

Newest Designation Reinforces Concerns About Validated End-User Program

June 10, 2009

Aviza Technology China is the newest Chinese company granted Validated End-User (VEU) status by the U.S. Commerce Department. This status means that the company is approved to receive certain sensitive controlled commodities from the United States without individual export licenses.¹ After a “rigorous national security review,”² Aviza can receive these items at five specified “eligible destinations” in China.³ But the attached documents show that one of these approved locations may in fact be owned by a company penalized by sanctions that the United States imposed in 2006 for proliferation to Iran and/or Syria. Other companies in China that became the first VEUs in October 2007⁴ posed a similar problem. A Wisconsin Project analysis showed that two of those five companies were linked to proliferators, to violators of U.S. export controls, and to China’s military production complex.⁵ This repeated failure of the selection process to choose “trusted” customers and locations continues to cast doubt on the wisdom of the VEU program itself.

One of the approved destinations for Aviza is “Beijing Bonded: CIES, Electronics Building, A23, Fuxing Road, Beijing, China 100036.”⁶ This is a warehouse owned by CIES,⁷ until recently a wholly-owned subsidiary company of China National Electronics Import and Export Corporation (CEIEC).⁸ And CEIEC is a state-owned firm that was under State Department sanctions (along with all of its subsidiaries) from December 2006 until December 2008.⁹ The Wisconsin Project’s original VEU analysis discussed at length the diversion and proliferation risks posed by CEIEC, including with respect to nuclear-usable pressure transducers (ECCN 2B230)¹⁰ – which are now eligible for shipment to the CIES warehouse without prior U.S. government scrutiny.¹¹ Responding to queries from U.S. customers after the sanctions were imposed, CIES claimed that in 2005 it underwent restructuring and formally changed its name from “CEIEC International Electronics Service Company” to “China International Electronics Service Co., Ltd. (CIES).”¹² CIES claimed that after this change it was no longer a subsidiary of CEIEC, and had “no relationship” with its former parent company, so the U.S. sanctions “should not include” it.¹³ However, the Wisconsin Project has discovered evidence that suggests a continuing relationship between the “eligible destination” warehouse owner CIES and the proliferator CEIEC.

At least 70 shipments from “CEIEC International Electronics Service Company” arrived in the United States in 2008. And such shipments continued to arrive in 2009, even though a company with that name is no longer supposed to exist.¹⁴ In fact, a search of bills of lading shows that as many shipments arrived in 2008 under the name of the supposedly-defunct predecessor company (“CEIEC International Electronics Service Company”) as did bearing the name of the successor company (“China International Electronics Service Co., Ltd.”).¹⁵ And all of these shipments give the same company address, “Electronics Building, A23, Fuxing Road, Beijing, China 100036” -- the address that has now been declared an approved destination by the Commerce Department.¹⁶ It appears that CIES continues to identify itself either as part of CEIEC or as related to it in some way.

Furthermore, the approval by the Commerce Department of this specific address is also problematic because the address is used by the recently sanctioned CEIEC itself,¹⁷ including its defense electronics department.¹⁸ The address, therefore, simultaneously qualifies as a “red flag” (for military and proliferation concerns) and a “trusted” location. This could lead to confusion among U.S. exporters.

These findings pose serious questions that the Commerce Department must answer:

- Who controls CIES, the owner of the “eligible destination” warehouse? CIES claims that it is now owned privately by nine shareholders, rather than by CEIEC.¹⁹ But who are these shareholders, and do they have

connections to CEIEC? If not, why does CIES continue to use its previous name (including “CEIEC”) on bills of lading?

- How can this warehouse be considered a safe destination, free from diversion risk, if it is in the building where CEIEC and its defense electronics department have their headquarters?
- How will the Commerce Department ensure that the “eligible destination” warehouse is not accessible to individuals (current or former employees of CEIEC and its subsidiaries) who were involved in the proliferation practices for which CEIEC was sanctioned, or may pose a risk of such involvement in the future?

¹ “New BIS Program Changes Export Rules on Targeted Products for Select Companies in China,” U.S. Department of Commerce, Bureau of Industry and Security, <http://www.bis.doc.gov/news/2007/china10182007.htm>, accessed on June 8, 2009.

