

consumer financial protection laws from the Board to the Bureau, effective July 21, 2011, including TISA. The Bureau issued the Bureau Interim Final Rule to implement TISA in connection with the transfer of TISA rulemaking authority to the Bureau. Pursuant to section 1029 of the Dodd-Frank Act, however, the Board retains rulemaking authority for consumer financial protection laws to the extent that such laws could cover motor vehicle dealers identified in section 1029(a) of the Dodd-Frank Act. The Board does not believe that any motor vehicle dealers identified in section 1029(a) of the Dodd-Frank Act are or could become depository institutions engaged in activities that would be subject to the Board's rulemaking authority under TISA. Consequently, the Board is repealing the Board's Regulation DD, 12 CFR part 230.

2. *Summary of issues raised by comments in response to the initial regulatory flexibility analysis.* The Board did not receive any comments on the initial regulatory flexibility analysis.

3. *Small entities affected by the final rule.* The Board does not believe that any motor vehicle dealers identified in section 1029(a) of the Dodd-Frank Act are or could become depository institutions engaged in activities that would be subject to the Board's rulemaking authority under TISA. Therefore, the Board believes the final rule would not affect any entity, including any small entity.

4. *Recordkeeping, reporting, and compliance requirements.* The final rule repeals the Board's Regulation DD, 12 CFR part 230, and would therefore not impose any recordkeeping, reporting, or compliance requirements on any entities.

5. *Significant alternatives to the final revisions.* Because the repeal of the Board's Regulation DD (12 CFR part 230) will have no impact, there are no significant alternatives that would further minimize the economic impact of the final rule on small entities.

## V. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3506; 5 CFR Part 1320, Appendix A.1), the Board reviewed the rule under the authority delegated to the Federal Reserve by the Office of Management and Budget. The final rule contains no collections of information under the PRA. See 44 U.S.C. 3502(3).

Accordingly, there is no paperwork burden associated with the final rule.

### List of Subjects in 12 CFR Part 230

Advertising, Banks, Banking, Consumer protection, Reporting and

recordkeeping requirements, Truth in savings.

### Authority and Issuance

For the reasons set forth in the preamble, based on the transfer of authority under 12 U.S.C. 5581, the Board removes and reserves Regulation DD, 12 CFR part 230.

### PART 230—[REMOVED AND RESERVED]

By order of the Board of Governors of the Federal Reserve System, May 22, 2014.

**Robert deV. Frierson,**

*Secretary of the Board.*

[FR Doc. 2014-12356 Filed 5-28-14; 8:45 am]

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## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

#### 15 CFR Part 748

[Docket No. 140506409-4409-01]

RIN 0694-AG15

### Amendments to Existing Validated End-User Authorizations in the People's Republic of China: Samsung China Semiconductor Co. Ltd and Semiconductor Manufacturing International Corporation

**AGENCY:** Bureau of Industry and Security, Commerce.

**ACTION:** Final rule.

**SUMMARY:** In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to revise existing authorizations for Validated End-Users (VEUs) Samsung China Semiconductor Co. Ltd. (Samsung China) and Semiconductor Manufacturing International Corporation (SMIC) in the People's Republic of China (PRC). Specifically, BIS amends Supplement No. 7 to part 748 of the EAR to change the address of the facility used by Samsung China. In addition, BIS adds a facility to the list of eligible destinations and an item to the list of eligible items for SMIC.

**DATES:** This rule is effective May 29, 2014.

**FOR FURTHER INFORMATION CONTACT:** Karen Nies-Vogel, Chair, End-User Review Committee, Bureau of Industry and Security, U.S. Department of Commerce, 14th Street & Pennsylvania Avenue NW., Washington, DC 20230; by telephone: (202) 482-5991, fax: (202) 482-3991, or email: [ERC@bis.doc.gov](mailto:ERC@bis.doc.gov).

