Dietary Supplements & Operation Supplement Safety

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USU CHAMP
Uniformed Services University Consortium for Health and Military Performance
Learning Objectives

- Describe some of the rules and regulations on dietary supplements (DS)
- Identify dangers and risks of selected DS categories
- Describe the purpose of Operation Supplement Safety (OPSS)
- Provide an overview of OPSS features
- Delineate the function of the OPSS “Ask the Expert” button
- Describe resources available for Healthcare providers, including Apps
• Defined dietary supplements/dietary ingredients

• “A product that contains substances like vitamins, minerals, herbals, botanicals, amino acids and is intended to supplement the usual intake of these substances. Dietary supplements are found in pill, tablet, capsule, powder or liquid form and are intended to be taken by mouth.”

Dietary Supplement Health and Education Act of 1994: DSHEA
Which is a Dietary Supplement?

A food

A dietary supplement

An OTC medication

Drug Facts

Active Ingredient (in each tablet): Chlorpheniramine maleate 2 mg. Purpose: Antihistamine.

Uses: temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: - sneezing, - runny nose, - itchy, watery eyes, - itchy throat.

Warnings:

Ask a doctor before use if you have:

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

When using this product:

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children.

Proprietary Blend: 2000 mg:
- Black Raspberry Seed Powder, Hullced Hemp Seeds
- Black Cumin Seed Powder, Black Cumin Seed Oil
- Black Raspberry Seed Oil.

ProprietaryBlend: 1200 mg:
- D-Ribose, Magnesium Malate, Malic Acid,
- Resveratrol, Marine Phytoplankton.

Other Ingredients: Water, Organic Cane Juice, Xylitol,
- Blackberry Juice Puree, Red Raspberry Juice Puree,
- Natural Flavors, Xanthan Gum, Citric Acid, Stevia, Methylcellulose,
- (Scutellaria Baicalensis Root Extract, Camellia Sinensis Leaf Extract, Houttuynia Cordata Leaf Extract, Artemisia Princeps Leaf Extract, Citrus Junos Fruit Extract, Glycerin).
What you may not know...

Food

**Nutrition Facts**

*Serving Size 1/2 cup (about 82g) Servings Per Container 8*

<table>
<thead>
<tr>
<th>Amount Per Serving</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Calories</strong> 200</td>
<td>Calories from Fat 130</td>
</tr>
<tr>
<td>% Daily Value*</td>
<td></td>
</tr>
<tr>
<td><strong>Total Fat</strong> 14g</td>
<td>22%</td>
</tr>
<tr>
<td>Saturated Fat 9g</td>
<td>45%</td>
</tr>
<tr>
<td>Trans Fat 0g</td>
<td></td>
</tr>
<tr>
<td><strong>Cholesterol</strong> 55mg</td>
<td>18%</td>
</tr>
<tr>
<td><strong>Sodium</strong> 40mg</td>
<td>2%</td>
</tr>
<tr>
<td><strong>Total Carbohydrate</strong> 17g</td>
<td>6%</td>
</tr>
<tr>
<td>Dietary Fiber 1g</td>
<td>4%</td>
</tr>
<tr>
<td>Sugars 14g</td>
<td></td>
</tr>
<tr>
<td><strong>Protein</strong> 3g</td>
<td></td>
</tr>
</tbody>
</table>

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs: Calories: 2,000 2,500

OTC Med

- Generally recognized as safe (GRAS)
- Proven evidence of efficacy and known safety

Supplements

- No requirement for evidence of safety or efficacy

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**Drug Facts**

*Active ingredient (in each tablet) Chlorpheniramine maleate 2 mg... Antihistamine*

**Uses**
- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - Sneezing
  - Itchy, watery eyes
  - Itchy, watery nose

**Warnings**
- Ask a doctor before use if you have:
  - Glaucoma
  - A breathing problem such as emphysema or chronic bronchitis
  - Trouble urinating due to an enlarged prostate gland

- Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

**When using this product**
- Drowsiness may occur
- Avoid alcoholic drinks
- Alcohol, sedatives, and tranquilizers may increase drowsiness
- Be careful when driving a motor vehicle or operating machinery
- Excitability may occur, especially in children

**Avoid**
- If pregnant or breast-feeding, ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or call a Poison Control Center right away.

**Directions**
- Adults and children 12 years and over: take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours.
- Children 6 years to under 12 years: take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours.
- Children under 6 years: ask a doctor.