² “BIS Announces Modifications, Additions, to Validated End-User Program,” Department of Commerce, Bureau of Industry and Security, April 29, 2009, available at http://www.bis.doc.gov/news/2009/bis_press04292009.htm, accessed on June 8, 2009.

³ “Additions and Revision 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),” Department of Commerce, Bureau of Industry and Security, Federal Register Vol. 74, No. 81, pp. 19382-19385, April 29, 2009 (attached).

⁴ “New BIS Program Changes Export Rules on Targeted Products for Select Companies in China,” U.S. Department of Commerce, Bureau of Industry and Security, <http://www.bis.doc.gov/news/2007/china10182007.htm>, accessed on June 8, 2009.

⁵ Wisconsin Project on Nuclear Arms Control, “In China We Trust?” available at <http://www.wisconsinproject.org/pubs/reports/2007/inchinawetrust.pdf>.

⁶ “Additions and Revision 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),” Department of Commerce, Bureau of Industry and Security, Federal Register Vol. 74, No. 81, pp. 19382-19385, April 29, 2009 (attached).

⁷ Company Introduction, China International Electronics Service Co., Ltd. World Wide Web site, <http://www.cies.com.cn/index-e.htm>, accessed on May 5, 2009.

⁸ “Explanations on the Sanctions by US Government to CEIEC,” China International Electronics Service Co., Ltd. World Wide Web site, <http://www.cies.com.cn/zysm.htm>, accessed on May 22, 2009 (attached).

⁹ “Imposition of Nonproliferation Measures Against Foreign Persons, Including a Ban on U.S. Government Procurement,” Department of State, Bureau of International Security and Nonproliferation, Federal Register Vol. 72, No. 3, p. 606, January 5, 2007 (attached).

¹⁰ Wisconsin Project on Nuclear Arms Control, “In China We Trust?” pp. 7-8, available at <http://www.wisconsinproject.org/pubs/reports/2007/inchinawetrust.pdf>.

¹¹ “Additions and Revision 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),” Department of Commerce, Bureau of Industry and Security, Federal Register Vol. 74, No. 81, pp. 19382-19385, April 29, 2009 (attached). Also eligible is equipment for the manufacturing of semiconductor devices or materials: anisotropic plasma dry etching equipment (ECCN 3B001.c.1.a) and automatic loading multi-chamber central wafer handling systems (ECCN 3B001.e).

¹² “Explanations on the Sanctions by US Government to CEIEC,” China International Electronics Service Co., Ltd. World Wide Web site, <http://www.cies.com.cn/zysm.htm>, accessed on May 22, 2009.

¹³ “Explanations on the Sanctions by US Government to CEIEC,” China International Electronics Service Co., Ltd. World Wide Web site, <http://www.cies.com.cn/zysm.htm>, accessed on May 22, 2009.

¹⁴ See attached sampling of bills of lading from 2007-2009.

¹⁵ This comparison is based on bill of lading searches for “CEIEC International Electronics Service” and “China International Electronics Service.”

¹⁶ “Additions and Revision 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),” Department of Commerce, Bureau of Industry and Security, Federal Register Vol. 74, No. 81, pp. 19382-19385, April 29, 2009; see also attached bills of lading.

¹⁷ Contact: World Trade, China National Electronics Import and Export Corporation World Wide Web site, <http://www.ceiec.com.cn/english/type/dept.aspx?code=07004>, accessed on June 8, 2009; Contact: System & Equipment, China National Electronics Import and Export Corporation World Wide Web site, <http://www.ceiec.com.cn/english/type/dept.aspx?code=03003>, accessed on June 8, 2009.

¹⁸ Contact List, Defence Electronics Department of CEIEC, China National Electronics Import & Export Corporation World Wide Web site, <http://www.ceiec.com.cn/english/type/dept.aspx?code=02003>, accessed on May 20, 2009.

¹⁹ “Explanations on the Sanctions by US Government to CEIEC,” China International Electronics Service Co., Ltd. World Wide Web site, <http://www.cies.com.cn/zysm.htm>, accessed on May 22, 2009.

