

329–4090; email: karl.schletzbaum@faa.gov. Before using any approved AMOC on any balloon to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product*: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements*: For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(h) Special Flight Permit

Special flight permits are prohibited.

(i) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No. 2016–0151, dated July 26, 2016, for related information. You may examine the MCAI on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2016–8989.

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on August 29, 2016 (81 FR 57449, August 23, 2016).

(i) BALÓNY KUBÍČEK spol. s r.o. Service Bulletin No. BB/50, BB–S/11, AB24 rev.1, dated May 12, 2016.

(ii) Reserved.

(4) For BALÓNY KUBÍČEK spol. s r.o. service information identified in this AD, contact BALÓNY KUBÍČEK spol. s r. o., Jarní 2a, 614 00 Brno, Czech Republic, telephone: +420 545 422 620; fax: +420 545 422 621; email: info@kubicekballoons.cz. Internet: <http://www.kubicekballoons.eu>.

(5) You may view this service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For

information on the availability of this material at the FAA, call (816) 329–4148. It is also available on the Internet at <http://www.regulations.gov> by searching for locating Docket No. FAA–2016–8989.

(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Kansas City, Missouri, on August 30, 2016.

Pat Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–21409 Filed 9–2–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 748

[Docket No. 160810722–6722–01]

RIN 0694–AH05

Amendments to Existing Validated End-User Authorization in the People's Republic of China: Boeing Tianjin Composites Co. Ltd.

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 the existing Validated End-User (VEU) list for the People's Republic of China (PRC) by updating the list of eligible destinations (facilities) for VEU Boeing Tianjin Composites Co. Ltd. (BTC). Specifically, BIS amends supplement No. 7 to part 748 of the EAR to change the written address of BTC's existing facility. The physical location of the facility has not changed. BIS updated the facility address after receiving notification of the change from BTC. The End-User Review Committee reviewed and authorized the amendment in accordance with established procedures. The updated address contributes to maintaining accurate location information for BTC's VEU.

DATES: This rule is effective September 6, 2016.

FOR FURTHER INFORMATION CONTACT:

Chair, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, U.S. Department of Commerce,

Phone: 202–482–5991; Email: 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 (facilities) and items are identified in supplement No. 7 to part 748 of the EAR. Under the terms described in that supplement, VEUs may obtain eligible items without an export license from BIS, in conformity with § 748.15 of the EAR. Eligible items vary between VEUs and 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 § 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, 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.

Amendment to Existing VEU Authorization for Boeing Tianjin Composites Co. Ltd. (BTC) in the People's Republic of China

Revision to the List of "Eligible Destinations" for BTC

In this rule, BIS amends supplement No. 7 to part 748 to revise BTC's VEU authorization. Specifically, in this rule, BIS updates the written address of BTC's facility in the People's Republic of China to which the company's eligible items may be exported, reexported or transferred (in-country). The physical location of the facility has not changed.

The amendment to the address of BTC's facility is in response to a request from BTC. This amendment was approved by the ERC. The revision is as follows:

Revision to Address of BTC's Eligible Destination (Facility)

Current address: Boeing Tianjin Composites Co. Ltd., No. 4-388 Hebei Road, Tanggu Tianjin, China.

New address: Boeing Tianjin Composites Co. Ltd., 4566 Hebei Road, Marine Hi-Tech Development Area, Tanggu District, Tianjin, China 300451.

Export Administration Act

Although the Export Administration Act expired on August 20, 2001, 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 by the Notice of August 4, 2016, 81 FR 52587 (August 8, 2016), has continued the Export Administration Regulations 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 the otherwise applicable requirement that this rule be subject to notice and the opportunity for public comment because it is 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 amends the authorization for an existing eligible VEU to update the address of the eligible destination (facility). This change has been made within the established regulatory framework of the 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 license applications are reviewed

through an interagency review process, 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 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**. However, BIS finds good cause to waive the 30-day delay in effectiveness for this rule pursuant to 5 U.S.C. 553(d)(3) because the delay would be contrary to the public interest. BIS is simply amending the authorization of an existing VEU to update the address of the eligible destination (facility). BIS amends the EAR in this rule 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 would likely cause confusion regarding which items are authorized by the U.S. Government to be shipped to which eligible destination (facility), which would 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.