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**Supplement Facts**

*Serving size: 1 oz Servings per container: 1*

<table>
<thead>
<tr>
<th>Amount per serving</th>
<th>% DV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Calories</strong> 15</td>
<td>5</td>
</tr>
<tr>
<td>Calories from Fat 5</td>
<td>7g 2%</td>
</tr>
<tr>
<td><strong>Total Carbohydrate</strong> 1g</td>
<td>1%</td>
</tr>
<tr>
<td>Dietary Fiber</td>
<td>1g</td>
</tr>
<tr>
<td>Sugars</td>
<td>4g</td>
</tr>
<tr>
<td>Sodium</td>
<td>5mg</td>
</tr>
</tbody>
</table>

*Proprietary EFA Blend 2000 mg* Black Raspberry Seed Powder, Hulled Hempseeds, Black Cumin Seed Powder, Black Cumin Seed Oil, Black Raspberry Seed Oil.

*Proprietary Blend 1200 mg* D-Riboce, Magnesium Malate, Salicylic Acid, Resveratrol, Marine Phytoplankton.

*Daily Values are based on a 2,000 calorie diet. Other Ingredients: Water, Organic Cane Juice, Xylitol, Blackberry Juice Puree, Red Raspberry Juice Puree, Natural Flavors, Xanthan Gum, Citric Acid, Stevia, Mesgupg (Scutellaria Baicalensis Root Extract, Camellina Senegalensis Leaf Extract, Houttuynia Cordata Leaf Extract, Artemisia Princes Leaf Extract, Citrus Junos Fruit Extract, Glucose).
<table>
<thead>
<tr>
<th>Status</th>
<th>Dietary Supplements</th>
<th>Foods (^a)</th>
<th>Food Additives (^e)</th>
<th>New Drugs (^b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premarket approval required</td>
<td>No (^c)</td>
<td>No (^d)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Risk-benefit analysis conducted by FDA before marketing</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Burden of proof for demonstrating safety (or lack thereof)</td>
<td>FDA</td>
<td>FDA</td>
<td>Manufacturer</td>
<td>Manufacturer</td>
</tr>
</tbody>
</table>

\(^a\) Foods (including conventional foods and dietary supplements), are considered safe (reasonable certainty of no harm), and thus do not require a risk-benefit analysis.

\(^b\) Applies to “new” drugs. Many over-the-counter drugs are regulated under FDA's Over-The-Counter Drug Review procedures, which do not provide for postmarketing surveillance.

\(^c\) A 75-day premarketing notification, but not premarketing approval, is required for dietary supplements containing ingredients not marketed before 1994.

\(^d\) In 2001, FDA proposed a rule requiring marketers of food developed through biotechnology to notify the agency at least 120 days before commercial distribution and to provide information to demonstrate that the product is as safe as its conventional counterpart.

\(^e\) A food additive is a substance used to enhance taste, appearance or shelf-life to a food.

Source: Adapted from IOM 2005
Gaps in DSHEA

• Manufacturer is responsible for ensuring products are properly labeled

• DS sold before October 15, 1994 are presumed to be safe and not subject to review by FDA

• FDA has to prove a product is NOT safe, if it is already on the market

• Government resources to monitor dietary supplement quality are extremely limited
Identify dangers and risks of selected dietary supplement categories
Issues of Concern

• Consumers generally uninformed
• Majority of consumers believe the FDA has “sufficient” oversight for safety and quality
• Most consumers unaware many DS products are adulterated
• Potential for adverse events/reactions (AEs)
• Thermogenic agents
• Stimulants
• Contaminants and adulterants: e.g. steroids, stimulants, prescription drugs, heavy metals
Supplements that appear safe could be dangerous products in disguise

Decoding the Dietary Supplement industry video
Operation Supplement Safety

• OPSS is THE DoD-wide effort, including partnerships with other government and professional organizations, to provide evidence-based, up-to-date information on dietary supplements.

Operation Supplement Safety

A Defense Center of Excellence

Uniformed Services University
CHAMP
Consortium for Health and Military Performance
Ask the Expert

All information is treated as confidential. It can take us 3 to 7 business days or more to prepare an answer to each question.

If this is an emergency, please call 911, the Military Crisis Line at 800-273-8255, or Military OneSource at 800-342-9647.