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 (VEUPRCAD E), by any of the following methods:

E-mail: publiccomments@bis.doc.gov. Include "RIN 0694–AE61 (VEUPRCAD E)" 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 (VEUPRCAD E).

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 (VEUPRCAD E))—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.	<p>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.</p> <p>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.</p> <p>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.</p> <p>Applied Materials (Xi'an Ltd.) No. 28 Xin Xi Ave., Xi'an High Tech Park Export Processing Zone, Xi'an Shanxi, China 710075.</p>
Aviza Technology China	2B230; 3B001.c.1.a; 3B001.e	<p>Aviza Technology China, Room B-1501, No. 188, Tomson Center, Zhang Yang Road, Shanghai, China 200122.</p> <p>Aviza Technology China, Room 612, International Business Center, No. 18, Hong Da North Road, Beijing Economics and Technology Development Area, Beijing, China.</p> <p>Beijing Bonded: CIES, Electronics Building, A23, Fuxing Road, Beijing, China 100036.</p> <p>Shanghai Bonded: SLC, Shanghai Industrial—Wailianfa International Logistics Co., Ltd., Address: 13F Waigaoqiao Building 889 Yang Gao Road (N), Pudong, Shanghai, China.</p> <p>HMG Logistics (Chengdu) Co., Ltd., Floor 1, No. 5 Standard Warehouse, EPZ (West Area), Chengdu, China 611731.</p>
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 Hebei 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.

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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

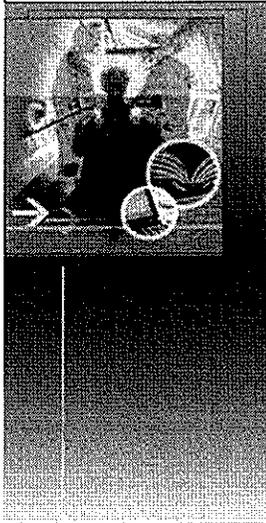
This document states our final conclusions on the labeling requirements in 21 CFR part 201 and requires that manufacturers include this labeling on their OTC IAAA drug products by the effective date identified in this document (see **DATES**). We are currently evaluating data and information regarding 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

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重要声明

近日，我公司获悉美国政府依据出口管理条例于2007年1月4日开始对中国电子进出口总公司等三家中国公司及其分支机构和子公司进行为期两年的制裁。

我公司特此声明，自2004年9月开始我公司已经按照中国法律的有关规定，完成了国有小型企业的改制工作，目前我公司不属于中国电子进出口总公司的分支机构，也不属于其子公司，美国政府的有关制裁不包括我公司。

我公司是一家依中国法律于2005年5月新注册的独立经营的股份制有限责任公司，是纯粹民营性质的非国有公司，我公司将为需要的客户提供相关证明资料 and 文件，以说明情况。我公司将继续在遵守中国法律和美国进出口管理条例的前提下开展对美国国际贸易和服务。

中国电子进出口国际电子服务有限公司

2007年1月11日

Explanations on the Sanctions by US Government to CEIEC

We have learned that US government declared, on Jan.4th, 2007, the two-year sanctions to CEIEC and its subsidiaries for forbidding all business including foreign trades, transfers of technology and other services between CEIEC and US government departments or representative companies. As a result, many of our American customers recently inquired us whether or not CIES is one of the subsidiaries of CEIEC for they need to deciding on the possibility for future business cooperation with CIES. Therefore it is an important time for us to clarify the ownership position of CIES.

CEIEC International Electronics Service Company began its ownership transformation early on Sep. 2004, permitted by China State-owned Assets Supervision and Administration Commission of the State Council (SASAC). And on May, 2005, CIES successfully transformed itself from a state-owned company to a private limited liability company and its name was hereby changed from "CEIEC International Electronics Service Company" to "China International Electronics Service Co., Ltd". From then on, CIES is no longer a state-owned subsidiary of CEIEC, but an independent private share-holding company with limited liabilities.

