

Dietary Supplements & Operation Supplement Safety

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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

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Dietary Supplement Health and Education Act of 1994: DSHEA

- 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."



Which is a Dietary Supplement? /////R





Nutrition Facts

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

Amount	Per	Serving	ı
Aillouit		Oct villig	ı

Calories 200 Calories from Fat 130

% Daily Value* Total Fat 14g 22% Saturated Fat 9a **45**%

Trans Fat 0g

18% Cholesterol 55mg

Sodium 40mg 2% 6%

Total Carbohydrate 17g

Dietary Fiber 1g 4% Sugars 14g

Protein 3q

Vitamin A 10% Vitamin C 0%

Calcium 10% Iron 6%

*Percent Daily Values are based on a 2.000 calorie diet. Your daily values may be higher or lower

2.500

30g

depending on your calorie needs: 2.000 Calories:

Total Fat 65g 80g Less than Saturated Fat Less than 20q 25q Cholesterol Less than 300mg 300 mg Sodium Less than 2,400mg 2,400mg Total Carbohydrate 300a 375g

Dietary Fiber Calories per gram:

Fat 9 • Carbohydrate 4 • Protein 4

25g



children under 6 years

A dietary supplement



An OTC medication



Active ingredient (in each table Chlorpheniramine maleate 2 mg	
Uses temporarily relieves these symptoms allergies: ■ sneezing ■ runny nose ■ it	
Warnings Ask a doctor before use if you have ■ glaucoma ■ a breathing problem such a ■ trouble urinating due to an enlarged prostat	
Ask a doctor or pharmacist before use if y	rou are taking tranquilizers or sedatives
When using this product ■ drowsiness may occur ■ avoid alcoholic ■ alcohol, sedatives, and tranquilizers may in ■ be careful when driving a motor vehicle or of ■ excitability may occur, especially in children	crease drowsiness operating machinery
If pregnant or breast-feeding, ask a health Keep out of reach of children. In case of o Control Center right away.	professional before use. verdose, get medical help or contact a Poison
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;

ask a doctor

SUPPLEMENT FACTS

Serving size: 1 oz Servings/container: 1

Parioun	e ber ser milde	~ ~ .
Calories	15	
Calories from Fat	5	
Total Carbohydrates	7 g	2%
Dietary Fiber	1 g	<1%
Sugars	4 g	*
Sodium	5 mg	<1%
Proprietary EFA Blend	2000 m	g *

Amount per serving:

Black Raspberry Seed Powder, Hulled Hemp Seeds, Black Cumin Seed Powder, Black Cumin Seed Oil, Black Raspberry Seed Oil.

Proprietary Blend 1200 mg * D- Ribose, Magnesium Malate, Malic Acid,

Resveratrol, Marine Phytoplankton.

* Daily Values not established. Percent 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, Mesg-pg

(Soutellaria Baicalensis Root Extract, Cameliia Sinensis Leaf Extract, Houttuynia Cordata Leaf Extract, Artemisia Princeps Leaf Extract, Citrus Junos Fruit Extract, Glycine).

What you may not know...

Food



Nutrition Facts

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

Calories 200 Calories from Fat 130

	% Daily Value*
Total Fat 14g	22%
Saturated Fat 9g	45%
Trans Fat 0g	

Cholesterol 55mg	18%
Sodium 40mg	2%

Journal Forms	
Total Carbohydrate 17g	6%
Dietary Fiber 1g	4%

Sugars 14g Protein 3g

Vitamin A 1	10% •	Vitamin	C 0%

Calcium 10% • Iron 6%

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

depending on your calone needs:				
	Calories:	2,000	2,500	
Total Fat	Less than	65g	80g	
Saturated Fat	Less than	20g	25g	
Cholesterol	Less than	300mg	300 mg	
Sodium	Less than	2,400mg	2,400mg	
Total Carbohydrate		300g	375g	
Dietary Fiber		25g	30g	

Calories per gram:

Fat 9 • Carbohydrate 4 • Protein 4



children under 6 years

Generally recognized as safe (GRAS)

OTC Med
Proven evidence of efficacy and known safety

Drug Facts Active ingredient (in each tablet) Purpose Chlorpheniramine maleate 2 mg... Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes 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 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 contact a Poison Control Center right away. Directions take 2 tablets every 4 to 6 hours; adults and children 12 years and over 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

ask a doctor

Supplements

No requirement for evidence of safety or efficacy

SUPPLEMENT FACTS

Serving size: 1 oz Servings/container: 1

	per serving:	% DV	
Calories	15		
Calories from Fat	5		
Total Carbohydrates	7 g	2%	
Dietary Fiber	1g	<1%	
Sugars	4 g	*	
Sodium	5 mg	<1%	
Proprietary EFA Blend	2000 m	a *	

Black Raspberry Seed Powder, Hulled Hemp Seeds, Black Cumin Seed Powder, Black Cumin Seed Oil,

Black Raspberry Seed Oil.

Proprietary Blend 1200 mg * D-Ribose, Magnesium Malate, Malic Acid,

Resveratrol, Marine Phytoplankton.

* Daily Values not established. Percent 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, Mesg-pg
(Soutellaria Baicalensis Root Extract, Cameliia Sinensis Leaf
Extract, Houttuvnia Cordata Leaf Extract, Artemisia Princeps

Leaf Extract, Citrus Junos Fruit Extract, Glycine).

Are Supplements Regulated? Yes, but ...



Status	Dietary Supplements	Foods ^a	Food Additives ^e	New Drugs ^b
Premarket approval required	No ^c	No ^d	Yes	Yes
Risk-benefit analysis conducted by FDA before marketing	No	No	Yes	Yes
Burden of proof for demonstrating safety (or lack thereof)	FDA	FDA	Manufacturer	Manufacturer

^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.

Source: Adapted from IOM 2005



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^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

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



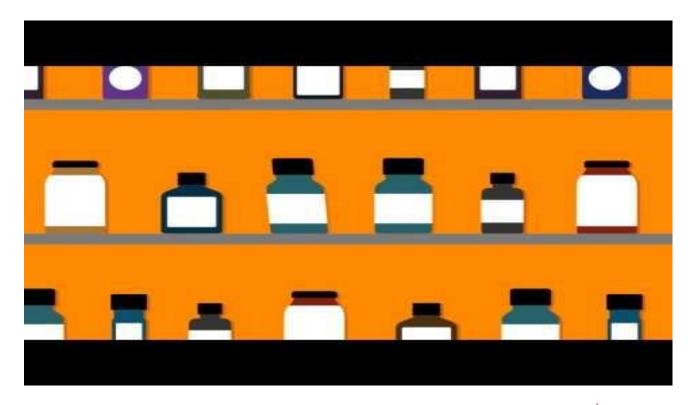
Issues of Concern

- 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





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Operation Supplement Safety

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





OPSS.org

ASK THE EXPERT

REPORT ADVERSE EVENTS

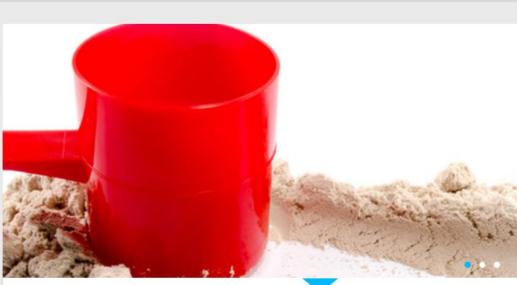
ARTICLES

AQS

MULTIMEDIA



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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 OPSS FOR PROVIDERS & LEADERS

FITNESS & PERFORMANCE

DIETARY SUPPLEMENT INGREDIENTS

WEIGHT LOSS

GENERAL/HEALTH



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 *			
,			
O*			
Question *			
I'm not a robot	2		
Till flot a lobot	reCAPTCHA		