What's your current role? *
- Select -

Status *
○ Active Duty
○ Reserve
○ N/A

Are you a Healthcare Provider? *
○ No
○ Yes

Your E-Mail Address *

Subject *

Question *

* You must choose one of the options in order to submit your question.
I have been looking all over the web for some answers on certain products from Blackstone Labs concerning military safety... I have seen very similar ingredients listed as banned but I am not exactly sure if they fall under the same category that would produce a false positive for a military urinalysis test. The following ingredients are:

- 19-NorAndrost-4-ene-3b-ol,170one
- 19-NorAndrost-4-ene-3b-ol,170one Decanoate
- 19-NorAndrost-4-ene-3b-ol,170one Enanthate
- 19-NorAndrost-4-ene-3b-ol,170one dUndercanoate
- 19-NorAndrost-4-ene-3b-ol,170one Caprylate

All of the following were labeled as DHEA supplements, which are legal as far as I could tell from my research...
What is an Adverse Event?

• ANY undesirable experience associated with the use of a dietary supplement in a patient

• Altered mental status, Anxiety, Cardiac dysrhythmia, Cerebral hemorrhage, Cramping, Dizziness, Fatigue, Hallucinations, Headaches, Heat illness, Heart palpitations, Hepatic injury/failure, Increased heart rate, Metabolic derangements, Myocardial infarction, Muscle cramps, Nausea, Nervousness, Nosebleeds, Renal injury/failure, Restlessness, Rhabdomyolysis, Seizures, Sleep disturbances, Syncope
OUR MISSION: YOUR READINESS

WHAT IS OPSS?
Operation Supplement Safety is a Department of Defense dietary supplement resource for the military community, leaders, healthcare providers, and DoD civilians.

OPSS FOR WARFIGHTERS & FAMILIES
- FITNESS & PERFORMANCE
- WEIGHT LOSS

OPSS FOR PROVIDERS & LEADERS
- DIETARY SUPPLEMENT INGREDIENTS
- GENERAL/HEALTH

A Defense Center of Excellence

United States University
CHAMP
Consortium for Health and Military Performance
Reporting AEs

Natural MedWatch

To report an adverse event or side effect related to a natural medicine, complete the form below. Your report will improve healthcare by aiding researchers and will be forwarded to the appropriate regulatory agency. Such as the Food and Drug Administration.

If you have any questions, see our Frequently Asked Questions (FAQ) or learn more about Natural MedWatch.

1. Your name:
   First: 
   Last: 

2. Your profession:
   Do you represent a product manufacturer?
   - Yes  - No
   Are you a health professional?
   - Yes  - No
   Occupation: 

3. Your contact information:
   Phone: 
   Email: 
   Street Address: 
   City: 
   State: 
   Zip Code: 
   International Address: 

4. Patient information if known:
   To protect privacy, do NOT enter patient names or any other patient identifiers. A tracking number will be issued upon completion of this report that you can use for the patient's records, if necessary.
   Did you personally experience this adverse event or side effect?
12. If the product was taken again, did the adverse event occur a second time?
   ☐ Yes  ☐ No  ☐ N/A

   Comments:

13. Other details include:

   

Confidentiality and Privacy Notice: No information will be collected or stored unless the person providing the information agrees. Natural MedWatch will never use information provided for any marketing purpose whatsoever. No information will be shared with any other person or party unless the person providing the information agrees. Persons submitting a report about a patient or another person are encouraged not to provide the patient's name or any information that would identify the patient. Data will be analyzed to identify potential safety issues and trends. Analysis of this data is only conducted in a patient and reporter de-identified manner. The reporter's identity is collected in the event that additional follow-up is needed. Information collected from this form will be forwarded to regulatory bodies, such as the Food and Drug Administration, and may be shared with product manufacturers and research organizations. If you have any questions or concerns about this, please email privacyofficer@naturalmedicineswatch.com or call, 209-472-2244.

Additional Privacy Options
It is OK for Natural MedWatch staff to follow-up with me if needed.
   ☐ Yes  ☐ No

It is OK to disclose my name to regulatory bodies, researchers, or product manufacturers.
   ☐ Yes  ☐ No

[☐] I give my permission to have this information shared as described above.
Third-Party Certification

- Select products with 3rd party certification/verification seals to ensure they have been evaluated for *quality* and *purity*:
  - Banned Substances Control Group (BSCG)
  - ConsumerLab.com
  - Informed-Choice
  - NSF International
  - United States Pharmacopeia Convention (USP)
FREQUENTLY ASKED QUESTIONS

5-HTP: Can 5-HTP in supplements help with depression, appetite, and other conditions?
Products with 5-HTP (short for 5-hydroxytryptophan) are promoted for a variety of conditions, including depression, anxiety, appetite control, fibromyalgia. ... Read More