Related Background Information: CEIEC International Electronics Service Company. was set up in 1987 as one of the branch companies wholly owned by CEIEC, under the permission of Ministry of Foreign Trade and Economic Cooperation of China. As China entered WTO and its foreign trade policy changed to favoring a more open economy, the government had step by step abandoned most of the restrictions on foreign trade business, through which China realized a free trade environment based on fair competitions. Adapting to such a change, the government also brought forward an ownership reform for most of the small state-owned foreign trade companies. Reflecting such a policy, CEIEC International Electronics Service Company began its ownership transformation on Sep. 2004. Through complicated legal procedures, a new private company, China International Electronics Service Co., Ltd(CIES) was finally registered on May, 2005. The newly set-up CIES put on new records with all business-related government departments such as Business Administration Bureau, Beijing Administration of Taxation, Customs, Commodity Inspection Bureau, Ministry of Commerce etc. Since then, CIES is a purely new share-holding company.

Formal Announcement: For all considerations and responsibilities, we now make the formal announcement here that CIES is a private limited liability company registered on May, 2005 and has no relationship with CEIEC after May, 2005. The sanctions by US government to CEIEC should not include CIES, an independent private limited company owned by nine shareholders. In the future, CIES will continue to carry out foreign trade and service business with American companies abiding by the terms of EAR and the regulations of China government as well.

For any questions or reference materials, please contact us at.

China International Electronics Service Co.,Ltd.

TEL: 008610-68296215

Fax: 008610-68222585

[工作机会](#) | [联系我们](#) | [网站地图](#) | [English](#)

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中国电子进出口国际电子服务有限公司制作 京ICP备05047661号

TEL: (010)68296518/68296438 FAX: (010)68296218/68222585

DEPARTMENT OF STATE

[Public Notice 5660]

Bureau of International Security and Nonproliferation; Imposition of Nonproliferation Measures Against Foreign Persons, Including a Ban on U.S. Government Procurement

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: A determination has been made that twenty-four foreign persons have engaged in activities that warrant the imposition of measures pursuant to Section 3 of the Iran and Syria Nonproliferation Act, which provides for penalties on entities and individuals for the transfer to or acquisition from Iran since January 1, 1999 or the transfer to or acquisition from Syria since January 1, 2005, of equipment and technology controlled under multilateral export control lists (Missile Technology Control Regime, Australia Group, Chemical Weapons Convention, Nuclear Suppliers Group, Wassenaar Arrangement) or otherwise having the potential to make a material contribution to the development of weapons of mass destruction (WMD) or cruise or ballistic missile systems. The latter category includes (a) items of the same kind as those on multilateral lists, but falling below the control list parameters, when it is determined that such items have the potential of making a material contribution to WMD or cruise or ballistic missile systems, (b) other items with the potential of making such a material contribution, when added through case-by-case decisions, and (c) items on U.S. national control lists for WMD/missile reasons that are not on multilateral lists.

DATES: *Effective Date:* December 28, 2006.

FOR FURTHER INFORMATION CONTACT: On general issues: Pamela K. Durham, Office of Missile Threat Reduction, Bureau of International Security and Nonproliferation, Department of State (202-647-4931). On U.S. Government procurement ban issues: Gladys Gines, Office of the Procurement Executive, Department of State (703-516-1691).

SUPPLEMENTARY INFORMATION: Pursuant to Sections 2 and 3 of the Iran and Syria Nonproliferation Act (Pub. L. 109-112), the U.S. Government determined on December 22, 2006 that the measures authorized in Section 3 of the Act shall apply to the following foreign persons identified in the report submitted pursuant to Section 2(a) of the Act: China National Electronic Import-Export Company (CEIEC) (China) and any