Important Links











.GOV Resources

Food and Drug Administration (FDA)

Food and Nutrition Information Center (USDA)

Federal Trade Commission (FTC)

National Center for Complementary and Integrative Health (NCCIH)

Office of Dietary Supplements (ODS)

MedlinePlus: Drugs, Herbs, and Supplements

Full list of dietary supplement fact sheets from

Dietary Supplement Label Database

APPS













Submit

Sample ATEs

As a medical provider on a Marine unit, I am trying to find out some supplements that I have encounter. The first one is to rebuild amino acids by Genetix, called AlphaX. The second one is a growth hormone by Genetix, called GH+. I am trying to make sure my Marines are taking the right thing.

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:

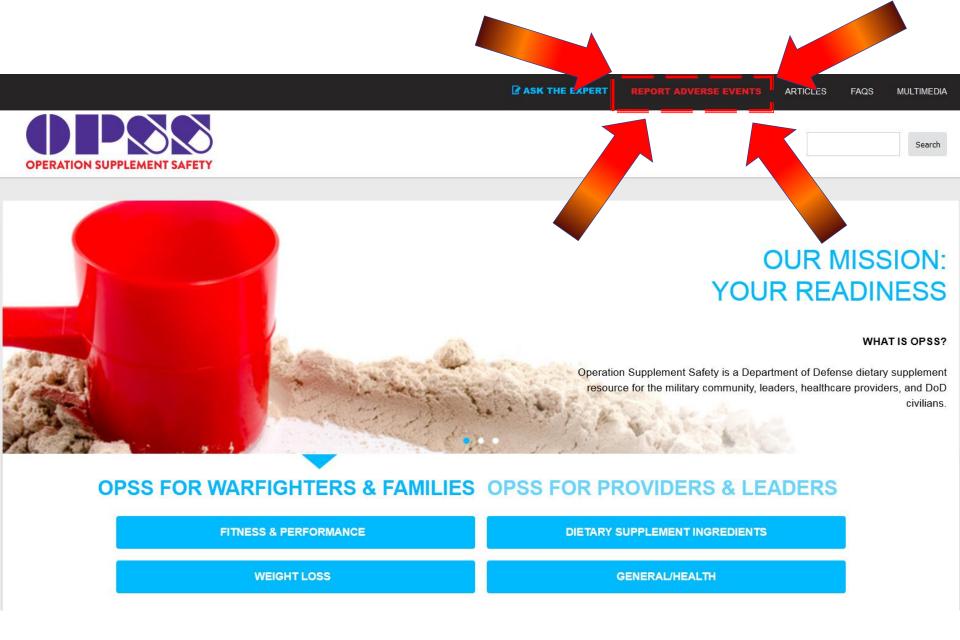
- 19-NorAndrost-4-ene-3b-ol,170one
- 19-NorAndrost-4-ene-3b-ol,170one Decanoate
- 19-NorAndrost-4-ene-3b-ol,170one Enanthate
- 19-NorAndrost-4-ene-3b-ol,170one dUndercanoate
- 19-NorAndrost-4-ene-3b-ol,170one Caprylate

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







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Reporting AEs



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⇔ Print ♀ Feedback



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:		Your Info
	First:		
	Last:		
2.	Your profession:		
	Do you represent a product ma	anufacturer?	
	Are you a health professional? Yes No		
	Occupation:	Select One ▼	
3.	Your contact information:		
	Phone:		
	Email:		
	Street Address:		
	City:		
	State:	AL ▼	
	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.

