

injunction or seizure) or an unresolved warning letter. Inclusion of U.S. dairy product manufacturers/processors on this list is voluntary. However, dairy products from firms not on this list could be refused entry at the Chilean port of entry. The guidance explains what information firms should submit to FDA in order to be considered for inclusion on the list and what criteria FDA intends to use to determine eligibility for placement on the list. The document also explains how FDA intends to update the list and how FDA intends to communicate any new information to Chile. Finally, the guidance notes that FDA will consider the information on this list, which will be posted on FDA's Internet site and communicated to Chile, to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4).

This guidance represents the agency's current thinking on the procedures for assisting Chile in determining which U.S. manufacturers or processors are eligible to export dairy products to Chile. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

This guidance document is being issued as a level 1 guidance consistent with FDA's good guidance practices (GGPs) regulation (§ 10.115 (21 CFR 10.115)). Consistent with GGPs, the agency will accept comment, but is implementing the guidance document immediately in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. The guidance document presents a less burdensome policy that is consistent with the public health.

### III. Comments

Interested persons may submit to the Dockets Management Branch (*see ADDRESSES*) written or electronic comments regarding this guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

### IV. Paperwork Reduction Act of 1995

The Office of Management and Budget (OMB) has approved this collection of

information under the emergency processing provision of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(j) and 5 CFR 1320.13) and has assigned OMB control number 0910-0509. As discussed in the **Federal Register** of April 10, 2003 (68 FR 17655), public reporting burden for this collection of information is estimated to be 1.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

### V. Electronic Access

Interested persons also may access the guidance document at <http://www.cfsan.fda.gov/guidance.html>.

Dated: May 15, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Bureau of Customs and Border Protection

#### List of Foreign Entities Violating Textile Transshipment and Country of Origin Rules

**AGENCY:** Bureau of Customs and Border Protection, Homeland Security.

**ACTION:** General notice.

**SUMMARY:** This document notifies the public of foreign entities which have been issued a penalty claim under section 592 of the Tariff Act of 1930, for certain violations of the customs laws. This list is authorized to be published by section 333 of the Uruguay Round Agreements Act.

**DATES:** This document notifies the public of the semiannual list for the 6-month period starting March 31, 2003, and ending September 30, 2003.

**FOR FURTHER INFORMATION CONTACT:** For information regarding any of the operational aspects, contact Gregory Olavsky, Fines, Penalties and Forfeitures Branch, Office of Field Operations, (202) 927-3119. For information regarding any of the legal aspects, contact Willem A. Daman, Office of Chief Counsel, (202) 927-6900.

#### SUPPLEMENTARY INFORMATION:

##### Background

Section 333 of the Uruguay Round Agreements Act (URAA) (Pub. L. 103-465, 108 Stat. 4809)(signed December 8,

1994), entitled Textile Transshipments, amended Part V of title IV of the Tariff Act of 1930 by creating a section 592A (19 U.S.C. 1592a), which authorizes the Secretary of the Treasury (and this authority has been delegated to the Secretary of Homeland Security and to the Commissioner of the Bureau of Customs and Border Protection) to publish in the **Federal Register**, on a semiannual basis, a list of the names of any producers, manufacturers, suppliers, sellers, exporters, or other persons located outside the Customs territory of the United States, when these entities and/or persons have been issued a penalty claim under section 592 of the Tariff Act, for certain violations of the customs laws, provided that certain conditions are satisfied.

The violations of the customs laws referred to above are the following: (1) Using documentation, or providing documentation subsequently used by the importer of record, which indicates a false or fraudulent country of origin or source of textile or apparel products; (2) Using counterfeit visas, licenses, permits, bills of lading, or similar documentation, or providing counterfeit visas, licenses, permits, bills of lading, or similar documentation that is subsequently used by the importer of record, with respect to the entry into the Customs territory of the United States of textile or apparel products; (3) Manufacturing, producing, supplying, or selling textile or apparel products which are falsely or fraudulently labeled as to country of origin or source and (4) Engaging in practices which aid or abet the transshipment, through a country other than the country of origin, of textile or apparel products in a manner which conceals the true origin of the textile or apparel products or permits the evasion of quotas on, or voluntary restraint agreements with respect to imports of textile or apparel products.

If a penalty claim has been issued with respect to any of the above violations, and no petition in response to the claim has been filed, the name of the party to whom the penalty claim was issued will appear on the list. If a petition or supplemental petition for relief from the penalty claim is submitted under 19 U.S.C. 1618, in accord with the time periods established by sections 171.2 and 171.61, Customs Regulations (19 CFR 171.2, 171.61) and the petition is subsequently denied or the penalty is mitigated, and no further petition, if allowed, is received within 60 days of the denial or allowance of mitigation, then the administrative action shall be deemed to be final and administrative remedies will be deemed to be exhausted. Consequently, the

name of the party to whom the penalty claim was issued will appear on the list. However, provision is made for an appeal to the Secretary of the Treasury (now delegated to the Secretary of Homeland Security) by the person named on the list, for the removal of its name from the list. If the Secretary finds that such person or entity has not committed any of the enumerated violations for a period of not less than 3 years after the date on which the person or entity's name was published, the name will be removed from the list as of the next publication of the list.

