

3 CFR, 2001 Comp., p. 783; Notice of August 12, 2011, 76 FR 50661 (August 16, 2011).

PART 760—[AMENDED]

- 18. The authority citation for 15 CFR part 760 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2011, 76 FR 50661 (August 16, 2011).

PART 762—[AMENDED]

- 19. The authority citation for 15 CFR part 762 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2011, 76 FR 50661 (August 16, 2011).

PART 764—[AMENDED]

- 20. The authority citation for 15 CFR part 764 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2011, 76 FR 50661 (August 16, 2011).

PART 766—[AMENDED]

- 21. The authority citation for 15 CFR part 766 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2011, 76 FR 50661 (August 16, 2011).

PART 768—[AMENDED]

- 22. The authority citation for 15 CFR part 768 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2011, 76 FR 50661 (August 16, 2011).

PART 770—[AMENDED]

- 23. The authority citation for 15 CFR part 770 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2011, 76 FR 50661 (August 16, 2011).

PART 772—[AMENDED]

- 24. The authority citation for 15 CFR part 772 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2011, 76 FR 50661 (August 16, 2011).

PART 774—[AMENDED]

- 25. The authority citation for 15 CFR part 774 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C.

7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; 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 12, 2011, 76 FR 50661 (August 16, 2011).

Dated: September 15, 2011.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2011-24227 Filed 9-20-11; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 743, 748, 772, and 774

[Docket No. 100325169-0629-01]

RIN 0694-AE90

Editorial Correction to the Export Administration Regulations

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This final rule corrects reference and typographical errors in the Export Administration Regulations (EAR). The corrections are editorial in nature and do not affect license requirements. In addition to the editorial corrections, this rule adds new definitions to the EAR that were inadvertently not incorporated by a previous rule.

DATES: Effective on September 21, 2011.

FOR FURTHER INFORMATION CONTACT: Sharron Cook, Office of Exporter Services, Bureau of Industry and Security, by telephone (202) 482-4890 or e-mail: Sharron.cook@bis.doc.gov.

SUPPLEMENTARY INFORMATION: This final rule updates five parts of the EAR and two categories of the Commerce Control List (CCL). Three parts of the EAR are updated to correct internal references and subsection designations, and the supplement to another part is updated to provide a complete and more accurate description of controls and the related items on the CCL. In addition, this rule adds definitions to another part of the EAR to harmonize it with the Wassenaar Arrangement on Export Controls for Conventional Arms and Dual-Use Goods and Technologies.

Part 743

This document revises a paragraph designation in the final rule that was published by BIS on May 22, 2009 (74

FR 23941, 23947). More specifically, the last paragraph of Section 743.3 was designated inconsistent with the section's alphabetical order. To use the appropriate alphabetical designation, this document redesignates the last paragraph (d) in Section 743.3 as (f). This change ensures that all relevant paragraphs in Section 743.3 are properly and consistently designated.

Part 748

This document revises the designation of a subparagraph in the final rule that was published by BIS on March 25, 1996 (61 FR 12812, 12829). The March 25, 1996 rule redesignated some paragraphs in Supplement No. 5 to part 748, but failed to redesignate the paragraph following (a)(6)(vi)(B)(2), which is designated (iii), as (a)(6)(vi)(C). This rule provides the correct designation, thereby ensuring that all relevant paragraphs in Supplement No. 5 to Part 748 are properly designated.

Part 772

This final rule adds two definitions to part 772 of the EAR to harmonize with definitions found in the list of terms that accompanies the Wassenaar Arrangement list of dual-use items and to ensure consistency within the EAR where these definitions are used. More specifically, the two definitions, "Communications Channel Controller" and "Network Access Controller" are added to Category 4 of the CCL. The addition of the terms to part 772 will ensure consistency.

Supplement No. 1 to Part 774

This rule revises entries on the CCL to provide a complete and more accurate description of controls in certain Export Control Classification Numbers (ECCNs). Specific amendments applying to ECCNs 3A001 and Notes of Category 5 part 2 of the CCL are described below.

Category 3 Electronics

ECCN 3A001.g is amended by adding a Technical Note that was removed on October 14, 2009.