successor, sub-unit, or subsidiary thereof;
 China National Aero-Technology Import and Export Company (CATIC) (China) and any successor, sub-unit, or subsidiary thereof;
 Zibo Chemet Equipment Company (China) and any successor, sub-unit, or subsidiary thereof;
 Defense Industries Organization (DIO) (Iran) and any successor, sub-unit, or subsidiary thereof;
 Iran Electronics Industries (IEI) (Iran) and any successor, sub-unit, or subsidiary thereof;
 Sanam Industrial Group (SIG) (Iran) and any successor, sub-unit, or subsidiary thereof;
 NAB Export Company (Iran) and any successor, sub-unit, or subsidiary thereof;
 Abu Hamadi (Iraq) and any successor, sub-unit, or subsidiary thereof;
 Kal Al-Zuhiry (Iraq);
 Korea Mining Development Corporation (KOMID) (North Korea) and any successor, sub-unit, or subsidiary thereof;
 Target Airfreight (Malaysia) and any successor, sub-unit, or subsidiary thereof;
 Aerospace Logistics Services (Mexico) and any successor, sub-unit, or subsidiary thereof;
 Arif Durrani (Pakistan);
 Rosoboronexport (Russia) and any successor, sub-unit, or subsidiary thereof;
 Kolomna Design Bureau of Machine-Building (KBM) (Russia) and any successor, sub-unit, or subsidiary thereof;
 Tula Design Bureau of Instrument Building (KBP) (Russia) and any successor, sub-unit, or subsidiary thereof;
 Alexey Safonov (Russia);
 Al Zarga Optical and Electronics Co. (Sudan) and any successor, sub-unit, or subsidiary thereof;
 Giad Industrial Complex (Sudan) and any successor, sub-unit, or subsidiary thereof;
 Yarmouk Industrial Complex (Sudan) and any successor, sub-unit, or subsidiary thereof;
 Army Supply Bureau (Syria) and any successor, sub-unit, or subsidiary thereof;
 Industrial Establishment of Defense (IED) (Syria) and any successor, sub-unit, or subsidiary thereof;
 Ministry of Defense (Syria) and any successor, sub-unit, or subsidiary thereof; and
 Scientific Studies and Research Center (SSRC) (Syria) and any successor, sub-unit, or subsidiary thereof.

Accordingly, pursuant to the provisions of the Act, the following

measures are imposed on these entities and individuals:

1. No department or agency of the United States Government may procure, or enter into any contract for the procurement of, any goods, technology, or services from these foreign persons;

2. No department or agency of the United States Government may provide any assistance to the foreign persons, and these persons shall not be eligible to participate in any assistance program of the United States Government;

3. No United States Government sales to the foreign persons of any item on the United States Munitions List (as in effect on August 8, 1995) are permitted, and all sales to these persons of any defense articles, defense services, or design and construction services under the Arms Export Control Act are terminated; and,

4. No new individual licenses shall be granted for the transfer to these foreign persons of items the export of which is controlled under the Export Administration Act of 1979 or the Export Administration Regulations, and any existing such licenses are suspended.

These measures shall be implemented by the responsible departments and agencies of the United States Government and will remain in place for two years from the effective date, except to the extent that the Secretary of State may subsequently determine otherwise. A new determination will be made in the event that circumstances change in such a manner as to warrant a change in the duration of sanctions.

Dated: December 28, 2006.

Andrew K. Semmel,

Acting Assistant Secretary of State for International Security and Nonproliferation, Department of State.

[FR Doc. E6-22630 Filed 1-4-07; 8:45 am]

BILLING CODE 4710-25-P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Aviation Proceedings, Agreements Filed the Week Ending December 22, 2006

The following Agreements were filed with the Department of Transportation under the Sections 412 and 414 of the Federal Aviation Act, as amended (49 U.S.C. 1383 and 1384) and procedures governing proceeding to enforce these provisions. Answers may be filed within 21 days after the filing of the application.

Docket Number: OST-2006-26662.

Date Filed: December 18, 2006.

Bill of Lading

SHIPPER

Ceiec International Electronic
 Electronics Building,jia No.23,
 Fuxing Road Beijing China

CONSIGNEE

Lg Electronics Alabama Inc
 201 James Record Road Huntsville
 Al 35824 Usa

63563247

1 310 667 4830

NOTIFY PARTIES

Fns Inc Lax
 18301 Broad Wick St., Rancho
 Dominguez Ca 90220 Usa

PACKAGING INFORMATION

Weight : 186 KG
Quantity : 13 CTN

Measurement : 1 CM

SHIPMENT DETAIL

Carrier Code : NAQA

Origin :