Acacia rigidula: Is it a legal ingredient in dietary supplements?
Acacia rigidula is an ingredient that has become popular in dietary supplement products for performance and bodybuilding. ... Read More

Aegeline: I recently heard that certain dietary supplement products were causing liver damage because of a specific ingredient, aegeline. What is aegeline and why is it a problem?
Aegeline is a new ingredient being added to dietary supplements; it can also appear on a product label as N-[2-hydroxy-2(4-methoxyphenyl)ethyl]-3-phenylo-2-p. ... Read More

Aromatase inhibitors: What are they and are they allowed for use by Service Members?
Aromatase inhibitors (AI), which prevent testosterone from being converted to estrogen, are used in bodybuilding products to supposedly improve muscle mass. ... Read More
<table>
<thead>
<tr>
<th>Date</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apr 16, 2018</td>
<td>FDA takes step to protect consumers against dietary supplements containing dangerously high levels of extremely concentrated or pure caffeine</td>
</tr>
<tr>
<td>Apr 16, 2018</td>
<td>FDA Warns Consumers About Pure and Highly Concentrated Caffeine</td>
</tr>
<tr>
<td>Feb 21, 2018</td>
<td>FDA Investigates Multistate Outbreak of Salmonella Infections Linked to Products Reported to Contain Kratom</td>
</tr>
<tr>
<td>Feb 21, 2018</td>
<td>FDA oversees destruction and recall of kratom products; and reiterates its concerns on risks associated with this opioid</td>
</tr>
<tr>
<td>Apr 16, 2018</td>
<td>Epic Products, LLC, Issues Voluntary Nationwide Recall of All Lots of Euphoric Capsules Due to Presence of Undeclared Sildenafil and Tadalafil</td>
</tr>
<tr>
<td>Apr 13, 2018</td>
<td>'Rhino 69 Extreme 50000' Recalled due to Presence of Active Ingredient 'Tadalafil'</td>
</tr>
<tr>
<td>Mar 28, 2018</td>
<td>Public Notification: Black Lion Pill contains hidden drug ingredient</td>
</tr>
<tr>
<td>Mar 28, 2018</td>
<td>Public Notification: Red Zone Xtreme 3000 contains hidden drug ingredient</td>
</tr>
</tbody>
</table>
OPSS & HEALTH CARE

Educating your patients about dietary supplement use is a crucial component of health care in the military.

OPSS FOR WARFIGHTERS & FAMILIES

OPSS FOR PROVIDERS & LEADERS

DIETARY SUPPLEMENT CLASSIFICATION SYSTEM

OPSS MARKETING MATERIALS

TRAINING/EDUCATION/MULTIMEDIA
Dietary Supplements Classification System

Dietary Supplements Classification Table

Click on the numbered cell in the table to see the Dietary Supplements in that Class and learn more about them.

<table>
<thead>
<tr>
<th>Potential Benefit</th>
<th>Minimal</th>
<th>Low</th>
<th>Moderate</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>2</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>Moderate</td>
<td>4</td>
<td>5</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Low</td>
<td>6</td>
<td>7</td>
<td>11</td>
<td>12</td>
</tr>
</tbody>
</table>

Disclaimer: This table includes consideration of the safety and potential benefits of dietary supplements based on use at appropriate doses and availability of current data in the literature. The table is meant to be informative and not prescriptive. For individual guidance, consult with a designated health professional for your respective service or specific organization. Scores of 1-3 are in the “Green Zone,” 4-8 in the “Amber Zone,” and 9-12 in the “Red Zone.”

Supplements by Zone

**Green Zone**
- Melatonin
- Multivitamins & Minerals
- Tyrosine
- Vitamin B Complex

**Amber Zone**
- Antioxidants
- Beta-Alanine (β-Alanine)
- *Caffeine
- Chromium
- Coenzyme Q10
- Creatine
- Glutamine
- L-Arginine
- L-Carnitine
- Megavitamins & Minerals
- Quercetin

**Red Zone**
- Ephedra
- Melatonin (for flight personnel)
- Bitter Orange (Synephrine)
- Testosterone Precursors/Boosters and Anabolic Compounds

*Excessive consumption is potentially dangerous and could lead to side effects and/or adverse reactions.

**Insufficient evidence to support a recommendation for use.

Note: Supplements in bold appear in more than one zone.
OPSS & HEALTH CARE

Educating your patients about dietary supplement use is a crucial component of health care in the military.
Creatine is a compound made by your body and found naturally in some foods, mainly meat and fish. It's also a popular ingredient found in dietary supplements.

