs Service	Office of International Trade, U.S. Customs and Border Protection
40. 111.1	prepared and filed with Customs using	prepared and filed with CBP using
41. 111.1	activities involving transactions with Customs	activities involving transactions with CBP
42. 111.1	charges assessed or collected by Customs	charges assessed or collected by CBP
43. 111.1	documents intended to be filed with Customs	documents intended to be filed with CBP
44. 111.1	data received for transmission to Customs	data received for transmission to CBP
45. 111.1	factors which Customs will consider include	factors which CBP will consider include
46. 111.1	maintenance of current editions of the Customs Regulations	maintenance of current editions of CBP Regulations
47. 111.1	Custom issuances	CBP issuances
48. 111.1	Treasury Department	Department of Homeland Security
49. 111.1	U.S. Department of the Treasury	U.S. Department of Homeland Security
50. 111.5(a)	Treasury Department	Department of Homeland Security
51. 111.5(b)	Treasury Department	Department of Homeland Security
52. 111.13(f)	Trade Programs, Office of Field Operations, U.S. Customs Service	Trade Policy and Programs, Office of International Trade, U.S. Customs and Border Protection
53. 111.13(f)	Customs	CBP
54. 111.13(f)	Secretary of the Treasury	Secretary of Homeland Security, or his designee,
55. 111.17(b)	Secretary of the Treasury	Secretary of Homeland Security, or his designee,

Section	Remove	Add
56. 111.17(c)	Secretary of the Treasury	Secretary of Homeland Security, or his designee,
57. 111.19(d)(2)	Customs	CBP
58. 111.19(d)(2)	Office of Field Operations	Office of International Trade
59. 111.19(d)(2)	Office of Field Operations, Customs Headquarters	Office of International Trade, CBP Headquarters
60. 111.19(e)	Office of Field Operations, Customs Headquarters	Office of International Trade, CBP Headquarters
61. 111.19(f)—introductory text	Office of Field Operations, U.S. Customs Service	Office of International Trade, U.S. Customs and Border Protection
62. 111.23(b)(2)—introductory text	Director, Regulatory Audit Division, U.S. Customs Service, 909 SE. First Avenue, Miami, Florida 33131	Office of International Trade, Regulatory Audit, 2001 Cross Beam Dr., Charlotte, North Carolina 28217
63. 111.23(b)(2)(iii)	Director, Regulatory Audit Division, in Miami	Office of International Trade, Regulatory Audit, in Charlotte
64. 111.24	Regulatory Audit Division	Office of International Trade, Regulatory Audit
65. 111.25	Customs	CBP
66. 111.26	Treasury Department	Department of Homeland Security
67. 111.27	Regulatory Audit Division	Regulatory Audit
68. 111.29(b)(1)	Customs charges	customs charges