Vessel Name : Maunawili

U.S. Port : 2709 - Long Beach, California

Voyage : 0046E

Foreign Port : 57035 - Shanghai, China

B/L : NAQASHTV7400433W

U.S. Dest :

Pre Carrier : Shanghai

Foreign Dest :

Vessel Code :

Mode of Transport : 11

Inbond Code : 00

Arrival Date : 2007-01-21

COMMODITIES

Container	Qty	Commodity Description
GSTU6318592	13	Repair Parts For Monitor

MARKS & NUMBERS

Container	Marks & Numbers
GSTU6318592	N/m

Bill of Lading**SHIPPER**

China International Electronic
Electronics Building,jia No.23
Fuxing Road.beijing,china

CONSIGNEE

Lg Electronics Alabama Inc
201 James Record Road
Huntsville Al35824 Usa

63563247

13106674830

NOTIFY PARTIES

Fns Inc Lax
18301 Broad Wick St., Rancho
Dominguez Ca 90220, U.s.a

PACKAGING INFORMATION**Weight :** 562 KG**Measurement :** 3 CM**Quantity :** 31 CTN**SHIPMENT DETAIL****Carrier Code :** NAQA**Origin :****Vessel Name :** Xin Yan Tian**U.S. Port :** 2709 - Long Beach, California**Voyage :** 0043E**Foreign Port :** 58023 - Busan, South Korea**B/L :** NAQASHTV7412301W**U.S. Dest :****Pre Carrier :** Shanghai**Foreign Dest :****Vessel Code :****Mode of Transport :** 11**Inbond Code :** 00**Arrival Date :** 2007-03-05**COMMODITIES**

Container	Qty	Commodity Description
CCLU6023010	31	Repair Parts For Refrigerator Monitor

MARKS & NUMBERS

Container	Marks & Numbers
CCLU6023010	N/m

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Bill of Lading

SHIPPER

China International Electronics Ser
 Electronics Building,jia No.23
 Fuxing Road
 Beijing, Bj Cn

CONSIGNEE

Lg Electronics Canada,inc
 550 Matheson Blvd.east
 Mississauga, On L4z 4g3 Ca

NOTIFY PARTIES

Lg Electronics Canada,inc
 550 Matheson Blvd.east

Mississauga On Ca

PACKAGING INFORMATION

Weight : 191 KG

Measurement : 4 CM

Quantity : 40 CAS

SHIPMENT DETAIL

Carrier Code : TCIJ

Origin :

Vessel Name : Oocl Shanghai

U.S. Port : 3001 - Seattle, Washington

Voyage : 60E43

Foreign Port : 58023 - Busan, South Korea

B/L : TCJSC12CA41579

U.S. Dest :

Pre Carrier : Tianjin

Foreign Dest :

Vessel Code :

Mode of Transport : 11

Inbond Code : 00

Arrival Date : 2007-11-11

COMMODITIES

Container	Qty	Commodity Description
TGHU7585722	40	Repair Parts For Room Air Conditioner,microwave Oven

MARKS & NUMBERS

Container	Marks & Numbers
TGHU7585722	N/m -

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Ceiec International Electronics Ser
 Electronics Building Jia No.23 Fuxi
 Beijing China T:01084679987
 Beijing, ,cn
 01084679987

CONSIGNEE

Lg Electronics Alabama Inc
 201 James Record Road Huntsville Al
 Usa T:3106674830
 Huntsville,al 35824,us
 3106674830

NOTIFY PARTIES

Lg Electronics Alabama Inc
 201 James Record Road Huntsville Al
 Usa T:3106674830
 Huntsville,al 35824,us
 Huntsville Al35824 Us

PACKAGING INFORMATION**Weight :** 5,912 KG**Measurement :** 0 CM**Quantity :** 48 PCS**SHIPMENT DETAIL****Carrier Code :** BGNL**Origin :****Vessel Name :** Cosco Qingdao**U.S. Port :** 2709 - Long Beach, California**Voyage :** 040E**Foreign Port :** 57017 - Xingang, China**B/L :** BGNL53700178**U.S. Dest :****Pre Carrier :** Xingang**Foreign Dest :****Vessel Code :** 9120762**Mode of Transport :** 11**Inbond Code :** 00**Arrival Date :** 2007-01-19**COMMODITIES**