Category 5, Part 2 Information Security

The introductory section of this Category is amended by adding "Technical Note: Parity bits are not included in the key length," because this Note was inadvertently removed from its previous place within ECCN 5A002. However, to remain consistent with the Wassenaar Arrangement and because this note regarding parity bits applies to all Category 5, part 2 ECCNs, BIS is including the additional language

at the end of the Notes that appear before the beginning of 5A002.

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, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a “not significant regulatory action,” under section 3(f) of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information, subject to the requirements of Paperwork Reduction Act, unless that collection of information displays a currently valid Office of Management and Budget Control Number. This rule does not affect any paperwork collection. This rule does not contain policies with Federalism implications as that term is defined under E.O. 13132.

3. The Department finds that there is good cause under 5 U.S.C. 553(b)(3)(B) to waive the provisions of the Administrative Procedure Act requiring prior notice and the opportunity for public comment because they are unnecessary. The revisions made by this rule are administrative in nature and do not affect the rights and obligations of the public. Because these revisions are not substantive changes to the EAR, it is unnecessary to provide notice and opportunity for public comment. In addition, the 30-day delay in effectiveness required by 5 U.S.C. 553(d) is not applicable because this rule is not a substantive rule. No other law requires that a notice of proposed rulemaking and opportunity for public comment be given for this rule. The analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable.

List of Subjects

CFR Part 743

Administrative practice and procedure, Reporting and recordkeeping requirements.

CFR Part 748

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

CFR Part 772

Exports.

CFR Part 774

Exports, Reporting and recordkeeping requirements.

Accordingly, parts 743, 748, 772 and 774 of the EAR (15 CFR parts 730–774) are amended as follows:

PART 743—[AMENDED]

■ 3. The authority citation for part 743 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2011, 76 FR 50661 (August 16, 2011).

■ 4. Section 743.3 is amended by redesignating paragraph (d) following paragraph (e) as paragraph (f).

PART 748—[AMENDED]

■ 5. The authority citation for 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 12, 2011, 76 FR 50661 (August 16, 2011).

Supplement No. 5 to Part 748—[Amended]

■ 6. Supplement No. 5 to part 748 is amended by redesignating paragraph (iii) that follows paragraph (a)(6)(vi)(B)(2) as paragraph (a)(6)(vi)(C).

Part 772—[AMENDED]

■ 7. The authority citation for part 772 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2011, 76 FR 50661 (August 16, 2011).

■ 8. Section 772.1 is amended by adding the definitions “Communications Channel Controller” and “Network Access Controller” in alphabetical order to read as follows:

§ 772.1 Definitions of terms as used in the Export Administration Regulations (EAR).

* * * * *

Communications Channel Controller. (Cat 4)—The physical interface which controls the flow of synchronous or asynchronous digital information. It is an assembly that can be integrated into computer or telecommunications equipment to provide communications access.

* * * * *

Network Access Controller. (Cat 4)—A physical interface to a distributed

switching network. It uses a common medium which operates throughout at the same “digital transfer rate” using arbitration (*e.g.*, token or carrier sense) for transmission. Independently from any other, it selects data packets or data groups (*e.g.*, IEEE 802) addressed to it. It is an assembly that can be integrated into computer or telecommunications equipment to provide communications access.

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Part 774—[AMENDED]

■ 9. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; 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 12, 2011, 76 FR 50661 (August 16, 2011).

■ 10. In Supplement No. 1 to part 774 (the Commerce Control List), Category 3 Electronics, ECCN 3A001 is amended by adding a technical note after the Note 2 of paragraph g.2.b in the Items paragraph of the List of Items Controlled section to read as follows:

Supplement No. 1 to Part 774—Commerce Control List

* * * * *

3A001 Electronic components and specially designed components therefor, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

* * * * *

Items:

* * * * *

g. * * *
g.2. * * *
g.2.b. * * *

Technical Note: For the purposes of 3A001.g, a “thyristor module” contains one or more thyristor devices.

* * * * *

■ 11. In Supplement No. 1 to part 774 (the Commerce Control List), Category 5, Telecommunications and “Information Security,” Part II Information Security, is amended by adding a Technical Note to the end of the notes appearing at the beginning of the Category, to read as follows:

Category 5—Telecommunications and “Information Security”

Part II. “Information Security”

* * * * *

Technical Note: Parity bits are not included in the key length.