69. 111.29(b)(1)	Customs	CBP
70. 111.29(b)(1)	U.S. Customs Service	U.S. Customs and Border Protection
71. 111.30(c)	Office of Field Operations, U.S. Customs Service	Office of International Trade, U.S. Customs and Border Protection
72. 111.31(a)	Treasury Department	Department of Homeland Security
73. 111.31(b)	Treasury Department	Department of Homeland Security
74. 111.32	Treasury Department	Department of Homeland Security
75. 111.34—heading	Undue influence upon Treasury Department employees	Undue influence upon Department of Homeland Security employees
76. 111.34	Treasury Department	Department of Homeland Security
77. 111.38	Treasury Department	Department of Homeland Security
78. 111.51(a)	Secretary of the Treasury	Secretary of Homeland Security, or his designee,
79. 111.66	Secretary of the Treasury	Secretary of Homeland Security, or his designee,
80. 111.69	Secretary of the Treasury	Secretary of Homeland Security, or his designee,
81. 111.70	Secretary of the Treasury	Secretary of Homeland Security, or his designee,
82. 111.71	Secretary of the Treasury	Secretary of Homeland Security, or his designee,
83. 111.72	Secretary of the Treasury	Secretary of Homeland Security, or his designee,
84. 111.74	Secretary of the Treasury	Secretary of Homeland Security, or his designee,
85. 111.75	Secretary of the Treasury	Secretary of Homeland Security, or his designee,
86. 111.76(b)	Secretary of the Treasury	Secretary of Homeland Security, or his designee,
87. 111.77	Secretary of the Treasury	Secretary of Homeland Security, or his designee,
88. 111.81	Secretary of the Treasury	Secretary of Homeland Security, or his designee,
89. 113.14	International Trade Compliance Division	Border Security and Trade Compliance Division, Regulations and Rulings, Office of International Trade
90. 113.15	International Trade Compliance Division	Border Security and Trade Compliance Division
91. 113.38(c)(1)	International Trade Compliance Division, Customs Headquarters	Border Security and Trade Compliance Division, CBP Headquarters
92. 113.38(c)(4)	International Trade Compliance Division, Customs Headquarters	Border Security and Trade Compliance Division, CBP Headquarters
93. 113.38(c)(4)	Customs officer	CBP officer
94. 113.38(c)(4)—(except for last sentence) ...	Customs	CBP
95. 113.39(a)—introductory text	International Trade Compliance Division	Border Security and Trade Compliance Division
96. 113.39(b)	International Trade Compliance Division	Border Security and Trade Compliance Division
97. 133.0	United States Customs Service	U.S. Customs and Border Protection
98. 133.1(a)	U.S. Customs Service	U.S. Customs and Border Protection