1. Creatine is only effective for explosive, high-intensity activities (such as lifting, jumping, and sprinting).
2. Not everyone will experience an improvement in performance. Some people respond better than others to creatine supplements.
3. Creatine monohydrate, the most common form of creatine in supplements, is generally safe and effective when used appropriately (~3 g/day - more is not better).
4. Creatine monohydrate is generally well-tolerated short-term, but less is known about its long-term safety.
5. More than 10 forms of creatine are available in supplements. There isn't enough evidence to support claims that any other form of creatine is better than creatine monohydrate.

**BOTTOM LINE: IF YOU CHOOSE TO USE CREATINE...**

- Look for "creatine monohydrate" as the only ingredient on the Supplement Facts panel.
- Choose a third-party certified/verified product. Look for any of these seals on the product label:
  - NSF
  - USP
  - IWFTP
  - USU
  - CHAMP

- Inform your healthcare provider of any supplements you use and discuss how to use supplements safely.

**Supplement Facts**

<table>
<thead>
<tr>
<th>Serving size: 1 scoop (3 g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Servings per container: 100</td>
</tr>
<tr>
<td><strong>Amount per serving</strong></td>
</tr>
<tr>
<td>Creatine monohydrate</td>
</tr>
</tbody>
</table>

* Daily Value not established

For more information about creatine supplements, visit OPSS.org

Operation Supplement Safety (OPSS.org)
EAT REAL FOOD INSTEAD!

TAKING DIETARY SUPPLEMENTS?

SUPPLEMENT: PRE-WORKOUT
FOODS THAT ENERGIZE YOU BEFORE YOUR WORKOUT:
- Nut butter and jam/jelly on whole-grain bread
- Low-fat Greek yogurt with fruit and water
- Oatmeal, banana, and water
- Low-fat granola and milk

SUPPLEMENT: POST-WORKOUT
FOODS THAT ENHANCE YOUR POST-WORKOUT RECOVERY:
- Tuna, whole-grain crackers, fruit, and water
- Chocolate milk (or soy milk) and fruit
- Yogurt, fruit, granola, and juice
- Nuts, fruit, and water

SUPPLEMENT: CASEIN PROTEIN
FOODS SOURCES OF CASEIN OR WHEY:
- Milk
- Cottage cheese
- Ricotta cheese
- Yogurt

SUPPLEMENT: BODYBUILDING
FOODS THAT PROMOTE MUSCLE GROWTH:
- Lean meats
- Poultry
- Fish and seafood
- Milk
- Greek yogurt
- Beans and lentils
- Nuts and seeds
- Tofu
- Eggs

SUPPLEMENT: BRANCHED-CHAIN AMINO ACIDS
FOODS SOURCES OF BCAAS:
- Meats
- Poultry
- Fish and seafood
- Milk
- Cottage cheese

SUPPLEMENT: WEIGHT LOSS
FOODS THAT HELP YOU LOSE WEIGHT:
- Fruits and veggies
- Whole grains (brown rice, quinoa, etc.)
- Lean proteins (fish, poultry, beans, nuts, and dairy)
- Unsweetened beverages (water, low-fat milk, tea, etc.)
PRE-WORKOUT SUPPLEMENTS

WATCH FOR STIMULANTS. READ THE LABEL.
Stimulants are intended to rev you up, but too much can negatively affect your training and performance.

WARNING

PROPONENTS
This product contains 1,3-dimethylamylamine, or DMAA, which is prohibited for use by Military Service Members.

BLENDING
Can you tell how much of each ingredient is in the product? This product contains a “proprietary blend” (also might be called a “matrix” or “complex”).

CAFFEINE
May contain 300 mg or more per serving (or an unknown amount in a proprietary blend). Consider all sources of caffeine (foods, beverages, and dietary supplements). Do not exceed 600 mg caffeine per day to avoid adverse effects such as racing heart, altered heart rhythms, insomnia, increased blood pressure, jitters, GI upset, and chest pain.

STIMULANTS
The product contains multiple stimulants (in red) that together could compromise mission readiness due to negative health effects (see Caffeine above). Insomnia from stimulants can adversely impact performance and sleep.

THIRD-PARTY CERTIFICATION
Only a third-party certification seal confirms what’s in the product.