Patient Info

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
Required 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)













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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-phenyl-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

Important Links











APPS



OPSS High-Risk Supplement List





OPSS/NMCD for Warfighters







NSF for Sport

ALERTS & ANNOUNCEMENTS



Apr 16, 2018

FDA takes step to protect consumers against dietary supplements containing dangerously high levels of extremely concentrated or pure caffeine

Apr 16, 2018

FDA Warns Consumers About Pure and Highly Concentrated Caffeine

Feb 21, 2018

FDA Investigates Multistate Outbreak of Salmonella Infections Linked to Products Reported to Contain Kratom

Feb 21, 2018

FDA oversees destruction and recall of kratom products; and reiterates its concerns on risks associated with this opioid

Apr 16, 2018

Epic Products, LLC, Issues Voluntary Nationwide Recall of All Lots of Euphoric Capsules Due to Presence of Undeclared Sildenafil and Tadalafil

Apr 13, 2018

'Rhino 69 Extreme 50000' Recalled due to Presence of Active Ingredient 'Tadalafil'

Mar 28, 2018

Public Notification: Black Lion Pill contains hidden drug ingredient

Mar 28, 2018

Public Notification: Red Zone Xtreme 3000 contains hidden drug ingredient

QUICK LINKS

OPSS High-Risk Supplement List

Natural Medicines Supplement Ratings

Is Your Supplement Clean?

CONNECT WITH US:







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Sign up to receive OPSS newsletters.

email address

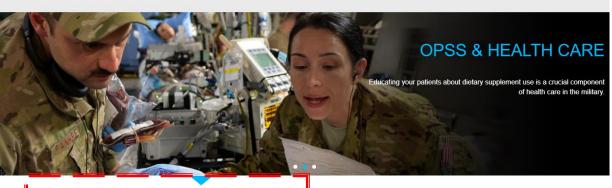
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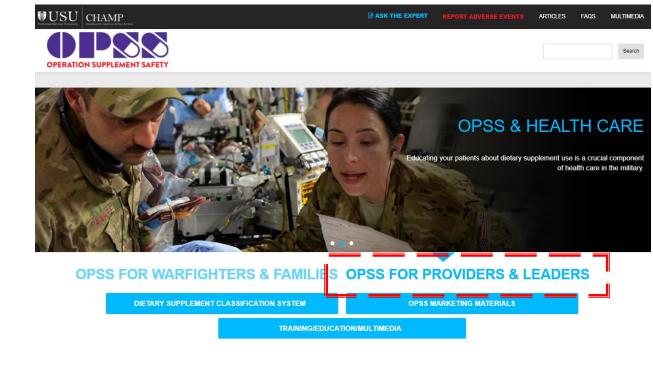
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FITNESS & PERFORMANCE

DIETARY SUPPLEMENT INGREDIENTS

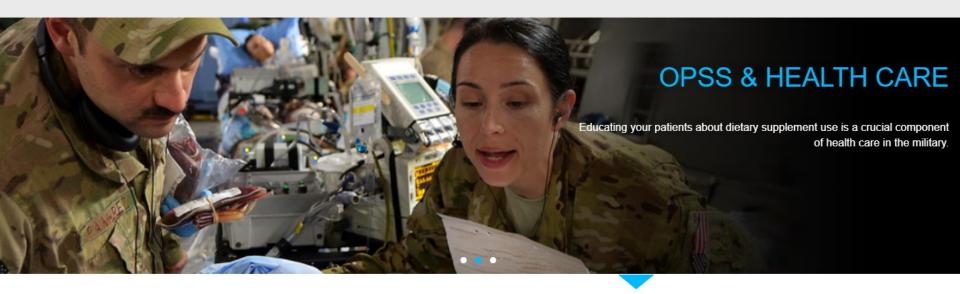
WEIGHT LOSS

GENERAL/HEALTH



ASK THE EXPERT

FAQS



OPSS FOR WARFIGHTERS & FAMILIES OPSS FOR PROVIDERS & LEADERS

DIETARY SUPPLEMENT CLASSIFICATION SYSTEM

OPSS MARKETING MATERIALS

TRAINING/EDUCATION/MULTIMEDIA

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Dietary Supplements Classification System

Dietary Supplements Classification Table Click on the numbered cell in the Risk (Safety Concerns) table to see the Dietary Supplements Minimal Moderate High in that Class and learn more about them. Low High 4 8 Moderate Potential Benefit 5 6 Low