Section	Remove	Add
99. 133.2—introductory text	Intellectual Property Rights Branch, U.S. Customs Service	Intellectual Property Rights (IPR) & Restricted Merchandise Branch, U.S. Customs and Border Protection
100. 133.2(e)—introductory text	Customs	CBP
101. 133.2(f)	Customs will publish	CBP will publish
102. 133.2(f)	Customs will examine	CBP will examine
103. 133.2(f)	until Customs has made	until CBP has made
104. 133.2(f)	Customs will publish	CBP will publish
105. 133.4(a)	United States Customs Service	U.S. Customs and Border Protection
106. 133.4(a)	Customs officers	U.S. Customs and Border Protection Officers
107. 133.4(c)	United States Customs Service	U.S. Customs and Border Protection
108. 133.6—introductory text	Intellectual Property Rights Branch	IPR & Restricted Merchandise Branch, CBP Headquarters
109. 133.6(b)	United States Customs Service	U.S. Customs and Border Protection
110. 133.7(a)—introductory text	Customs	CBP
111. 133.7(a)—introductory text	Intellectual Property Rights Branch	IPR & Restricted Merchandise Branch
112. 133.7(a)(3)	United States Customs Service	U.S. Customs and Border Protection
113. 133.7(b)	Intellectual Property Rights Branch	IPR & Restricted Merchandise Branch
114. 133.12—introductory text	Intellectual Property Rights Branch, U.S. Customs Service	IPR & Restricted Merchandise Branch
115. 133.13(b)	United States Customs Service	U.S. Customs and Border Protection
116. 133.15—heading	Term of Customs trade name recordation	Term of CBP trade name recordation
117. 133.15	Intellectual Property Rights Branch	IPR & Restricted Merchandise Branch
118. 133.26	Customs custody	CBP custody
119. 133.26	Customs Form	CBP Form
120. 133.32—introductory text	Customs protection	customs protection
121. 133.32—introductory text	Intellectual Property Rights Branch, U.S. Customs Service	IPR & Restricted Merchandise Branch, U.S. Customs and Border Protection
122. 133.35(a)	United States Customs Service	CBP
123. 133.35(a)	Intellectual Property Rights Branch	IPR & Restricted Merchandise Branch
124. 133.35(b)(2)	United States Customs Service	U.S. Customs and Border Protection
125. 133.36—introductory text	Intellectual Property Rights Branch	IPR & Restricted Merchandise Branch
126. 133.36(b)	United States Customs Service	CBP
127. 133.36(b)	made payable to the United States Customs Service	made payable to U.S. Customs and Border Protection
128. 133.37(b)	Intellectual Property Rights Branch	IPR & Restricted Merchandise Branch
129. 133.37(c)(3)	United States Customs Service	U.S. Customs and Border Protection
130. 133.43(d)(1)(ii)	Customs Headquarters	CBP Headquarters
131. 133.43(d)(1)(ii)	International Trade Compliance Division, Office of Regulations and Rulings	Border Security and Trade Compliance Division, Regulations and Rulings, Office of International Trade
132. 142.3a	Customs	CBP
133. 142.3a(d)	port director	Assistant Commissioner, Office of International Trade, or his designee
134. 142.3a(e)	port director	Assistant Commissioner, Office of International Trade, or his designee
135. 143.7(a)	Director, Trade Compliance	Executive Director, Trade Policy and Programs, Office of International Trade
136. 143.8	Director, Trade Compliance	Executive Director, Trade Policy and Programs, Office of International Trade
137. 143.8	Customs officer	CBP officer
138. 146.81(b)	Director, International Trade Compliance Division	Assistant Commissioner, Office of International Trade, or his designee
139. 146.83(a)	Director, International Trade Compliance Division	Executive Director, Regulations and Rulings, Office of International Trade
140. 146.83(a)	Customs	CBP
141. 151.12—introductory text	Customs	CBP
142. 151.12(a)	Office of Field Operations, U.S. Customs Service	Office of Information and Technology, or his designee, U.S. Customs and Border Protection
143. 151.12(a)	Customs	CBP
144. 151.12(a)	U.S. Customs Laboratory Methods Manual	Customs and Border Protection Laboratory (CBPL) Methods
145. 151.12(a)	U.S. Customs Service	U.S. Customs and Border Protection
146. 151.12(a)	Customs Internet Web site: http://www.customs.gov .	CBP Web site: www.cbp.gov .
147. 159.63(a)	Customs	CBP
148. 159.63(a)	Office of Regulations and Rulings	Office of Finance
149. 162.74(c)	Customs Headquarters, Office of Regulations and Rulings	Office of International Trade
150. 162.74(c)	Customs	CBP
151. 162.74(c)	Customs Headquarters	CBP Headquarters