Supplement Facts
Serving size: 1 scoop (approx. 13.2 g)
Serving per container: 30

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Amount per serving</th>
<th>% Daily Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Niacin Vitamin B12</td>
<td>60 mg</td>
<td>1%</td>
</tr>
<tr>
<td>Sodium</td>
<td>80 mg</td>
<td>3%</td>
</tr>
<tr>
<td>Potassium</td>
<td>60 mg</td>
<td>1%</td>
</tr>
<tr>
<td>Amino Blend</td>
<td>1 g</td>
<td></td>
</tr>
<tr>
<td>Alanine &amp; Glycine</td>
<td>2 g</td>
<td></td>
</tr>
<tr>
<td>Taurine</td>
<td>3 g</td>
<td></td>
</tr>
<tr>
<td>Coffeeine</td>
<td>7,000 mg</td>
<td></td>
</tr>
</tbody>
</table>

Other ingredients: citric acid, malic acid, natural & artificial flavor, cornstarch, annatto, silicon dioxide, potassium, FD&C Red No. 40
Screen your supplement for safety. Read the label on your supplement and mark 1 for “yes” and 0 for “no.”

<table>
<thead>
<tr>
<th>Key questions you can answer</th>
<th>Yes=1</th>
<th>No=0</th>
</tr>
</thead>
<tbody>
<tr>
<td>These seals show your product has been certified/verified for product quality. Is any one of these seals on the label?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are there less than six ingredients on the Supplement Facts panel?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the label free of any blends or complexes, such as proprietary blends or complexes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Can you pronounce the names of each ingredient on the Supplement Facts panel?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the amount of caffeine listed on the label 200 mg or less per serving? (If caffeine is not listed, mark “1.”)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the label free of “quick fix” claims?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the Daily Value (%DV) less than 200% for each ingredient on the Supplement Facts panel?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total: Add up the “1s.” 4 or more is okay. Less than 4 is a “no-go.”</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If you still want to consider the supplement, get more information. If you have a .mil email address, you can use the Natural Medicines database for free: info.therapeuticresearch.com/dod
OPSS & HEALTH CARE

Educating your patients about dietary supplement use is a crucial component of health care in the military.
Dietary supplement “ingredients” prohibited by the Department of Defense

The following are substances that have at one time appeared, or currently appear, as ingredients in products labeled as dietary supplements that FDA or the U.S. Armed Services have disallowed for one reason or other. In addition, all prescription drugs and controlled substances are not permitted for use in or as dietary supplements, but only a few are listed here. Since DoD follows federal guidelines with regard to dietary supplements, this list is provided to help military service members keep track of things to avoid when considering dietary supplement products.

<table>
<thead>
<tr>
<th>Common name</th>
<th>Other names</th>
<th>Reason “not allowed”</th>
<th>Reference links</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acacia rigidula</td>
<td>A. rigidula, Vachellia rigidula, Chaparral Prieto, blackbrush</td>
<td>New dietary ingredient lacking evidence for safe use</td>
<td>FDA: Acacia rigidula in Dietary Supplements</td>
</tr>
<tr>
<td>Acenitine</td>
<td>Aconitum, wortblume</td>
<td>Potentially fatal poison. Listed in FDA’s poisonous plant database</td>
<td>In FDA’s Poisonous Plant Database (examples of more than 200 entries; see search)</td>
</tr>
<tr>
<td>Aegeline</td>
<td>N-2-Hydroxy-2(4-methoxyphenyl)ethyl-3-phenoxy-2-propanomide, Aegle marmelos, baal</td>
<td>New dietary ingredient lacking evidence for safe use. Associated adverse events reported</td>
<td>FDA Investigation Summary: Acute Hepatitis Liferices Linked to Certain OxyElite Pro Products and FDA Consumer Update: OxyElite Pro Supplements Recalled</td>
</tr>
</tbody>
</table>

Including, but not limited to:
- 1,4,6-triiodothyronine
- 5A-Reductase Inhibitors
- Drugs, etc.
Guidelines for taking a comprehensive dietary supplement history

It’s important for providers to be aware of all dietary supplements, if any, that their patients are taking due to the potential for interactions with other supplements, medications, and some medical conditions. In addition, some products might contain unsafe ingredients, including ones legitimately available only through prescription, which can result in adverse reactions. Even products with documented health and/or performance benefits for specific conditions—such as iron, vitamin D, whey protein, and creatine—should be evaluated holistically.

Just as you would ask about a patient’s medications as a part of the medication-reconciliation process to determine potential risk, remember always to ask about his or her supplement use too. Although having your patient bring his or her supplements into the office is the best way to get this information, the guidelines here will help you obtain a comprehensive dietary supplement history.