**SUPPLEMENTARY INFORMATION:**

## Background

### Authorization Validated End-User

Validated End-Users (VEUs) are designated entities located in eligible destinations to which eligible items may be exported, reexported, or transferred (in-country) under a general authorization instead of a license. The names of the VEUs, as well as the dates they were so designated, and their respective eligible destinations and items are identified in Supplement No. 7 to part 748 of the Export Administration Regulations (EAR). Under the terms described in that supplement, VEUs may obtain eligible items without an export license from the Bureau of Industry and Security (BIS), in conformity with Section 748.15 of the EAR. Eligible items vary between VEUs, but may include commodities, software, and technology, except those controlled for missile technology or crime control reasons on the Commerce Control List (CCL) (part 774 of the EAR).

VEUs are reviewed and approved by the U.S. Government in accordance with the provisions of Section 748.15 and Supplement Nos. 8 and 9 to part 748 of the EAR. The End-User Review Committee (ERC), composed of representatives from the Departments of State, Defense, Energy, and Commerce, and other agencies, as appropriate, is responsible for administering the VEU program. BIS amended the EAR in a final rule published on June 19, 2007 (72 FR 33646) to create Authorization VEU.

### Amendments to Existing Validated End-User Authorizations in the People's Republic of China (PRC)

*Revision to the List of "Eligible Items (By ECCN)" for Validated End-User Samsung China Semiconductor Co. Ltd (Samsung China)*

This final rule amends Supplement No. 7 to part 748 of the EAR to change the address of the Samsung China facility to which eligible items may be exported, reexported or transferred (in-country) using Authorization VEU. BIS makes this change pursuant to a request from Samsung China advising BIS that Samsung China received verification of the final address of its facility from the Chinese government. Samsung China's VEU-eligible facility, which is located in an area being newly developed for corporate use, has not moved. The list of eligible items for Samsung China remains the same. BIS added Samsung China as a VEU in Supplement No. 7 to part 748 in a rule published in the **Federal Register** on July 10, 2013 (78 FR 41291).

*Prior Address of Samsung China Destination:*

Samsung China Semiconductor Co. Ltd.,  
Xinglong Street, Chang'an District,  
Xi'an, People's Republic of China  
710065.

*New Address for Samsung China:*

Samsung China Semiconductor Co. Ltd.,  
No. 1999, North Xiaohe Road, Xi'an,  
China 710119.

*Revisions to the List of "Eligible Destinations" and "Eligible Items (By ECCN)" for Validated End-User Semiconductor Manufacturing International Corporation (SMIC)*

This final rule also amends Supplement No. 7 to part 748 of the EAR to add a facility to the list of SMIC facilities to which eligible items may be exported, reexported or transferred (in-country) using Authorization VEU, bringing the number of SMIC's VEU-authorized facilities in the PRC to a total of five. BIS also adds an ECCN to SMIC's list of eligible items that may be sent to the five facilities. The ECCN added in this rule to SMIC's VEU authorization is ECCN 3A233 (certain types of mass spectrometers). BIS makes these changes pursuant to requests from SMIC. SMIC requested the addition of the new VEU-eligible destination in order to facilitate shipments to its new business venture.

*Additional SMIC Destination:*

Semiconductor Manufacturing North China (Beijing) Corporation, No. 18 Wen Chang Road, Building 9, Beijing Economic-Technological Development Area, Beijing, China 100176.

*Eligible Items (by ECCN) That May Be Exported, Reexported or Transferred (In-Country) to the Eligible Destination Identified Under Semiconductor Manufacturing International Corporation Validated End-User Authorization*

ECCNs 1C350.c.3, 1C350.d.7, 2B006.b.1, 2B230, 2B350.d.2, 2B350.d.3, 2B350.g.3, 2B350.i.3, 3A233, 3B001.a, 3B001.b, 3B001.c, 3B001.e, 3B001.f, 3C001, 3C002, 3C003, 3C004, 5B002, and 5E002 (limited to "technology" according to the General Technology Note for the "production" of integrated circuits controlled by ECCN 5A002 that have been classified by BIS as eligible for License Exception ENC under paragraph (b)(2) or (b)(3) of Section 740.17 of the EAR, or classified by BIS as a mass market item under paragraph (b)(3) of Section 748.15 of the EAR).