Section	Remove	Add
152. 163.5(b)(1)	Director, Regulatory Audit Division, U.S. Customs Service, 909 SE. First Avenue, Miami, Florida 33131	Regulatory Audit, U.S. Customs and Border Protection, 2001 Cross Beam Dr., Charlotte, North Carolina 28217
153. 163.5(b)(1)	Director of the Miami regulatory audit field office	Director of Regulatory Audit, Charlotte office
154. 163.5(b)(1)	Customs	CBP
155. 163.11(a)(5)	Director, Regulatory Audit Division at Customs Headquarters	Executive Director, Regulatory Audit, Office of International Trade, at CBP Headquarters
156. 163.11(b)	Customs	CBP
157. 163.11(b)	Director, Regulatory Audit Division, U.S. Customs Service, Washington, DC 20229	Executive Director, Regulatory Audit, Office of International Trade, U.S. Customs and Border Protection, Washington, DC 20229
158. 163.12(b)(2)	Director, Regulatory Audit Division, U.S. Customs Service, 909 SE. First Avenue, Miami, Florida 33131	Regulatory Audit, U.S. Customs and Border Protection, 2001 Cross Beam Dr., Charlotte, North Carolina 28217
159. 163.12(b)(2)	Regulatory Audit Division, Office of Strategic Trade, U.S. Customs Service, 909 SE. First Avenue, Miami, Florida 33131	Executive Director, Regulatory Audit, Office of International Trade, U.S. Customs and Border Protection, 1300 Pennsylvania Ave., NW., Washington, DC 20229
160. 163.12(c)(1)	Miami regulatory audit field office	Charlotte regulatory audit field office
161. 163.12(c)(1)	Customs	CBP
162. 163.13(d)(1)	Director, Regulatory Audit Division, U.S. Customs Service, Washington, DC 20229	Executive Director, Regulatory Audit, Office of International Trade, U.S. Customs and Border Protection, Washington, DC 20229
163. 163.13(d)(1)	Director, Regulatory Audit Division	Executive Director, Regulatory Audit
164. 163.13(d)(2)	Customs	CBP
165. 163.13(d)(2)	Director, Regulatory Audit Division, U.S. Customs Service, Washington, DC 20229	Executive Director, Regulatory Audit, U.S. Customs and Border Protection, Office of International Trade, Washington, DC 20229
166. 163.13(d)(2)	Director, Regulatory Audit Division	Executive Director, Regulatory Audit
167. 171.12—heading	Petitions acted on at Customs Headquarters	Petitions acted on at CBP Headquarters
168. 171.12	Office of Regulations and Rulings, Customs Headquarters	Regulations and Rulings, Office of International Trade, CBP Headquarters
169. 171.14	Director, International Trade Compliance Division, Office of Regulations and Rulings, Customs Headquarters	Director, Border Security and Trade Compliance Division, Regulations and Rulings, Office of International Trade, CBP Headquarters, or his designee
170. 171.14	Customs	CBP
171. 171.62(a)	Office of Regulations and Rulings	Border Security and Trade Compliance Division, Regulations and Rulings, Office of International Trade
172. 171.62(b)—heading	Decisions of Customs Headquarters	Decisions of CBP Headquarters
173. 171.62(b)	Office of Regulations and Rulings, Customs Headquarters	Regulations and Rulings, Office of International Trade, CBP Headquarters
174. 171.62(b)	International Trade Compliance Division, Customs Headquarters	Border Security and Trade Compliance Division, CBP Headquarters
175. Part 171, App. C, XIII	Brokers Compliance Branch, Office of Trade Compliance	Trade Policy and Programs, Office of International Trade
176. 172.14	International Trade Compliance Division, Office of Regulations and Rulings, Customs Headquarters	Border Security and Trade Compliance Division, Regulations and Rulings, Office of International Trade, CBP Headquarters
177. 172.14	Customs	CBP
178. 172.42(b)—heading	Decisions of Customs Headquarters	Decisions of CBP Headquarters
179. 172.42(b)	Office of Regulations and Rulings, Customs Headquarters	Regulations and Rulings, Office of International Trade, CBP Headquarters
180. 172.42(b)	International Trade Compliance Division	Border Security and Trade Compliance Division, Regulations and Rulings
181. 172.42(c)—heading	Authority of Assistant Commissioner	Authority of Executive Director
182. 172.42(c)	Assistant Commissioner, Office of Regulations and Rulings, or his designee	Executive Director, Regulations and Rulings, Office of International Trade, or his designee
183. 177.0	United States Customs Service	CBP
184. 177.0	any Customs Service field office	any CBP field office
185. 177.0	Customs Headquarters Office other than the Office of Regulations and Rulings	CBP Headquarters Office other than Regulations and Rulings, Office of International Trade
186. 177.1(d)(6)	Office of Regulations and Rulings	Regulations and Rulings, Office of International Trade
187. 177.1(d)(6)	United States Customs Service	U.S. Customs and Border Protection
188. 177.2(a)	Commissioner of Customs	Commissioner of Customs and Border Protection