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

PART 748—[AMENDED]

- 1. The authority citation for part 748 continues to read as follows:

Authority: 50 U.S.C. 4601 *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 4, 2016, 81 FR 52587 (August 8, 2016).

- 2. Amend supplement No. 7 to part 748 by revising the entry for “Boeing Tianjin Composites Co. Ltd.” 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
Nothing in this Supplement shall be deemed to supersede other provisions in the EAR, including but not limited to § 748.15(c).				
*	*	*	*	*
	Boeing Tianjin Composites Co. Ltd.	1B001.f, 1D001 (limited to “software” specially designed or modified for the “use” of equipment controlled by 1B001.f), 2B001.b.2 (limited to machine tools with accuracies no better than (<i>i.e.</i> , not less than) 13 microns), 2D001 (limited to “software,” other than that controlled by 2D002, specially designed or modified for the “use” of equipment controlled by 2B001.b.2), and 2D002 (limited to “software” for electronic devices, even when residing in an electronic device or system, enabling such devices or systems to function as a “numerical control” unit, capable of coordinating simultaneously more than 4 axes for “contouring control” controlled by 2B001.b.2).	Boeing Tianjin Composites Co. Ltd., 4566 Hebei Road, Marine Hi-Tech Development Area, Tanggu District, Tianjin, China 300451.	72 FR 59164, 10/19/07. 74 FR 19382, 4/29/09. 77 FR 10953, 2/24/12. 77 FR 40258, 7/9/12. 81 FR [INSERT PAGE NUMBER], September 6, 2016.
*	*	*	*	*

Dated: August 30, 2016.

Kevin J. Wolf,
Assistant Secretary for Export Administration.

[FR Doc. 2016-21333 Filed 9-2-16; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. FDA-1975-N-0012; Formerly Part of Docket No. 1975N-0183H]

RIN 0910-AF69

Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is issuing this final rule establishing that certain active ingredients used in over-the-counter (OTC) consumer antiseptic products intended for use with water (referred to throughout this document as consumer

antiseptic washes) are not generally recognized as safe and effective (GRAS/GRAE) and are misbranded. FDA is issuing this final rule after considering the recommendations of the Nonprescription Drugs Advisory Committee (NDAC); public comments on the Agency’s notices of proposed rulemaking; and all data and information on OTC consumer antiseptic wash products that have come to the Agency’s attention. This final rule amends the 1994 tentative final monograph (TFM) for OTC antiseptic drug products that published in the **Federal Register** of June 17, 1994 (the 1994 TFM). The final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES: This rule is effective September 6, 2017.

ADDRESSES: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule into the “Search” box and follow the prompts, and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Pranvera Ikonomi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 22, Rm. 5418, Silver Spring, MD 20993-0002, 240-402-0272.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Introduction
 - A. Terminology Used in the OTC Drug Review Regulations
 - B. Topical Antiseptics
 - C. This Final Rule Covers Only Consumer Antiseptic Washes
- II. Background
 - A. Significant Rulemakings Relevant to This Final Rule
 - B. Public Meetings Relevant to This Final Rule
 - C. Scope of This Final Rule
 - D. Eligibility for the OTC Drug Review
- III. Comments on the Proposed Rule and FDA Response
 - A. Introduction
 - B. Description of General Comments and FDA Response
 - C. Comments on Effectiveness and FDA Response
 - D. Comments on Safety and FDA Response
 - E. Comments on Individual Active Ingredients and FDA Response
 - F. Comments on the Preliminary Regulatory Impact Analysis and FDA Response
- IV. Ingredients Not Generally Recognized as Safe and Effective
- V. Effective Date
- VI. Summary of Regulatory Impact Analysis
 - A. Introduction
 - B. Summary of Costs and Benefits
- VII. Paperwork Reduction Act of 1995