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	Amber Zone	Red Zone		
Melatonin	Antioxidants	Ephedra		
Multivitamins & Minerals	Beta-Alanine (B-Alanine)	Melatonin (for flight personnel)		
Tyrosine	*Caffeine	Bitter Orange (Synephrine)		
Vitamin B Complex	Chromium	Testosterone Precursors/Boosters and Anabolic Compounds		
	Coenzyme Q10			
	Creatine			
	Glutamine			
	L-Arginine			
	L-Carnitine			
	Megavitamins & Minerals			
	Quercetin			
	Other Sports Products			
Sports Drinks	*Energy Drinks	**Energy Shots		
Sports Gels				

*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.







Important Links











APPS



OPSS High-Risk Supplement List







OPSS/NMCD for Warfighters







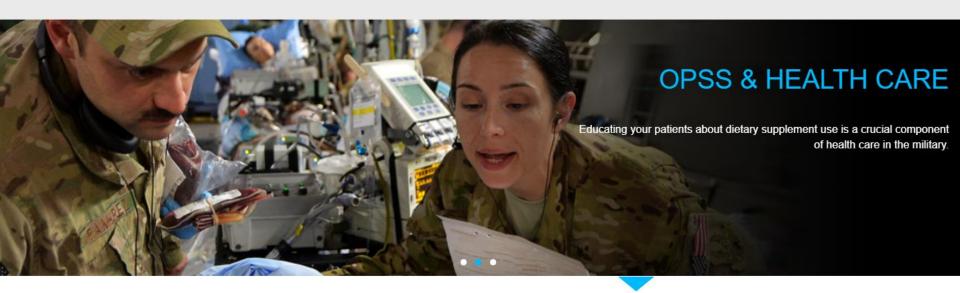
NSF for **Sport**

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DIETARY SUPPLEMENT CLASSIFICATION SYSTEM

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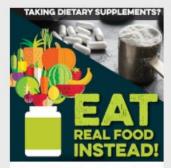




Search

OPSS has materials for you to make available to your client base. Either print high-resolution versions for handouts or order materials through the Army Public Health Center's Health Information Products e-Catalog for more professional versions appropriate for use at health fairs or in display racks.

Home » For Providers & Leaders



Taking Dietary Supplements? Eat Real Food Instead! [PDF]



Creatine: Just the Facts [PDF]



Caffeine and Performance [PDF]



OPSS Banner



OPSS Campaign Button



OPSS: Fueled for Fitness brochure, 8.5x11



Ripped or Ripped Off Poster, Tray Mat, and Table Tent



OPSS Adverse Events Poster, 11.75x15.875









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CREATINE JUST THE FACTS

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.







Creatine is only effective for explosive, high-intensity activitie (such as lifting, jumping, and sprinting).



Not everyone will experience an improvement in performance.

Some people respond better than others to creatine supplements.



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).



Creatine monohydrate is generally well-tolerated short-term, but less is known about its long-term safety.



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...





Choose a thirdparty certified/ verified product. Look for any of these seals on the product label:



Other ingredients: None

* Daily Value not established

 ${\bf FOR\ MORE\ INFORMATION\ ABOUT\ CREATINE\ SUPPLEMENTS,\ VISIT\ OPSS.ORG.}$











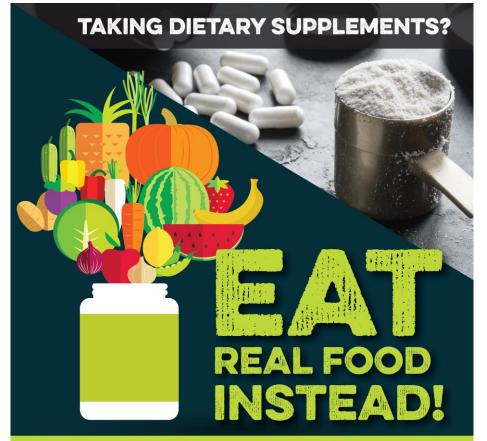
Inform your healthcare provider of any supplements you use and discuss how to use supplements safely.