Container	Qty	Commodity Description
CBHU1290170	48	Repair Parts For Room Air Conditioner Microwa Re Oven

MARKS & NUMBERS

Container	Marks & Numbers
CBHU1290170	N/m

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Bill of Lading**SHIPPER**

China International Electronics
Service Co., Ltd
Electronics Building, Jia No. 23
Fuxing Road
Beijing Cn

CONSIGNEE

Jabil Global Services
4601 Cromwell Road
Memphis Tn 38118 Us

NOTIFY PARTIES**PACKAGING INFORMATION****Weight :** 3,481 KG**Measurement :** 27 CM**Quantity :** 272 CTN**SHIPMENT DETAIL****Carrier Code :** WBLC**Origin :****Vessel Name :** Ever Urban**U.S. Port :** 2704 - Los Angeles, California**Voyage :** 56E**Foreign Port :** 57035 - Shanghai, China**B/L :** WBLCWWSHA711052**U.S. Dest :****Pre Carrier :** Shanghai**Foreign Dest :****Vessel Code :** 9169160**Mode of Transport :** 10**Inbond Code :** 00**Arrival Date :** 2007-12-11**COMMODITIES**

Container	Qty	Commodity Description
INBU3509177	272	Repair Parts For V.c.r.

MARKS & NUMBERS

Container	Marks & Numbers
INBU3509177	No Marks

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Bill of Lading**SHIPPER**

Ceiec International
 Electronics Service Company
 Electronics Building
 Jia No. 23, Fuxing Road
 Beijing Cn

CONSIGNEE

Jabil Global Services
 4601 Cromwell Road
 Memphis Tn 38118 Us

NOTIFY PARTIES**PACKAGING INFORMATION****Weight :** 1,257 KG**Measurement :** 10 CM**Quantity :** 102 CAS**SHIPMENT DETAIL****Carrier Code :** WBLC**Origin :****Vessel Name :** Xin Hai Kou**U.S. Port :** 2704 - Los Angeles, California**Voyage :** 34E**Foreign Port :** 57035 - Shanghai, China**B/L :** WBLCWWSHA703013G**U.S. Dest :****Pre Carrier :** Shanghai**Foreign Dest :****Vessel Code :** 9309954**Mode of Transport :** 10**Inbond Code :** 00**Arrival Date :** 2007-04-03**COMMODITIES**

Container	Qty	Commodity Description
SESU2060854	102	V.c.r.

MARKS & NUMBERS

Container	Marks & Numbers
SESU2060854	No Marks

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Bill of Lading

SHIPPER

Ceiec International Electronics
 Service Company Electronics
 Building A23 Fuxing Road, Beijing
 Beijing Cn

CONSIGNEE

Gea Parts Llc
 1251 Port Road
 Parts Distrubtion Center
 Jeffersonville In 47130 Us

NOTIFY PARTIES

PACKAGING INFORMATION

Weight : 4,089 KG
Quantity : 151 CTNS

Measurement : 19 CM

SHIPMENT DETAIL

Carrier Code : EXDO
Vessel Name : Cosco Antwerp
Voyage : 00042
B/L : EXDO6380046521
Pre Carrier : Tianjin
Vessel Code : 9246396
Inbond Code : 00

Origin :
U.S. Port : 3001 - Seattle, Washington
Foreign Port : 57017 - Xingang, China
U.S. Dest :
Foreign Dest :
Mode of Transport : 11
Arrival Date : 2007-01-04

COMMODITIES

Container	Qty	Commodity Description
HJCU4219221	151	Repair Parts For Room Air Conditioner Microwave Oven

MARKS & NUMBERS

Container	Marks & Numbers
HJCU4219221	No Marks

Bill of Lading**SHIPPER**

China International Electronics
Service Co.,Ltd. Electronics
Building,jia No.23, Fuxing Road,
Beijing Cn