Section	Remove	Add
189. 177.2(a)	Office of Regulations and Rulings	Regulations and Rulings, Office of International Trade
190. 177.2(a)	National Commodity Specialist Division, U.S. Customs	National Commodity Specialist Division, Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection, New York, New York, 10119
191. 177.2(a)	Customs Service	Customs and Border Protection
192. 177.2(b)(2)(i)	relevant Customs and related laws	relevant customs and related laws
193. 177.2(b)(2)(ii)(C)	Commercial Rulings Division, U.S. Customs Service	Commercial and Trade Facilitation Division, Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection
194. 177.9(c)	Customs	CBP
195. 177.9(c)	Commissioner of Customs	Commissioner of Customs and Border Protection
196. 177.9(c)	Office of Regulations and Rulings	Regulations and Rulings, Office of International Trade
197. 177.13(b)(1)	Office of Regulations and Rulings, U.S. Customs Service	Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection
198. 177.22(b)—introductory text	Commercial Rulings Division	Commercial and Trade Facilitation Division, Regulations and Rulings
199. 177.22(b)—introductory text	U.S. Customs Service	U.S. Customs and Border Protection
200. 177.22(b)—introductory text	Customs	CBP
201. 177.22(b)(3)	Customs	CBP
202. 177.22(c)	Assistant Commissioner, Office of Regulations and Rulings	Executive Director, Regulations and Rulings, Office of International Trade
203. 177.22(c)	U.S. Customs Service	U.S. Customs and Border Protection
204. 177.26	Director, Office of Regulations and Rulings	Executive Director, Regulations and Rulings, Office of International Trade
205. 177.26	U.S. Customs Service	U.S. Customs and Border Protection
206. 181.22(b)(1)	Customs	CBP
207. 181.92(a)(3)	Office of Regulations and Rulings	Regulations and Rulings, Office of International Trade
208. 181.92(a)(3)	United States Customs Service	U. S. Customs and Border Protection
209. 181.92(a)(6)	National Commodity Specialist Division, United States Customs Service	National Commodity Specialist Division, U.S. Customs and Border Protection
210. 181.93(a)	Commissioner of Customs	Commissioner of Customs and Border Protection
211. 181.93(a)	Office of Regulations and Rulings	Regulations and Rulings, Office of International Trade
212. 181.93(a)	United States Customs Service, 6 World Trade Center, New York, NY 10048	U. S. Customs and Border Protection, One Penn Plaza, 10th Floor, New York, NY 10119
213. 181.100(a)(3)	Commissioner of Customs	Commissioner of Customs and Border Protection
214. 181.100(a)(3)	Office of Regulations and Rulings	Regulations and Rulings, Office of International Trade
215. 181.102(a)(1)—introductory text	Customs Headquarters	CBP Headquarters
216. 181.102(a)(1)—introductory text	Assistant Commissioner, Office of Regulations and Rulings, U.S. Customs Service	Executive Director, Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection
217. 191.7(c)—heading	Review and action by Customs	Review and action by CBP
218. 191.7(c)(3)	Customs Headquarters	CBP Headquarters
219. 191.7(c)(3)	Duty and Refund Determination Branch, Office of Regulations and Rulings	Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade
220. 191.8(d)	Customs Headquarters	CBP Headquarters
221. 191.8(d)	Duty and Refund Determination Branch, Office of Regulations and Rulings	Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade
222. 191.8(e)—heading	Review and action by Customs	Review and action by CBP
223. 191.8(e)—introductory text	Customs Headquarters	CBP Headquarters
224. 191.8(e)(2)	Customs Headquarters	CBP Headquarters
225. 191.8(e)(2)	Commercial Rulings Division	Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade
226. 191.8(g)(1)	Customs Headquarters	CBP Headquarters
227. 191.8(g)(1)	Duty and Refund Determination Branch, Office of Regulations and Rulings	Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade
228. 191.8(g)(2)(ii)	Customs Headquarters	CBP Headquarters