#### Reasonable Care Required

Section 592A also requires any importer of record entering, introducing, or attempting to introduce into the commerce of the United States textile or apparel products that were either directly or indirectly produced, manufactured, supplied, sold, exported, or transported by such named person to show, to the satisfaction of the Secretary, that such importer has exercised reasonable care to ensure that the textile or apparel products are accompanied by documentation, packaging, and labeling that are accurate as to its origin. Reliance solely upon information regarding the imported product from a person named on the list is clearly not the exercise of reasonable care. Thus, the textile and apparel importers who have some commercial relationship with one or more of the listed parties must exercise a degree of reasonable care in ensuring that the documentation covering the imported merchandise, as well as its packaging and labeling, is accurate as to the country of origin of the merchandise. This degree of reasonable care must involve reliance on more than information supplied by the named party.

In meeting the reasonable care standard when importing textile or apparel products and when dealing with a party named on the list published pursuant to section 592A of the Tariff Act of 1930, an importer should consider the following questions in attempting to ensure that the documentation, packaging, and labeling is accurate as to the country of origin of the imported merchandise. The list of questions is not exhaustive but is illustrative.

(1) Has the importer had a prior relationship with the named party?

(2) Has the importer had any detentions and/or seizures of textile or apparel products that were directly or indirectly produced, supplied, or transported by the named party?

(3) Has the importer visited the company's premises and ascertained that the company has the capacity to produce the merchandise?

(4) Where a claim of an origin conferring process is made in accordance with 19 CFR 102.21, has the importer ascertained that the named party actually performed the required process?

(5) Is the named party operating from the same country as is represented by that party on the documentation, packaging or labeling?

(6) Have quotas for the imported merchandise closed or are they nearing closing from the main producer countries for this commodity?

(7) What is the history of this country regarding this commodity?

(8) Have you asked questions of your supplier regarding the origin of the product?

(9) Where the importation is accompanied by a visa, permit, or license, has the importer verified with the supplier or manufacturer that the visa, permit, and/or license is both valid and accurate as to its origin? Has the importer scrutinized the visa, permit or license as to any irregularities that would call its authenticity into question?

The law authorizes a semiannual publication of the names of the foreign entities and/or persons. On October 15, 2002, Customs published a notice in the **Federal Register** (67 FR 63729) which identified 3 (three) entities which fell within the purview of section 592A of the Tariff Act of 1930

#### 592A List

For the period ending March 30, 2003, Customs has identified 3 (three) foreign entities that fall within the purview of section 592A of the Tariff Act of 1930. This list reflects no new entities and no removals to the 3 entities named on the list published on October 15, 2002. The parties on the current list were assessed a penalty claim under 19 U.S.C. 1592, for one or more of the four above-described violations. The administrative penalty action was concluded against the parties by one of the actions noted above as having terminated the administrative process.

The names and addresses of the 3 foreign parties which have been assessed penalties by Customs for violations of section 592 are listed below pursuant to section 592A. This list supersedes any previously published list. The names and addresses of the 3 foreign parties are as follows (the parenthesis following the listing sets forth the month and year in which

the name of the company was first published in the **Federal Register**):

Everlite Manufacturing Company, P.O. Box 90936, Tsimshatsui, Kowloon, Hong Kong (3/01).

Fairfield Line (HK) Co. Ltd., 60-66 Wing Tai Commer., Bldg. 1/F, Sheung Wan, Hong Kong (3/01).

G.P. Wedding Service Centre, Lee Hing Industrial Building, 10 Cheung Yue Street 11th Floor, Cheung Sha Wan, Kowloon, Hong Kong (10/00).

Any of the above parties may petition to have its name removed from the list. Such petitions, to include any documentation that the petitioner deems pertinent to the petition, should be forwarded to the Assistant Commissioner, Office of Field Operations, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Washington, DC 20229.

Dated: May 14, 2003.

**Jayson P. Ahern,**

*Assistant Commissioner, Office of Field Operations.*

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## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[FEMA-1466-DR]

#### Alabama; Amendment No. 2 to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Alabama, (FEMA-1466-DR), dated May 12, 2003, and related determinations.

**EFFECTIVE DATE:** May 14, 2003.

#### FOR FURTHER INFORMATION CONTACT:

Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-2705.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the State of Alabama is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of May 12, 2003:

Chambers, Clay, Cleburne, Lauderdale, Randolph and Russell Counties for Public Assistance (already declared for Individual Assistance).