Authorization VEU eliminates the burden on exporters and reexporters of preparing individual license applications because the export, reexport and transfer (in-country) of the

eligible items specified for each VEU may be made under general authorization instead of under individual licenses.

**Export Administration Act**

Since August 21, 2001, the Export Administration Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp., p. 783 (2002)), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended most recently by the Notice of August 8, 2013, 78 FR 49107 (August 12, 2013), has continued the EAR in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222, as amended by Executive Order 13637.

**Rulemaking Requirements**

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. This rule involves collections previously approved by the Office of Management and Budget (OMB) under Control Number 0694-0088, "Multi-Purpose Application," which carries a burden hour estimate of 43.8 minutes to prepare and submit form BIS-748; and for recordkeeping, reporting and review requirements in connection with Authorization VEU, which carries an estimated burden of 30 minutes per submission. This rule is expected to result in a decrease in license applications submitted to BIS. Total burden hours associated with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA) and OMB Control Number 0694-0088 are not expected to increase significantly as a result of this rule.

Notwithstanding any other provisions of law, no person is required to respond to, nor be subject to a penalty for failure to comply with a collection of information subject to the requirements of the PRA, unless that collection of

information displays a currently valid OMB Control Number.

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. Pursuant to the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), BIS finds good cause to waive requirements that this rule be subject to notice and the opportunity for public comment because they are unnecessary. In determining whether to grant VEU designations, a committee of U.S. Government agencies evaluates information about and commitments made by candidate companies, the nature and terms of which are set forth in 15 CFR part 748, Supplement No. 8. The criteria for evaluation by the committee are set forth in 15 CFR 748.15(a)(2).

The information, commitments, and criteria for this extensive review were all established through the notice of proposed rulemaking and public comment process (71 FR 38313 (July 6, 2006) (proposed rule), and 72 FR 33646 (June 19, 2007) (final rule)). Given the similarities between the authorizations provided under the VEU program and export licenses (as discussed further below), the publication of this information does not establish new policy. In publishing this final rule, BIS updates the address of an existing VEU and adds an eligible destination and an item to a second existing VEU. These changes have been made within the established regulatory framework of the Authorization VEU program. Further, this rule does not abridge the rights of the public or eliminate the public's option to export under any of the forms of authorization set forth in the EAR.

Publication of this rule in other than final form is unnecessary because the authorizations granted in the rule are consistent with the authorizations granted to exporters for individual licenses (and amendments or revisions thereof), which do not undergo public review. In addition, as with license applications, VEU authorization applications contain confidential business information, which is necessary for the extensive review conducted by the U.S. Government in assessing such applications. This information is extensively reviewed according to the criteria for VEU authorizations, as set out in 15 CFR 748.15(a)(2). Additionally, just as the interagency reviews license applications, the authorizations granted under the VEU program involve interagency deliberation and result from review of public and non-public sources, including licensing data, and

the measurement of such information against the VEU authorization criteria. Given the nature of the review, and in light of the parallels between the VEU application review process and the review of license applications, public comment on this authorization and subsequent amendments prior to publication is unnecessary. Moreover, because, as noted above, the criteria and process for authorizing and administering VEU's were developed with public comments, allowing additional public comment on this amendment to individual VEU authorizations, which was determined according to those criteria, is unnecessary.

Section 553(d) of the APA generally provides that rules may not take effect earlier than thirty (30) days after they are published in the **Federal Register**. BIS finds good cause to waive the 30-day delay in effectiveness under 5 U.S.C. 553(d)(3) because the delay would be contrary to the public interest. BIS is simply amending the list of VEU authorizations by adding a new end

user, consistent with established objectives and parameters administered and enforced by the responsible designated departmental representatives to the End-User Review Committee. Delaying this action's effectiveness could cause confusion regarding which facilitates and items are authorized by the U.S. Government and in turn stifle the purpose of the VEU Program. Accordingly, it is contrary to the public interest to delay this rule's effectiveness.

No other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required under the APA or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. As a result, no final regulatory flexibility analysis is required and none has been prepared.

**List of Subjects in 15 CFR Part 748**

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

Dated: May 21, 2014.