Promos





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



FOODS THAT ENHANCE YOUR POST-WORKOUT RECOVERY:

- · Tuna, whole-grain crackers, fruit, and water
- · Chocolate milk (or soymilk) and fruit

SUPPLEMENT:

- · Yogurt, fruit, granola, and juice
- · Nuts, fruit, and water



FOODS THAT PROMOTE MUSCLE GROWTH:

SUPPLEMENT:

BODYBUILDING

- · Lean meats Beans and lentils
- Poultry · Nuts and seeds
- Fish and seafood Tofu
- Milk and
- Greek yogurt

• Eggs

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.)



SUPPLEMENT: WHEY OR CASEIN PROTEIN

FOODS SOURCES OF WHEY OR CASEIN:

- Milk
- · Cottage cheese
- · Ricotta cheese
- Yogurt



FOODS SOURCES OF BCAAS:

• Meats

- · Poultry
- · Fish and seafood
- Milk
- · Cottage cheese





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PRE-WORKOUT WATCH FOR STIMULANTS. SUPPLEMENTS Stimulants are intended to rev you up, but too much can negatively affect your training and performance.

WARNING

PROHIBITED This product contains

INGREDIENTS 1,3-dimethylamylamine, or

DMAA, which is prohibited for use by Military Service Members.

BLENDS 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 Only a third-party certification seal CERTIFICATION confirms what's in the product.





















Screen your supplement for safety. Read the label on your supplement and mark 1 for "yes" and 0 for "no."

Key questions you can answer:			
These seals show your product has been certified/verified for product quality. Is any one of these seals on the label?			
Are there less than six ingredients on the Supplement Facts panel?			
Is the label free of any blends or complexes, such as proprietary blends or complexes?			
Can you pronounce the names of each ingredient on the Supplement Facts panel?			
Is the amount of caffeine listed on the label 200 mg or less per serving? (If caffeine is not listed, mark "1.")			
Is the label free of "quick fix" claims?			
Is the Daily Value (%DV) less than 200% for each ingredient on the Supplement Facts panel?			

Total: Add up the "1s." 4 or more is okay. Less than 4 is a "no-go."

QUESTIONS ABOUT DIETARY SUPPLEMENTS?

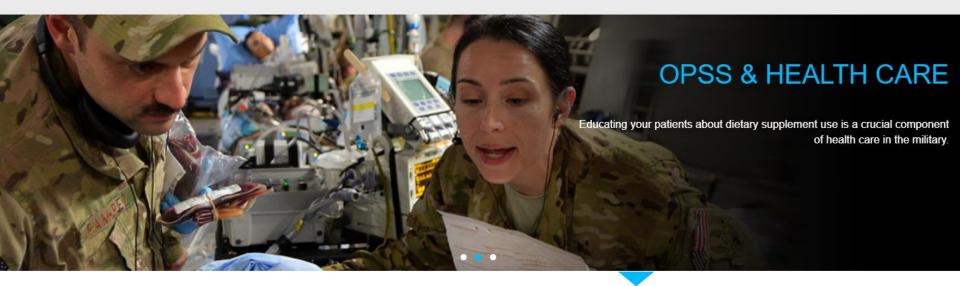
Ask the OPSS experts at OPSS.org/ask-the-expert

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

ASK THE EXPERT





OPSS FOR WARFIGHTERS & FAMILIES OPSS FOR PROVIDERS & LEADERS

DIETARY SUPPLEMENT CLASSIFICATION SYSTEM

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USMC Public Safety Advisory: Cannabidiol and "vaping"



Guidelines for taking a comprehensive dietary supplement history



A service member's message to others after taking dietary supplements [Video]



OPSS short presentation slides for providers & leaders



OPSS short presentation slides for Warfighters



Dietary supplement "ingredients" prohibited by the Department of Defense



Stimulants found in dietary supplements



Dietary Supplements and Other Commercial Products Containing SARMs



Important Links











APPS

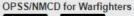


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Related OPSS Content

5-HTP: Can 5-HTP in supplements help with depression, appetite, and other conditions?



