once in the last 3 years and prior to the planting of the potatoes or root crops;

(ii) Pale cyst nematode has not been found in the field; and

(iii) No more than one pale cyst nematode host crop, as listed in § 301.86–2(b), has been grown in the field in the last 3 years.

Done in Washington, DC, this 23rd day of April 2009.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E9–9724 Filed 4–28–09; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 748

[Docket No. 090415662–9687–01]

RIN 0694–AE61

Additions and Revisions to the List of Approved End-Users and Respective Eligible Items for the People's Republic of China (PRC) Under Authorization Validated End-User (VEU)

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: In this final rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to add a name to the list of end-users for the People's Republic of China (PRC) approved to receive exports, reexports and transfers of certain items under Authorization Validated End-User (VEU). This rule also amends the EAR to add and revise eligible items and destinations for existing VEU authorizations. Specifically, this rule amends the EAR to authorize one additional VEU and identify its respective eligible items for export and reexport to the PRC. This rule also amends the authorizations of two pre-existing VEUs in the PRC. Finally, this rule makes a modification to the listed name of an existing VEU in the PRC. In a final rule published in the **Federal Register** on June 19, 2007, BIS revised and clarified U.S. export control policy for the PRC, establishing Authorization VEU and identifying the PRC as the initial eligible destination. In a final rule published in the **Federal Register** on October 19, 2007, BIS published the names of the first five validated end-users in the PRC that were approved to receive certain specified items under Authorization VEU.

DATES: This rule is effective April 29, 2009. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis.

ADDRESSES: You may submit comments, identified by RIN 0694–AE61 (VEUPRCADE), by any of the following methods:

E-mail: publiccomments@bis.doc.gov. Include ''RIN 0694–AE61 (VEUPRCADE)'' in the subject line of the message.

Fax: (202) 482–3355. Please alert the Regulatory Policy Division, by calling (202) 482–2440, if you are faxing comments.

Mail or Hand Delivery/Courier: Sheila Quarterman, U.S. Department of Commerce, Bureau of Industry and Security, Regulatory Policy Division, 14th Street & Pennsylvania Avenue, NW., Room 2705, Washington, DC 20230, Attn: RIN 0694–AE61 (VEUPRCADE).

Send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden to Jasmeet Seehra, Office of Management and Budget (OMB), by e-mail to *jseehra@omb.eop.gov* or by fax to (202) 395–7285. Comments on this collection of information should be submitted separately from comments on the final rule (*i.e.,* RIN 0694–AE61 (VEUPRCADE))—all comments on the latter should be submitted by one of the three methods outlined above.

FOR FURTHER INFORMATION CONTACT: Karen Nies-Vogel, Chairman, 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) 482–3811, or by e-mail to *kniesv@bis.doc.gov*.

SUPPLEMENTARY INFORMATION:

Background

Authorization Validated End-User (VEU): Additions and Modifications to the List of Approved End-Users, Eligible Items and Destinations

Consistent with U.S. Government policy to facilitate trade for civilian end-users in the PRC, BIS amended the EAR in a final rule on June 19, 2007 (72 FR 33646) by creating a new authorization for ''validated end-users'' (VEUs) located in eligible destinations to which eligible items (commodities, software and technology, except those controlled for missile technology or crime control reasons) may be exported, reexported or transferred under a general authorization instead of a license, in conformance with Section 748.15 of the EAR.

Authorization VEU is a mechanism to facilitate increased high-technology exports to companies in the PRC and India that have a record of using such items responsibly. VEUs may obtain eligible items that are on the Commerce Control List without having to wait for their suppliers to obtain export licenses from BIS. A wide range of items are eligible for shipment under Authorization VEU. In addition to U.S. exporters, Authorization VEU may be used by foreign reexporters, and does not have an expiration date.

