Subject: **ALFOODACT 002-2014, UPDATE to ALFOODACTs 044-2011, 041-2011, 036-2011, and 034-2011 Dimethylamylamine (DMAA) Is Placed On Medical Hold Due To Possible Serious Adverse Health Effects**

Date Issued: **January 16, 2014**

1. REFERENCES:

a. DLAR 4155.26/AR 40-660/NAVSUPINST 10110.8c/AFI 48-116/MCO 10110.38c, DOD Hazardous Food & Nonprescription Drug Recall System.

b. Allied Communications Publication 121, US SUPP-1 (f).

2. BACKGROUND/UPDATE:

On April 27, 2012 The U.S. Food and Drug Administration issued warning letters to ten manufacturers and distributors of dietary supplements containing dimethylamylamine, more popularly known as DMAA, for marketing products for which evidence of the safety of the product had not been submitted to FDA.

"Before marketing products containing DMAA, manufacturers and distributors have a responsibility under the law to provide evidence of the safety of their products. They haven't done that and that makes the products adulterated," said Daniel Fabricant, Ph.D., Director of FDA's Dietary Supplement Program.

Specifically, the warning letters cite the companies for marketing products for which a notification had not been submitted for the use of DMAA as a New Dietary Ingredient (NDI). Under current law, dietary supplement manufacturers or distributors who use certain dietary ingredients not marketed in a dietary supplement prior to October 15, 1994, are responsible for notifying the FDA of evidence to support their conclusion that their dietary supplements containing NDIs are safe. Manufacturers or distributors must submit notification at least 75 days before marketing their products. The companies warned today were marketing products for which this requirement had not been met.

The FDA warning letters also advised the companies that the agency is not aware of evidence or history of use to indicate that DMAA is safe. Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), manufacturers, marketers and distributors of dietary supplements are responsible for ensuring that they are marketing a safe product.

The FDA letters noted that DMAA is known to narrow the blood vessels and arteries, which can elevate blood pressure and may lead to cardiovascular events ranging from shortness of breath and tightening in the chest to heart attack. The agency has received 42 adverse event reports on products containing DMAA. While the complaints do not establish that DMAA was the cause of the incidents, some of the reports have included cardiac disorders, nervous system disorders, psychiatric disorders, and death.

The agency additionally warned the companies that synthetically-produced DMAA is not a "dietary ingredient" and, therefore, is not eligible to be used as an active ingredient in a dietary supplement. DSHEA defines a dietary ingredient as a vitamin, mineral, amino acid, herb or other botanical, a dietary substance for use by man to supplement the diet, or a concentrate, metabolite, constituent, extract, or combination of these substances.

Additional information can be concerning the FDA's "Warning Letter" please go to http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/ucm346576.htm

**DETERMINATION FOR DISPOSITION: (Refer to paragraph seven below for additional instructions)

Immediately inventory stocks to identify the above items either “DESTORY them or RETURN them to the vendor” refund or credit.

Consumers should look for DMAA listed on the product label. It may also be listed as:

•1,3-DMAA

•1,3-Dimethylamylamine

•1,3-Dimethylpentylamine

•2-Amino-4-methylhexane

•2-Hexanamine

•4-Methyl-2-hexanamine

•4-Methyl-2-hexylamine

•4-methyl- (9CI)

•Dimethylamylamine

•Geranamine

•Methylhexanamine

•Methylhexanenamine

Some products also will list Pelargonium graveolens extract or Geranium extract, which may indicate that the product contains DMAA.

3. PRODUCTION DATES/IDENTIFYING CODES:

Listed below are known products that contain Dimethylamylamine (DMAA), this list is "NOT ALL INCLUSIVE":

USPlabs Jack 3D (Tropical Fruit and Lemon Lime)

USPlabs Oxy Elite Pro

Nutrex Lipo 6 Black Caps (his and hers)

Nutrex Lipo 6 Black Ultra Concentrated (his and hers)

Nutrex Hemo Rage Black Powder, Punch, Berry

Isatori PWR

Muscletech Neurocore

Muscletech Hydroxystim

Fahrenheit Nutrition Lean EFX

Muscle Warfare Napalm

SNI Nitric Blast

BIORhythm SSIN Juice

Muscle Meds Code Red

SEI MethhlHex 4, 2

Gaspari Nutrition Spirodex

4. MANUFACTURER/DISTRIBUTOR: Various Manufacturers

5. DISTRIBUTION: All

6. REASON FOR ACTION: Due to possible association with serious adverse health effects.

7. INSTRUCTIONS AND ADDITIONAL INFORMATION FOR MESSAGE RECIPIENTS:

a. Immediately inventory stocks to identify the above items either “DESTORY them or RETURN them to the vendor”. POSITIVE FINDINGS should be reported to Accountable Officers/Vendor Representatives of that facility. Accountable Officer/Agency representatives/Buyers/Contracting Officers should seek/refund/credit/ through the normal distribution channel with which the product was received (i.e. Distribution Centers, Prime Vendors, or Manufacturers).

b. Ships at sea are authorized to destroy or dispose of recalled products at their discretion. Documentation for the number of pounds and cases, and any additional pertinent information must be signed by the Accountable Officer and is required for the purpose of recouping to the government the cost of the product involved. In order to get credit please use a SF 364 and forward to your supporting FISC and copy furnished to NAVSUP 51.

8. The Point of Contact for this ALFOODACT message is CW4 Tony Hemphill, Consumer Safety Officer at DLA-FTW. VOICE, DSN: 444-2922, Commercial (215) 737-2922, or by FAX, DSN: 444-7526, or Commercial, (215) 737-7526, email dscpconssafofc@dla.mil .

9. Individuals or groups that would like to receive recall messages electronically can forward their email address to dscpconssafofc@dla.mil , with "add to list" in the subject line. To be removed from the list place "remove from list" in the subject line.

10. Previous recalls and frequently asked questions are available at the following web site: http://www.troopsupport.dla.mil/subs/fso/alfood/alfood.asp . The navigation tool to the left allows you to also view DLA Troop Support Alerts and Archived Vendor Recalls.

Regards,

Mr. Hemphill

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