Section	Remove	Add
229. 191.8(g)(2)(ii)	Duty and Refund Determination Branch, Office of Regulations and Rulings	Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade
230. 191.11(c)	Duty and Refund Determination Branch, Office of Regulations and Rulings, Customs Headquarters	Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade, CBP Headquarters
231. 191.32(c)(1)	Duty and Refund Determination Branch, Office of Regulations and Rulings	Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade
232. 191.36(d)	Customs	CBP
233. 191.36(d)	Customs Headquarters, Office of Field Operations, Office of Trade Operations	CBP Headquarters, Office of International Trade, Trade Policy and Programs
234. 191.36(d)	Customs Headquarters	CBP Headquarters
235. 191.61(d)(1)	Customs Headquarters	CBP Headquarters
236. 191.61(d)(1)	Duty and Refund Determination Branch, Office of Regulations and Rulings	Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade
237. 191.61(d)(2)	Customs Headquarters	CBP Headquarters
238. 191.61(d)(2)	Duty and Refund Determination Branch, Office of Regulations and Rulings	Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade
239. 191.61(d)(3)—heading	Customs Headquarters	CBP Headquarters
240. 191.61(d)(3)	Customs Headquarters	CBP Headquarters
241. 191.91(g)	Customs Headquarters, Office of Field Operations, Office of Trade Operations	CBP Headquarters, Office of International Trade, Trade Policy and Programs
242. 191.91(g)	Customs Headquarters	CBP Headquarters
243. 191.92(h)	Customs Headquarters, Office of Field Operations, Office of Trade Operations	CBP Headquarters, Office of International Trade, Trade Policy and Programs
244. 191.92(h)	Customs Headquarters	CBP Headquarters
245. 191.156(d)	Office of Field Operations, Customs Headquarters	Office of International Trade, CBP Headquarters
246. 191.194(a)(1)	Customs Headquarters	CBP Headquarters
247. 191.194(a)(1)	Customs processing	CBP processing
248. 191.194(a)(2)—introductory text	Customs review	CBP review
249. 191.194(a)(2)—introductory text	Customs	CBP
250. 191.194(a)(2)(i)	Customs charges	customs charges
251. 191.194(a)(2)(i)	Customs	CBP
252. 191.194(c)	Customs	CBP
253. 191.194(d)	Customs	CBP
254. 191.194(e)(1)(ii)	Customs laws and regulations	customs laws and CBP regulations
255. 191.194(e)(2)	Customs	CBP
256. 191.194(f)(1)	Customs Headquarters, Office of Field Operations, Office of Trade Programs	CBP Headquarters, Trade Policy and Programs, Office of International Trade
257. 191.194(f)(1)	Customs Headquarters	CBP Headquarters
258. 191.194(f)(2)	Customs Headquarters, Office of Field Operations, Office of Trade Programs	CBP Headquarters, Trade Policy and Programs, Office of International Trade
259. 191.194(f)(2)	Customs	CBP
260. Part 191, App. A, II, K	Customs Regulations	CBP Regulations
261. Part 191, App. A, II, M, 6	Customs Regulations	CBP Regulations
262. Part 191, App. A, III, D, 6	Customs Regulations	CBP Regulations
263. Part 191, App. A, IV, I	Customs Regulations	CBP Regulations
264. Part 191, App. A, IV, K, 6	Customs Regulations	CBP Regulations
265. Part 191, App. A, V, I	Customs Regulations	CBP Regulations
266. Part 191, App. A, V, K, 6	Customs Regulations	CBP Regulations
267. Part 191, App. A, VI, I	Customs Regulations	CBP Regulations
268. Part 191, App. A, VI, K, 6	Customs Regulations	CBP Regulations
269. Part 191, App. A, VII, I	Customs Regulations	CBP Regulations
270. Part 191, App. A, VII, K, 6	Customs Regulations	CBP Regulations
271. Part 191, App. A, VIII, H	Customs Regulations	CBP Regulations
272. Part 191, App. A, VIII, J, 6	Customs Regulations	CBP Regulations
273. Part 191, App. A, IX, M, 6	Customs Regulations	CBP Regulations
274. Part 191, App. A, X, J	Customs Regulations	CBP Regulations
275. Part 191, App. A, X, L, 6	Customs Regulations	CBP Regulations
276. Part 191, App. A, XI, Y, 6	Customs Regulations	CBP Regulations
277. Part 191, App. A, XII, J	Customs Regulations	CBP Regulations
278. Part 191, App. A, XII, L, 6	Customs Regulations	CBP Regulations
279. Part 191, App. A, XIII, J	Customs Regulations	CBP Regulations
280. Part 191, App. A, XIII, L, 6	Customs Regulations	CBP Regulations
281. Part 191, App. A, XIV, I	Customs Regulations	CBP Regulations
282. Part 191, App. A, XIV, K, 6	Customs Regulations	CBP Regulations
283. Part 191, App. B, I	Customs Headquarters	CBP Headquarters
284. Part 191, App. B, I	Customs issues	CBP issues