Additional VEUs in the PRC and Their Respective ''Eligible Items (By ECCN)'' and ''Eligible Destinations''

This final rule amends Supplement No. 7 to Part 748 of the EAR to identify an additional company with eligible facilities in the PRC as a VEU and to identify the items that may be exported, reexported or transferred to it under Authorization VEU. This new entry is for Aviza Technology China. It lists Export Control Classification Numbers (ECCNs) 2B230, 3B001.c.1.a and 3B001.e under ''Eligible Items (By ECCN),'' and includes the following facility names and addresses under ''Eligible Destination:''

Aviza Technology China, Room B–1501, No. 188, Tomson Center, Zhang Yang Road, Shanghai, China 200122.

Aviza Technology China, Room 612, International Business Center, No. 18, Hong Da North Road, Beijing Economics and Technology Development Area, Beijing, China.

Beijing Bonded: CIES, Electronics Building, A23, Fuxing Road, Beijing, China 100036.

Shanghai Bonded: SLC, Shanghai Industrial-Wailianfa International Logistics Co., Ltd., Address: 13F Waigaoqiao Building, 889 Yang Gao Road(N), Pudong, Shanghai, China.

HMG Logistics (Chengdu) Co., Ltd., Floor 1, No. 5 Standard Warehouse, EPZ (West Area), Chengdu, China 611731.

Modifications to Existing VEU Authorizations

This final rule also amends Supplement No. 7 to Part 748 of the EAR to implement requests received from existing VEUs for modifications in their authorizations to include additional eligible items and additional destinations, and to list a change of name for an existing VEU. Specifically, this rule makes the following amendments to Supplement No. 7 to Part 748:

(1) The authorization for Applied Materials China, Ltd. now also includes ECCN 2B006.b.1.a under ''Eligible Items (By ECCN)'' and the following facility name and address under ''Eligible Destination:'' Applied Materials (Xi'an Ltd.), No. 28 Xin Xi Ave., Xi'an High Tech Park, Export Processing Zone, Xi'an Shanxi, China 710075.

(2) Based upon notification from existing VEU BHA Aerocomposite Parts Co., Ltd. that the company's name has legally been changed, the name ''BHA Aerocomposite Parts Co., Ltd.'' shown in Supplement No. 7 to Part 748 of the EAR prior to this rule has been changed to ''Boeing Tianjin Composites Co. Ltd.,'' under both the ''Validated End-User'' and ''Eligible Destination'' columns. Further, the authorization for Boeing Tianjin Composites Co. Ltd., formerly BHA Aerocomposite Parts Co., Ltd., now also includes ECCN 2B001.b.2 (limited to machine tools with accuracies no better than (*i.e.,* less than) 13 microns), and replaces ECCN 2B001.e.1.a. with 2B001.e. under ''Eligible Items (By ECCN).'' ECCN 2B001.e. encompasses all parameters of its subparagraphs.

With the publication of this final rule, the total number of VEUs in the PRC is six and the total number of eligible facilities is twenty. The VEUs listed in Supplement No. 7 to Part 748 were 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.

Approving this new end-user as a VEU is expected to further facilitate exports to civil end-users in the PRC. Approval of this company also represents a significant savings of time for suppliers and end-users. Authorization VEU will eliminate the burden on exporters and reexporters of preparing license applications and on BIS for processing such applications, as exports and reexports will be made under general authorization instead of under license. This savings will enable exporters and reexporters to supply VEUs much more quickly, thus enhancing the competitiveness of the exporters, reexporters, and end-users in the PRC.

To ensure appropriate facilitation of exports and reexports, on-site reviews of the VEUs may be warranted pursuant to paragraph 748.15(a)(2) and Section 7(iv) of Supplement No. 8 to Part 748 of the EAR. If such reviews are warranted, BIS will inform the PRC Ministry of Commerce.

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 extended most recently by the Notice of July 23, 2008 (73 FR 43603, July 25, 2008), has continued the EAR in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222.

Rulemaking Requirements

1. This final rule has been determined to be not significant for the purposes of Executive Order 12866.

2. 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 Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule involves collections previously approved by the OMB under control number 0694–0088, ''Multi-Purpose Application,'' which carries a burden hour estimate of 58 minutes to prepare and submit form BIS–748; and for recordkeeping, reporting and review requirements in connection with Authorization Validated End-User, 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 and Office of Management and Budget control number 00694–0088 are not expected to increase significantly as a result of this rule.