A Mother's Plea [Video]



A service member's message to others after taking dietary supplements [Video]

Acacia rigidula: Is it a legal ingredient in dietary supplements?

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?

Are testosterone booster

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.

Common name	Other names	Reason "not allowed"	Reference links
Acacia rigidula	A. rigidula Vachellia rigidula Chaparro Prieto blackbrush	New dietary ingredient lacking evidence for safe use	FDA: Acacia rigidula in Dietary Supplements
Aconite	Aconitum wolfsbane	Potentially fatal poison. Listed in FDA's poisonous plant database	In FDA's Poisonous Plant-Database: (one example of more than 200 entries; see search)
Aegeline	N-2-hydroxy-2(4-methoxyphenyl) ethyl-3-phenyl-2-propenamide Aegle marmelos, bael	New dietary ingredient lacking evidence for safe use. Associated adverse events reported **	FDA Investigation Summary: Acute Hepatitis Illnesses Linked to Certain OxyElite Pro Products and FDA Consumer Update: OxyElite Pro Supplements Recalled
	Including, but not limited to: 1,4,6 etioallocholan-dione	Drugo como	

Important Links











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Food and Drug Administration (FDA)

Food and Nutrition Information Center (USDA)

Federal Trade Commission (FTC)

National Center for Complementary and Integrative Health (NCCIH)

Office of Dietary Supplements (ODS)

MedlinePlus: Drugs, Herbs, and Supplements

Full list of dietary supplement fact sheets from

Dietary Supplement Label Database



OPSS High-Risk Supplement List











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Related OPSS Content



A Mother's Plea [Video]



A service member's message to others after taking dietary supplements [Video]



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
- 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.)

Important Links











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Office of Dietary Supplements (ODS)

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Full list of dietary supplement fact sheets from ODS

Dietary Supplement Label Database

APPS



OPSS High-Risk Supplement List









OPSS High-Risk Supplement List



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5-HTP: Can 5-HTP in supplements help with depression, appetite, and other conditions?

Acacia rigidula: Is it a legal ingredient in dietary supplements?

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?

Am I allowed to use a weightloss (diet) prescription medication?

Are there any safe supplements to help me lose weight?

Aromatase inhibitors: What are they and are they allowed for use by Service Members?

Bacopa monnieri: Is it safe to take in the military?

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 capsaicinioids for weight loss. Consuming too much capsaicinioids (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 penners to your foods, but

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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



Important Links









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Federal Trade Commission (FTC)

National Center for Complementary and Integrative Health (NCCIH)

Office of Dietary Supplements (ODS)