Ask your patients:

☐ Are you currently taking any dietary supplements? Think about the different forms your supplements might come in. Are you taking any of the following:

- Bars
- Capsules or tablets
- Chews or gummies
- Gels or goos
- Liquids or extracts
- Fills
- Powders
- Shakes

Be sure to describe examples of dietary supplements—such as single- and multi-vitamin/mineral supplements, protein powders or shakes, fish oil, probiotics, fiber powders or gummies, “pre-workouts,” testosterone boosters, and nootropics (cognitive enhancers)—to get the “whole picture.”

☐ Are you currently using *botanicals* and/or other products that contain caffeine, such as coffee, tea, soda, energy drinks/shots, or “pre-workouts”? (See the OPSS FAQ about hidden sources of caffeine for names of other sources of caffeine.)
Capsaicin and capsaicinoids: Can they help with weight loss?

If you've ever eaten something spicy and felt a burning sensation on your tongue, then you've eaten capsaicinoids. Capsaicinoids (including capsaicin, dihydrocapsaicin, and others) are the substances found in chili peppers that give them their spiciness. Although humans have been eating peppers for thousands of years, capsaicinoids only recently have come into the supplement spotlight. As a dietary supplement ingredient, capsaicinoids are often labeled as "cayenne pepper" or "capsicum," after the family of peppers that naturally contain capsaicinoids.

Capsaicinoids are purported to aid weight loss in three ways: increase energy use, burn fat, and decrease appetite. Some scientific evidence supports these statements, but results are mixed, and many studies only looked at the short-term effects of consuming capsaicinoids. Whether capsaicinoids can affect metabolism and appetite enough to result in meaningful weight loss or help with weight maintenance remains in question.

Moreover, additional research would be needed to determine the optimal dose and duration of capsaicinoids for weight loss. Consuming too much capsaicinoids (whether from food or supplements) can cause gastrointestinal issues for some people. Also, long-term effects of taking supplemental capsaicinoids, especially at high doses, are still unknown, so their safety over time needs further investigation.

Bottom line: More research is needed to determine if capsaicinoids can help you lose weight, but if you still want to include them in your diet, try adding some chili peppers to your foods, but avoid consuming supplements.
OPSS High-Risk Supplement List

Some dietary supplement products contain stimulants, steroids, hormone-like ingredients, controlled substances, or unapproved drugs. The Operation Supplement Safety (OPSS) High-Risk Supplement List helps you identify supplements that might pose a potential risk to your health or career. Not all supplements on the list are illegal or banned, but all pose potential health risks. In addition, the list is not exhaustive, so something that isn’t on the list can still be unsafe.

The Food and Drug Administration (FDA) is the federal regulatory agency responsible for enforcing legislation about dietary supplements. FDA routinely issues public statements about adulterated, illegal, and dangerous dietary supplements; see their Tainted Products widget displayed to the right on this page.

The information in the OPSS High-Risk Supplement List is not intended to be a substitute for professional advice. You should contact a healthcare provider for specific medical or nutritional advice. Any reliance on the information provided in the OPSS High-Risk Supplement List is solely at your own risk. Please visit other sections of the OPSS website for further education to help you make wise decisions about dietary supplements.

Note: In order to access the list, an account is required. Sign up for an account to access current and future updated lists.