Section	Remove	Add
285. Part 191, App. B, II COMPANY LETTER-HEAD (Optional).	U.S. Customs Service, Duty and Refund De-termination Branch	U.S. Customs and Border Protection, Entry Process and Duty Refunds, Regulations and Rulings, Office of International Trade CBP Regulations
286. Part 191, App. B, II COMPANY LETTER-HEAD (Optional).	Customs Regulations	CBP Regulations
287. Part 191, App. B, II NAME AND ADDRESS AND IRS NUMBER (WITH SUFFIX) OF APPLICANT.	Customs Regulations	CBP Regulations
288. Part 191, App. B, II PERSONS WHO WILL SIGN DRAWBACK DOCUMENTS.	Customs Regulations	CBP Regulations
289. Part 191, App. B, II CUSTOMS OFFICE WHERE DRAWBACK CLAIMS WILL BE FILED—heading.	CUSTOMS OFFICE	CBP OFFICE
290. Part 191, App. B, II INVENTORY PROCEDURES.	Customs Regulations	CBP Regulations
291. Part 191, App. B, II BASIS OF CLAIM FOR DRAWBACK.	Customs Regulations	CBP Regulations
292. Part 191, App. B, II AGREEMENTS	Customs Regulations	CBP Regulations
293. Part 191, App. B, III COMPANY LETTERHEAD (Optional).	U.S. Customs Service, Duty and Refund De-termination Branch	U.S. Customs and Border Protection, Commercial and Trade Facilitation Division, Regulations and Rulings, Office of International Trade CBP Regulations
294. Part 191, App. B, III NAME AND ADDRESS AND IRS NUMBER (WITH SUFFIX) OF APPLICANT.	Customs Regulations	CBP Regulations
295. Part 191, App. B, III PERSONS WHO WILL SIGN DRAWBACK DOCUMENTS.	Customs Regulations	CBP Regulations
296. Part 191, App. B, III CUSTOMS OFFICE WHERE DRAWBACK CLAIMS WILL BE FILED—heading.	CUSTOMS OFFICE	CBP OFFICE
297. Part 191, App. B, III INVENTORY PROCEDURES.	Customs Regulations	CBP Regulations
298. Part 191, App. B, III BASIS OF CLAIM FOR DRAWBACK.	Customs Regulations	CBP Regulations
299. Part 191, App. B, III AGREEMENTS	Customs Regulations	CBP Regulations
300. Part 191, App. B, IV COMPANY LETTERHEAD (Optional).	U.S. Customs Service, Duty and Refund De-termination Branch	U.S. Customs and Border Protection, Commercial and Trade Facilitation Division, Regulations and Rulings, Office of International Trade CBP Regulations
301. Part 191, App. B, IV NAME AND ADDRESS AND IRS NUMBER (WITH SUFFIX) OF APPLICANT.	Customs Regulations	CBP Regulations
302. Part 191, App. B, IV PERSONS WHO WILL SIGN DRAWBACK DOCUMENTS.	Customs Regulations	CBP Regulations
303. Part 191, App. B, IV CUSTOMS OFFICE WHERE DRAWBACK CLAIMS WILL BE FILED Heading.	CUSTOMS OFFICE	CBP OFFICE
304. Part 191, App. B, IV INVENTORY PROCEDURES.	Customs Regulations	CBP Regulations
305. Part 191, App. B, IV BASIS OF CLAIM FOR DRAWBACK.	Customs Regulations	CBP Regulations
306. Part 191, App. B, IV AGREEMENTS	Customs Regulations	CBP Regulations
307. Part 191, App. B, V COMPANY LETTERHEAD (Optional).	U.S. Customs Service, Duty and Refund De-termination Branch	U.S. Customs and Border Protection, Commercial and Trade Facilitation Division, Regulations and Rulings, Office of International Trade CBP Regulations
308. Part 191, App. B, V NAME AND ADDRESS AND IRS NUMBER (WITH SUFFIX) OF APPLICANT.	Customs Regulations	CBP Regulations
309. Part 191, App. B, V PERSONS WHO WILL SIGN DRAWBACK DOCUMENTS.	Customs Regulations	CBP Regulations
310. Part 191, App. B, V CUSTOMS OFFICE WHERE DRAWBACK CLAIMS WILL BE FILED—heading.	CUSTOMS OFFICE	CBP OFFICE
311. Part 191, App. B, V INVENTORY PROCEDURES.	Customs Regulations	CBP Regulations
312. Part 191, App. B, V BASIS OF CLAIM FOR DRAWBACK.	Customs Regulations	CBP Regulations
313. Part 191, App. B, V AGREEMENTS	Customs Regulations	CBP Regulations