**Kevin J. Wolf**,  
*Assistant Secretary for Export Administration.*

Accordingly, part 748 of the EAR (15 CFR parts 730-774) is amended as follows:

**PART 748—[AMENDED]**

■ 1. The authority citation for 15 CFR part 748 continues to read as follows:

**Authority:** 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

■ 2. Amend Supplement No. 7 to part 748 by:

- a. Revising the the entry for “Samsung China Semiconductor Co. Ltd.” in “China (People’s Republic of)”;
- b. Revising the entry for “Semiconductor Manufacturing International Corporation” in “China (People’s Republic of)” to read as follows:

**SUPPLEMENT NO. 7 TO PART 748—AUTHORIZATION VALIDATED END-USER (VEU): LIST OF VALIDATED END-USERS, RESPECTIVE ITEMS ELIGIBLE FOR EXPORT, REEXPORT AND TRANSFER, AND ELIGIBLE DESTINATIONS**

Country	Validated end-user	Eligible items (By ECCN)	Eligible destination	Federal Register citation
<b>Nothing in this Supplement shall be deemed to supersede other provisions in the EAR, including but not limited to § 748.15(c).</b>				
	*	*	*	*
	Samsung China Semiconductor Co. Ltd	1C350.c.3, 2B350.g.3, 3A233, 3B001.a.1, 3B001.b, 3B001.c, 3B001.e, 3B001.f, 3B001.h, 3C002, 3C004, 3D002, and 3E001 (limited to “technology” for items classified under 3C002 and 3C004 and “technology” for use consistent with the International Technology Roadmap for Semiconductors process for items classified under ECCNs 3B001 and 3B002).	Samsung China Semiconductor Co. Ltd., No. 1999, North Xiaohu Road, Xi’an, China 710119.	78 FR 41291, 7/10/13. 78 FR 69535, 11/20/13. 79 FR [INSERT PAGE NUMBER], 5/29/14.
	Semiconductor Manufacturing International Corporation.	1C350.c.3, 2B350.d.2, 2B350.d.3, 2B350.g.3, 2B350.i.3, 3A233, 3B001.a, 3B001.b, 3B001.c, 3B001.e, 3B001.f, 3C001, 3C002, 3C003, 3C004, 5B002, and 5E002 (limited to “technology” according to the General Technology Note for the “production” of integrated circuits controlled by ECCN 5A002 that have been classified by BIS as eligible for License Exception ENC under paragraph (b)(2) or (b)(3) of Section 740.17 of the EAR, or classified by BIS as a mass market item under paragraph (b)(3) of Section 748.15 of the EAR).	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 (Shenzhen) Corporation, Qier Road, Export Processing Zone, Pingshan New Area, Shenzhen, China 518118.	72 FR 59164, 10/19/07. 75 FR 67029, 11/1/10. 77 FR 10953, 2/24/12. 78 FR 69535, 11/20/13. 79 FR [INSERT PAGE NUMBER], 5/29/14.
	*	*	*	*
			Semiconductor Manufacturing North China (Beijing) Corporation, No. 18 Wen Chang Road, Building 9, Beijing Economic-Technological Development Area, Beijing, China 100176.	

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 1 and 16

[Docket No. FDA–2013–N–0365]

#### Administrative Detention of Drugs Intended for Human or Animal Use

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is implementing administrative detention authority with respect to drugs intended for human or animal use as authorized by amendments made to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by the Food and Drug Administration Safety and Innovation Act (FDASIA). FDA’s administrative detention authority with respect to drugs allows FDA to better protect the integrity of the drug supply chain. Specifically, FDA is able to administratively detain drugs encountered during an inspection that an authorized FDA representative conducting an inspection has reason to believe are adulterated or misbranded. This authority is intended to protect the public by preventing distribution or subsequent use of drugs encountered during inspections that are believed to be adulterated or misbranded, until FDA has had time to consider what action it should take concerning the drugs, and to initiate legal action, if appropriate.