MedlinePlus: Drugs, Herbs, and Supplements

Full list of dietary supplement fact sheets from

Dietary Supplement Label Database

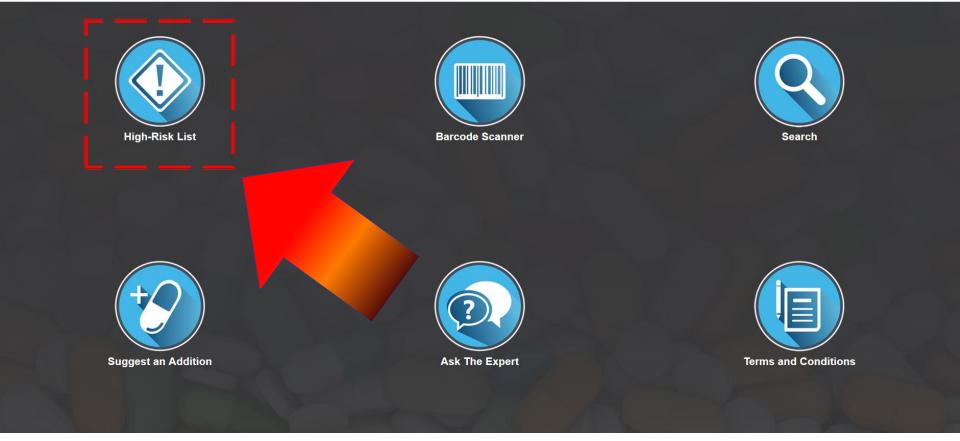


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*					OPERATION SUPPLEMENT SAFETY	
Supplement	Brand Name	Company	Could Contain	Notes/Comments	Updated	
ISD BONS	1,3D BOMB	TBN	Stimulants	For more information please see the <u>OPSS FAQ on DMAA</u> and the <u>OPSS FAQ on stimulants</u> .	02/05/2016	
	1-Andro	LG Sciences	Anabolic agents	For more information please see the OPSS FAQ on anabolic substances.	05/09/2016	
	1-Andro Liquid	Advanced Muscle Science (AMS)	Anabolic agents	For more information please see the OPSS FAQ on anabolic substances.	11/14/2014	
ANDRE	1-Andro Max V2	Primeval Labs	Anabolic agents	For more information please see the OPSS FAQ on DHEA.	09/11/2017	
	1-Andro RDe Chrome	Advanced Muscle Science (AMS)	Anabolic agents	Testing of Lot #1330 revealed the presence of 1-androstenediol and androsterone. For more information please see the OPSS FAQ on anabolic substances.	05/20/2015	
	1-Andro RX	IronMagLabs	Anabolic agents	For more information please see the <u>OPSS FAQ on DHEA</u> .	03/13/2014	
0 24	1024	Achievement Through Sciences (ATS) Labs	Anabolic agents	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.	07/24/2015	
	11-OxoDerm	Platinum Nutraceuticals	Anabolic agents	For more information please see the OPSS FAQ on anabolic substances.	12/04/2015	

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A service member's message to others after taking dietary supplements [Video]

Acacia rigidula: Is it a legal ingredient in dietary supplements?

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Are testosterone booster dietary supplement products safe and effective?

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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National Center for Complete Integrative Health (NCCIH)

Office of Dietary Supplements (ODS)

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Full list of dietary supplement fact sheets from ODS

Dietary Supplement Label Database



OPSS High-Risk Supplement List



OPSS/NMCD for Warfighters



NSF for Sport

ALERTS & ANNOUNCEMENTS



TAINTED PRODUCTS MARKETED AS DIETARY SUPPLEMENTS

Feb 21, 2018

FDA oversees destruction and recall of kratom products; and reiterates its concerns on risks associated with this opioid

Feb 21, 2018

FDA Investigates Multistate Outbreak of Salmonella Infections Linked to **Products Reported to Contain Kratom**

Feb 07, 2018

Statement from FDA...evidence on the presence of opioid compounds in kratom, underscoring its potential for abuse

△ Jan 22, 2018

Flawless Beauty, LLC Issues Voluntary Recall of Unapproved Drugs

Dec 13, 2017

Marmex Corp Issues Voluntary Nationwide Recall Of Blue Pearl All Natural Male Enhancement Supplement, Due To Undeclared Sildenafil

Public Notification: Chao Jimengnan contains hidden drug ingredient

Natural Medicines



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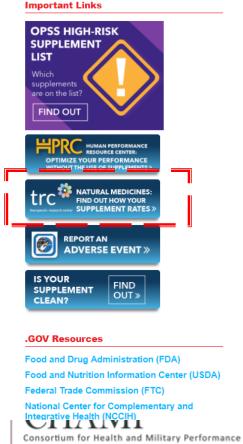
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Welcome DoD Warfighters and Healthcare Professionals

Natural Medicine: 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

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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









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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

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Andrea.lindsey.ctr@usuhs.edu



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