Enter the OPSS High-Risk Supplement List
<table>
<thead>
<tr>
<th>Supplement</th>
<th>Brand Name</th>
<th>Company</th>
<th>Could Contain</th>
<th>Notes/Comments</th>
<th>Updated</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,3D BOMB</td>
<td>TBN</td>
<td>Stimulants</td>
<td></td>
<td>For more information please see the OPSS FAQ on DMAA and the OPSS FAQ on stimulants</td>
<td>02/05/2016</td>
</tr>
<tr>
<td>1-Andro</td>
<td>LG Sciences</td>
<td>Anabolic agents</td>
<td></td>
<td>For more information please see the OPSS FAQ on anabolic substances.</td>
<td>05/09/2010</td>
</tr>
<tr>
<td>1-Andro Liquid</td>
<td>Advanced Muscle Science (AMS)</td>
<td>Anabolic agents</td>
<td></td>
<td>For more information please see the OPSS FAQ on anabolic substances.</td>
<td>11/14/2014</td>
</tr>
<tr>
<td>1-Andro Max V2</td>
<td>Primeval Labs</td>
<td>Anabolic agents</td>
<td></td>
<td>For more information please see the OPSS FAQ on DHEA.</td>
<td>09/11/2017</td>
</tr>
<tr>
<td>1-Andro RDe Chrome</td>
<td>Advanced Muscle Science (AMS)</td>
<td>Anabolic agents</td>
<td></td>
<td>Testing of Lot #1330 revealed the presence of 1-androstenediol and androsterone. For more information please see the OPSS FAQ on anabolic substances.</td>
<td>05/20/2015</td>
</tr>
<tr>
<td>1-Andro RX</td>
<td>IronMagLabs</td>
<td>Anabolic agents</td>
<td></td>
<td>For more information please see the OPSS FAQ on DHEA.</td>
<td>03/13/2014</td>
</tr>
<tr>
<td>1024</td>
<td>Achievement Through Sciences (ATS) Labs</td>
<td>Anabolic agents</td>
<td></td>
<td>Testing of a sample purchased June 2015 revealed the presence of boldione, methasterone, and androsta-1,4,6-trienedione. For more information please see the OPSS FAQ on anabolic substances.</td>
<td>07/24/2015</td>
</tr>
<tr>
<td>11-OxoDerm</td>
<td>Platinum Nutraceuticals</td>
<td>Anabolic agents</td>
<td></td>
<td>For more information please see the OPSS FAQ on anabolic substances.</td>
<td>12/04/2015</td>
</tr>
</tbody>
</table>
scientific evidence. There is also concern that supplements marketed for these purposes might create “false assurances,” leading patients with TBI to resume their activities before they are ready. This could result in worsened symptoms or slower recovery. For more information, please read FDA’s Consumer Update.

Although omega-3 supplements haven’t been proven to help with TBI, omega-3s are still important for your brain, heart, and overall health. It’s best to get your omega-3s from food, but if you choose to take supplements, do so under the supervision of your doctor. For more information on omega-3 supplements, please read “Omega-3 Supplements: In Depth” from the National Center for Complementary and Integrative Health.

TBI is a serious health condition that can have short- and long-term effects on how you think and feel. To learn more about preventing and addressing TBIs, visit the Traumatic Brain Injury section of the Human Performance Resource Center’s website, as well as the Centers for Disease Control and Prevention’s web page on traumatic brain injury and concussion.

Updated 09 January 2018
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Welcome DoD Warfighters and Healthcare Professionals

Natural Medicines provides in-depth information about dietary supplement products and ingredients based on the best available scientific evidence. You can get ratings for the safety and effectiveness of products along with the uses, benefits, side effects, drug interactions, etc., of the ingredients found in dietary supplement products.

This is offered in collaboration with Natural Medicines and the Consortium for Health and Military Performance (CHAMP), a Defense Center of Excellence. Complimentary access to Natural Medicines is available using a .mil email address.

Healthcare Professionals: Access Natural Medicines here:

- Professional Version
- Create Login

Warfighters: Access the Consumer Version of Natural Medicines here:

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- Create Login

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NATURAL MEDICINES

The most authoritative resource available on dietary supplements, natural medicines, and complementary alternative and integrative therapies.

LEARN MORE
About Us

Background & Overview

Many military service members use dietary supplements—for promoting health, improving performance, bodybuilding, losing weight, and more. Unfortunately, some supplements have resulted in adverse events that compromise rather than improve performance, and in some cases result in positive drug tests.

In January 2012 the Assistant Secretary for Health Affairs requested a DoD-wide educational campaign on dietary supplements. In response to this request, the DoD Dietary Supplement Subcommittee (DSSC), the U.S. Army Public Health Command, and the Consortium for Health and Military Performance (CHAMP) at the Uniformed Services University of the Health Sciences (USU) began developing a DoD-wide educational campaign—Operation Supplement Safety, or OPSS—to increase awareness within the DoD community about potential health risks and how to choose safe dietary supplements.

OPSS is now a DoD-wide effort, including partnerships with other government and professional organizations, to provide evidence-based, up-to-date information on dietary supplements. OPSS educates service members and retirees, their family members, leaders, healthcare providers, and DoD civilians about dietary supplements and gives them tools to be informed supplement users—or non-users.

Our Partners

- Dietary Supplement Label Database, National Institutes of Health
- Federal Trade Commission
- Food and Drug Administration
- National Center for Complementary and Integrative Health
- Office of Dietary Supplements, National Institutes of Health
- Natural Medicines
- United States Anti-Doping Agency
Summary

• OPSS is the DoD “go to” for all information regarding dietary supplements
• Information changes regularly, so check the website often
• Sign-up for our OPSS newsletter
• Give us your feedback!
For Further Information

Please contact:
Andrea Lindsey, Director, OPSS

Andrea.lindsey.ctr@usuhs.edu