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

4. The provisions of the Administrative Procedure Act requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (5 U.S.C. 553(a)(1)). Further, 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 to be given for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Sheila Quarterman, Regulatory Policy Division, Bureau of Industry and Security, U.S. Department of Commerce, 14th Street & Pennsylvania Avenue, NW., Room 2705, Washington, DC 20230

List of Subjects in 15 CFR Part 748

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

■ Accordingly, part 748 of the Export Administrative Regulations (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 July 23, 2008, 73 FR 43603 (July 25, 2008).

■ 2. Supplement No. 7 to Part 748 is amended by:

■ a. Revising the entry for ''Applied Materials China, Ltd.'';

■ b. Adding, in alphabetical order, an entry for ''Aviza Technology China''; and

■ c. Revising the entry for ''BHA Aerocomposite Parts Co., Ltd.''.

The revisions and addition read as follows:

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

Validated end-user	Eligible items (by ECCN)	Eligible destination
Applied Materials China, Ltd.	2B006.b.1.a; 2B230; 2B350.g.3; 3B001.b.1; 3B001.c.2; 3B001.e; 3B001.f.3; 3C001; 3C002.	Applied Materials China, Ltd.—Shanghai Depot c/o Shanghai Applied Materials Technical Service Center, 368 Zhang Jiang Road, Pudong Zhangjiang Hi-Tech Park, Shanghai, China 201203. Applied Materials China, Ltd.—Beijing Depot c/o Beijing Applied Materials Technical Service Center Bldg. 9, Area A, No. 1 North Di Sheng Street, BDA Beijing, China 100176. Applied Materials China, Ltd.—Wuxi Depot c/o Sinotrans Jiangsu Group Fuchang Co. J5 A–B Wuxi Export Processing Zone, 287 Gaolang Road, Wuxi New District, Wuxi Jiangsu China 214028. Applied Materials (Xi'an Ltd.) No. 28 Xin Xi Ave., Xi'an High Tech Park Export Processing Zone, Xi'an Shanxi, China 710075.
Aviza Technology China	2B230; 3B001.c.1.a; 3B001.e	Aviza Technology China, Room B–1501, No. 188, Tomson Center, Zhang Yang Road, Shanghai, China 200122. Aviza Technology China, Room 612, International Business Center, No. 18, Hong Da North Road, Beijing Economics and Technology Development Area, Beijing, China. Beijing Bonded: CIES, Electronics Building, A23, Fuxing Road, Beijing, China 100036. Shanghai Bonded: SLC, Shanghai Industrial—Wailianfa International Logistics Co., Ltd., Address: 13F Waigaoqiao Building 889 Yang Gao Road (N), Pudong, Shanghai, China. HMG Logistics (Chengdu) Co., Ltd., Floor 1, No. 5 Standard Warehouse, EPZ (West Area), Chengdu, China 611731.
Boeing Tianjin Composites Co. Ltd.	1A002.a; 1B001.f; 1C010.b; 1C010.e; 1D001 (limited to ''software'' specially designed or modified for the ''development'', ''production'' or ''use'' of equipment controlled by 1B001.f) 1E001 (limited to ''technology'' according to the General Technology Note for the ''development'' or ''production'' of items controlled by 1A002.a, 1B001.f, 1C010.b & .e, and 2B001.a); 2B001.b.2 (limited to machine tools with accuracies no better than (i.e., less than) 13 microns); 2B001.e; 2D001 (limited to ''software,'' other than that controlled by 2D002, specially designed or modified for the ''development'', ''production'' or ''use'' of equipment controlled by 2B001.b.2 and 2B001.e); 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 and 2B001.e).	Boeing Tianjin Composites Co. Ltd., No. 4–388 Heibei Road, Tanggu Tianjin, China.
* * * * *		* *

Dated: April 24, 2009.

Matthew S. Borman,

Acting Assistant Secretary for Export Administration.