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Dated: September 15, 2011.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2011-24229 Filed 9-20-11; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2011-D-0633]

Revised Guidance on Marketed Unapproved Drugs; Compliance Policy Guide Sec. 440.100; Marketed New Drugs Without Approved NDAs or ANDAs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of compliance policy guide.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance entitled “Marketed Unapproved Drugs—Compliance Policy Guide Sec. 440.100, Marketed New Drugs Without Approved NDAs or ANDAs” (CPG 440.100). CPG 440.100 describes how FDA intends to exercise its enforcement discretion with regard to drug products marketed in the United States that do not have required FDA approval for marketing. CPG 440.100 has been revised to state that the enforcement priorities and potential exercise of enforcement discretion discussed in the CPG apply only to unapproved new drug products that are being commercially used or sold as of September 19, 2011. All unapproved new drugs introduced onto the market after that date are subject to immediate enforcement action at any time, without prior notice and without regard to the enforcement priorities set forth in CPG 440.100.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your

requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Sakineh Walther, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5242, Silver Spring, MD 20993-0002, 301-796-3349.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised guidance entitled “Marketed Unapproved Drugs—Compliance Policy Guide Sec. 440.100, Marketed New Drugs Without Approved NDAs or ANDAs”. This CPG is being issued consistent with FDA’s good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). This CPG is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). The Agency made this determination because, in light of the fact that revised CPG 440.100 establishes the date after which the enforcement priorities and potential exercise of enforcement discretion discussed in it do not apply to newly introduced unapproved drugs, delayed implementation of revised CPG 440.100 would provide an incentive for manufacturers to rush new unapproved drugs to market during the comment and finalization period, in order to be subject to enforcement priorities that may be perceived as more advantageous to extended marketing of illegal, unapproved drug products. The potential increase in marketing of new unapproved drugs raises public health concerns; because unapproved drug products have not been approved by FDA for safety, effectiveness, and quality, patients may be at greater risk when using unapproved drug products than when using FDA-approved drug products. In light of the concerns about potential increased marketing of new unapproved drugs, FDA has determined that it is not appropriate to seek comment before implementing revised CPG 440.100. Although CPG 440.100 is immediately in effect, it remains subject to comment in accordance with the Agency’s GGP regulation.

Under the Federal Food, Drug, and Cosmetic Act, drug products that require approval must obtain that approval prior to introduction into interstate commerce (*see* 21 U.S.C. 355). Manufacturers and distributors of products that enter the market without complying with these long-standing statutory requirements are acting in violation of the law. In June 2006, FDA announced a new drug safety initiative to remove unapproved drugs from the market. As part of the Unapproved Drugs Initiative, FDA issued a final CPG entitled “Marketed Unapproved Drugs—Compliance Policy Guide Sec. 440.100, Marketed New Drugs Without Approved NDAs or ANDAs” (CPG 440.100) (*see* 71 FR 33466, June 9, 2006). CPG 440.100 describes how FDA intends to exercise its enforcement discretion regarding currently marketed unapproved new drugs. CPG 440.100 describes six categories of unapproved drug products that are the Agency’s highest enforcement priorities, and the circumstances in which the Agency intends to bring enforcement actions consistent with those priorities. FDA has initiated 17 actions against unapproved new drugs under the Unapproved Drugs Initiative and engaged in significant outreach to manufacturers, distributors, consumers and prescribers under this Initiative, resulting in the removal of over a thousand unapproved new drugs from the market (*see* <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm238675.htm>).

Despite both the long-standing statutory requirement that new drugs must obtain approval prior to marketing (21 U.S.C. 355) and FDA’s outreach efforts under the Marketed Unapproved Drugs Initiative, FDA is aware that unapproved new drugs have continued to come onto the market after the issuance of the 2006 CPG. In some cases, these unapproved new drugs come onto the market to compete with other unapproved new drugs that are already on the market. In other cases, unapproved new drugs are introduced to the market when a manufacturer perceives that there may be an “opportunity” to gain a share of the market after actions taken by FDA, including enforcement actions that remove similar unapproved new drugs from the market. In either case, FDA must expend additional scarce resources to address unapproved products in situations where manufacturers and distributors have had ample notice that the products they are introducing onto