**DATES:** This rule is effective June 30, 2014.

**FOR FURTHER INFORMATION CONTACT:** Charlotte Hinkle, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4343, Silver Spring, MD 20993–0002, 301–796–5300, [FDASIAImplementationORA@fda.hhs.gov](mailto:FDASIAImplementationORA@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### Executive Summary

##### *Purpose of the Regulatory Action*

FDA’s administrative detention authority with respect to drugs intended for human or animal use allows FDA to better protect the integrity of the drug supply chain. Specifically, administrative detention is intended to protect the public by preventing

distribution or subsequent use of drugs encountered during inspections that may be adulterated or misbranded, until FDA has had time to consider what action it should take concerning the drugs, and to initiate legal action, if appropriate. FDA already has the authority to administratively detain devices, tobacco, and foods that FDA has reason to believe are adulterated or misbranded.

FDA is issuing this final rule under section 304(g) of the FD&C Act (21 U.S.C. 334(g)), as amended by section 709 of FDASIA, and section 701 of the FD&C Act (21 U.S.C. 371). Section 304(g) of the FD&C Act also authorizes FDA to administratively detain devices and tobacco products.

#### Summary of the Major Provisions

This final rule implements a regulation for the administrative detention of drugs. FDA is amending parts 1 and 16 (21 CFR parts 1 and 16) to create an implementing rule for this authority. The changes set forth the procedures for detention of drugs believed to be adulterated or misbranded and amend the scope of FDA’s part 16 regulatory hearing procedures to include the administrative detention of drugs.

#### Costs and Benefits

The primary public health benefits from adoption of the final rule would be the value of the illnesses or deaths prevented because the Agency administratively detained a drug it has reason to believe is adulterated or misbranded; this benefit occurs only if the drug would not have been prevented from entering the market using one of the Agency’s other enforcement tools. The estimated primary costs to FDA include marking or labeling the detained product and costs associated with appeals of detention orders. The Agency estimates the net annual social costs to be between \$0 and \$602,602.

#### I. Background

In the **Federal Register** of July 15, 2013 (78 FR 42381), FDA proposed regulations to implement its new authority to administratively detain drugs that an authorized FDA representative conducting an inspection under section 704 of the FD&C Act (21 U.S.C. 374) has reason to believe are adulterated or misbranded. As discussed in the preamble to the proposed rule, on July 9, 2012, President Obama signed into law FDASIA (Public Law 112–144). Title VII of FDASIA provides FDA with important new authorities to help it better protect the integrity of the drug

supply chain. One of those new authorities is section 709, which amends section 304(g) of the FD&C Act to provide FDA with administrative detention authority with respect to drugs. Section 304(g) of the FD&C Act, as amended by FDASIA, provides FDA the same authority to detain drugs that section 304(g) already provides FDA with respect to devices and tobacco products. Once these implementing regulations with respect to drugs take effect, the amendments to section 304(g) of the FD&C Act will allow FDA to administratively detain drugs that an authorized FDA representative conducting an inspection under section 704 of the FD&C Act has reason to believe are adulterated or misbranded, until FDA has had time to consider what action it should take concerning the drugs, and to initiate legal action, if appropriate.

#### II. Overview of the Final Rule Including Changes to the Proposed Rule

##### A. Revisions to Part 1

FDA is amending title 21 of the Code of Federal Regulations, part 1 to create an implementing regulation for the administrative detention of drugs. The amendment to part 1 consists of one section, § 1.980, under a new subpart, which is titled “Subpart Q—Administrative Detention of Drugs Intended for Human or Animal Use.” Section 1.980 sets forth the procedures for the administrative detention of drugs encountered during an inspection that are believed to be adulterated or misbranded. The new regulation is closely modeled on the current regulation for the administrative detention of devices (21 CFR 800.55). There are minor differences from the device regulation, including updates to statutory references to refer to drugs instead of devices and changes to language to conform to current **Federal Register** requirements. Since FDA issued the proposed rule on administrative detention of drugs, FDA has issued other regulations in part 1, requiring reassignment of the section number within part 1. No other changes have been made to the substance of the proposed regulation. Other than renumbering the section, FDA is finalizing the implementing regulations as proposed.

##### B. Revisions to Part 16

The amendment to part 16 is a technical change. This change amends a statement in § 16.1 so that the scope of part 16 regulatory hearing procedures also will include administrative