[FR Doc. E9–9817 Filed 4–28–09; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. FDA–1977–N–0013] (formerly Docket No. 1977N–0094L)

RIN 0910–AF36

Organ-Specific Warnings; Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to require important new organ-specific warnings and related labeling for over-the-counter (OTC) internal analgesic, antipyretic, and antirheumatic (IAAA) drug products. The new labeling informs consumers about the risk of liver injury when using acetaminophen and the risk of stomach bleeding when using nonsteroidal anti-inflammatory drugs (NSAIDS). The new labeling is required for all OTC IAAA drug products whether marketed under an OTC drug monograph or an approved new drug application (NDA).

DATES: *Effective Date*: This final rule is effective April 29, 2010.

Compliance Date: The compliance date for all products subject to this final rule, including products with annual sales less than $25,000, is April 29, 2010.

FOR FURTHER INFORMATION CONTACT: Arlene Solbeck, Center for Drug Evaluation and Research , Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, MS 5411, Silver Spring, MD 20993, 301–796–2090.

SUPPLEMENTARY INFORMATION:

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Glossary

(The definitions of terms used throughout this document are included in this glossary because these terms are likely to be unfamiliar to many readers.)

AERS: FDA's Adverse Event Reporting System; a database of adverse events reported to FDA for drugs and medical devices

Acute Liver Failure: Severe liver injury without a history of chronic liver disease that is associated with coagulopathy and encephalopathy

ALT: Alanine aminotransferase; a liver enzyme that is often tested to evaluate individuals for liver disease

AST: Aspartate aminotransferase; a liver enzyme that is often tested to evaluate individuals for liver disease

CFR: The Code of Federal Regulations; list of regulations created by the executive departments and agencies of the Federal Government

GRAS/E: Generally recognized as safe and effective

GSH: Glutathione; tripeptide (protein fragment) necessary for acetaminophen metabolism to avoid accumulation of the toxic metabolite N-acetyl-p-benzo-quinone imine (NAPQI)

HIV: Human immunodeficiency virus; a retrovirus that can lead to acquired immunodeficiency syndrome (AIDS)

IAAA: Internal analgesic, antipyretic, and antirheumatic drug products

INR: International normalized ratio; measurement that evaluates the ability of blood to clot

IU/L: International units per liter

NAQPI: N-acetyl-p-benzo-quinone imine; a harmful by-product of acetaminophen metabolism that can cause severe liver injury

NDA: New Drug Application; application needed for approval of a new drug by the FDA prior U.S. marketing

NSAIDs: Nonsteroidal anti-inflammatory drugs (such as aspirin and ibuprofen)

PDP: Principal display panel; part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

I. Overview of This Document

This document addresses comments and data in the 19 submissions that we received in response to the December 26, 2006 (proposed rule) (71 FR 77314), which is described in section II of this document. The submissions comment on the labeling that we proposed for 21 CFR parts 201 and 343 as well as other issues where specific comments were sought in the 2006 proposed rule. The proposed rule asked for comments on issues related to the following:

- The safe and effective daily dose of acetaminophen
- Daily dose recommendation for alcohol abusers
- Combination products of acetaminophen combined with methionine or acetylcysteine
- Package size and configuration limitations with acetaminophen products
- Label warnings for individuals with Human Immunodeficiency Virus (HIV)
- Drug interactions between acetaminophen and warfarin

This document states our final conclusions on the labeling requirements in 21 CFR part 201 and requires that manufacturers include this labeling on their OTC IAAA drug products by the effective date identified in this document (see **DATES**). We are currently evaluating data and information regarding the remaining issues discussed in the proposed rule, some of which include the following:

- Safe daily dose for acetaminophen (healthy users)
- Safe daily dose for acetaminophen users with chronic liver disease
- Safe daily dose for acetaminophen with alcohol use
- Appropriate dosage for acetaminophen efficacy
- Package size restrictions for OTC IAAA drug products
- Pediatric dosing for OTC IAAA drug products
- Various warnings for OTC IAAA drug products that were proposed in 21 CFR part 343 but not part 21 CFR part 201
- Acetaminophen-narcotic combinations
- Combinations of acetaminophen and N-acetylcysteine (NAC) or methionine
- Prescription labeling for OTC IAAA drug products