CONSIGNEE

Gea Parts Llc
1251 Port Road
Parts Distrubtion Center
Jeffersonville In 47130 Us

NOTIFY PARTIES**PACKAGING INFORMATION****Weight :** 825 KG**Measurement :** 4 CM**Quantity :** 15 CTNS**SHIPMENT DETAIL****Carrier Code :** EXDO**Origin :****Vessel Name :** Hanjin Ottawa**U.S. Port :** 3001 - Seattle, Washington**Voyage :** 00055**Foreign Port :** 58023 - Busan, South Korea**B/L :** EXDO6380055233**U.S. Dest :****Pre Carrier :** Tianjin**Foreign Dest :****Vessel Code :** 9200718**Mode of Transport :** 11**Inbond Code :** 00**Arrival Date :** 2007-11-23**COMMODITIES**

Container	Qty	Commodity Description
HJCU7436257	15	Microwave Oven Parts

MARKS & NUMBERS**Container****Marks & Numbers**

HJCU7436257

Dest:usjfv Item:mwo Buyer:gea Asia P/o # :w558400-10 C/t #:1-15 Made In China

Bill of Lading

SHIPPER

Ceiec International Electronics
 Service Company Electronics
 Building A23 Fuxing Road Beijing
 China

CONSIGNEE

Samsung Electronics America Inc.
 Samsung Global Parts Center(sea)
 18600 Broladwice Street Rancho
 Domincuez Ca 90220 Usa

NOTIFY PARTIES

Samsung Electronics America Inc.
 Samsung Global Parts Center(sea)
 18600 Broladwice Street Rancho
 Domincuez Ca 90220 Usa

PACKAGING INFORMATION

Weight : 256 KG **Measurement :** 1 CM
Quantity : 2 PKG

SHIPMENT DETAIL

Carrier Code : PCND	Origin :
Vessel Name : Oocl China	U.S. Port : 2704 - Los Angeles, California
Voyage : 17E19	Foreign Port : 57017 - Xingang, China
B/L : PCNDTUS85116LAX	U.S. Dest :
Pre Carrier : Xingang	Foreign Dest :
Vessel Code : 9108178	Mode of Transport : 10
Inbond Code : 00	Arrival Date : 2008-05-23

COMMODITIES

Container	Qty	Commodity Description
NYKU4052892	2	Video Tape Recorder Parts

MARKS & NUMBERS

Container	Marks & Numbers
NYKU4052892	Usa V100004359 7300003249

Bill of Lading

SHIPPER

Ceiec International Electronics
 Service Company Electronics
 Buildinga23 Fuxing Road, Beijing
 China

CONSIGNEE

Ceis-samsung Electronics
 America, 18600 S.broadwick St
 Rancho Domicuez Ca 90220 Usa

NOTIFY PARTIES

Ceis-samsung Electronics
 America, 18600 S.broadwick St
 Rancho Domicuez Ca 90220 Usa

PACKAGING INFORMATION
Weight : 346 KG
Measurement : 3 CM
Quantity : 3 PKG

SHIPMENT DETAIL
Carrier Code : PCND
Origin :
Vessel Name : Msc Lucy
U.S. Port : 2709 - Long Beach, California
Voyage : O912A
Foreign Port : 57020 - Ningbo, China
B/L : PCNDTUS93100LAX
U.S. Dest :
Pre Carrier : Xingang
Foreign Dest :
Vessel Code : 9289104
Mode of Transport : 10
Inbond Code : 00
Arrival Date : 2009-04-09

COMMODITIES

Container	Qty	Commodity Description
MSCU4247361	3	Facsimile-printe Parts Color Television Pa Rts Camcorder Parts

MARKS & NUMBERS

Container	Marks & Numbers
MSCU4247361	9000 No M



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Contact List	
Department	Defence Electronics Department of CEIEC
Address	Electronics Building, A23 Fuxing Road. Beijing, China P.C.
Post Code	100036
Business Tel.	++86-10-68296510
Support Tel.	++86-10-68296510
Fax	++86-10-68212361 , ++86-10-68212352
To	Ms Wu
E-Mail	defence@ceiec.com.cn

Copyright China National Electronics Import & Export Corporation Hotline:(010)68219550 EMail : webmaster@ceiec.com.cn