PART 171—FINES, PENALTIES, AND FORFEITURES

■ 2. The authority citation for part 171, CBP Regulations, continues to read as follows:

Authority: 18 U.S.C. 983; 19 U.S.C. 66, 1592, 1593a, 1618, 1624; 22 U.S.C. 401; 31 U.S.C. 5321; 46 U.S.C. App. A. 320.

Subpart F also issued under 19 U.S.C. 1595a, 1605, 1614.

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§ 171.62 [Amended]

■ 3. Section 171.62 is amended by removing paragraphs (c) and (d).

§ 171.63 [Removed and reserved]

■ 4. Section 171.63 is removed and reserved.

Dated: October 12, 2007.

W. Ralph Basham,

Commissioner, U.S. Customs and Border Protection.

[FR Doc. E7–20471 Filed 10–18–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 880**

[Docket No. 2007N–0328]

Medical Devices; General Hospital and Personal Use Devices; Classification of Remote Medication Management System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the remote medication management systems into class II (special controls). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document entitled, “Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Remote Medication Management System,” which will serve as the special control for this device type. The agency is classifying this device type into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of these devices.

DATES: This final rule is effective November 19, 2007. The classification was effective June 13, 2007.

FOR FURTHER INFORMATION CONTACT: Richard Chapman, Center for Devices

and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2585.

SUPPLEMENTARY INFORMATION:**I. What is the Background of This Rulemaking?**

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless the device is classified or reclassified into class I or class II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of FDA’s regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on September 20, 2006, classifying the INRange Remote Medication Management System in class III because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II. On September 25, 2006, INRange Systems, Inc., submitted a petition requesting classification of the INRange Remote Medication Management System under section

513(f)(2) of the act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that remote medication management systems can be classified into class II with the establishment of special controls. FDA believes that these special controls, in addition to general controls, are adequate to provide reasonable assurance of the safety and effectiveness of the device. The device is assigned the generic name “Remote Medication Management System.” A remote medication management system is a device composed of clinical and communications software, a medication delivery unit, and medication packaging. The system is intended to store the patient’s prescribed medications in a delivery unit, to permit a health care professional to remotely schedule the patient’s prescribed medications, to notify the patient when the prescribed medications are due to be taken, to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient’s command, and to record a history of the event for the health care professional. The system is intended for use as an aid to health care professionals in managing therapeutic regimens for patients in the home or clinic.

FDA has identified the following risks to health associated with this type of device:

- Improper dosage delivered to patient,
- Cross-contamination of medications—unintended drug interactions,
- Compromised information security,
- Failure of the device—inability to deliver medication,
- Electromagnetic interference—electromagnetic emissions interfering with other medical devices or electromagnetic susceptibility causing the device to function improperly due to emissions of other devices, and
- Electrical and mechanical hazards—electrical shock, pinching.