

Supplements Information Packet

Naval Safety Center

Updated 5/7/2013

Ms. Kelsey Leo

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OPERATION SUPPLEMENT SAFETY

HPRC

HPRC has received a number of questions about whether dietary supplements—especially those used for bodybuilding and weight loss—could result in a positive result on military drug tests.

**U.S. Army, Fort Meade, MD**  
(301) 677-7085  
[FTDTL\\_MSupport@amedd.army.mil](mailto:FTDTL_MSupport@amedd.army.mil)

**U.S. Army, Tripler AMC, HI**  
(808) 433-5176  
[FTDTLWeb.Portal@amedd.army.mil](mailto:FTDTLWeb.Portal@amedd.army.mil)

**U.S. Navy, Great Lakes, IL**  
847-688-2045, press 2 or ext 113  
[NDSLGL-tech-help@med.navy.mil](mailto:NDSLGL-tech-help@med.navy.mil)

**U.S. Navy, San Diego, CA**  
(619) 532-5180  
[NDSLSD-scientificsupport@med.navy.mil](mailto:NDSLSD-scientificsupport@med.navy.mil)

**U.S. Navy, Jacksonville, FL**  
(904) 542-7755, press 2 or ext 104  
[DLJAX@djdndsl.med.navy.mil](mailto:DLJAX@djdndsl.med.navy.mil)

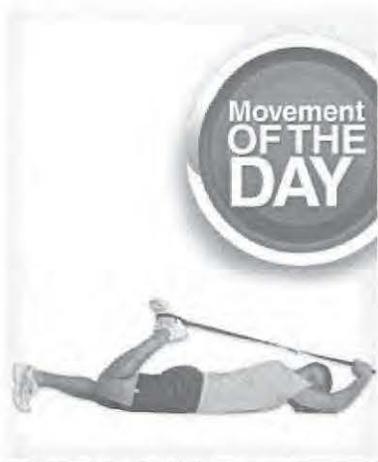
**U.S. Air Force, Lackland AFB, TX**  
(210) 292-3089  
[aaron.jacobs.3@us.af.mil](mailto:aaron.jacobs.3@us.af.mil)

## DIETARY SUPPLEMENTS AND DRUG TESTING

**Military drug testing begins with urine**, which is first screened and then followed by additional tests depending on the outcome of the screen. You can get extensive information about the DoD drug policy and drug testing from the TRICARE website section on the Drug Demand Reduction Program (DDRP), including military testing. And for answers about the potential effects of specific dietary supplements on drug screening tests, you can contact your service's military drug testing laboratory by phone or email (list to the left).

**Positive urinalysis results due to dietary supplement use** can occur because products on the market may contain undeclared drug ingredients—that is, controlled substances that are not stated/listed on the product label. More information can be found in the FDA News Release from 2010 in which this was brought to the public's attention. There is no way to know if a particular supplement contains an undeclared drug without laboratory testing, but the FDA does keep track of such products once identified through its MedWatch program. One of the best ways to check for such products—and other potential health issues related to dietary supplements—is through the FDA website's [Dietary Supplements Alerts](#) section.

**The Department of Defense (DoD) currently has no formal policy** on the use of dietary supplements and no list of either banned or safe supplements. For more on this topic, read HPRC's article "[Is there a list of dietary supplements/substances banned by the military?](#)"



Quad Stretch - Strap

#### Announcements

[DMAA list updated for January 2013](#)

[Fueling Performance Photo Campaign](#)

Share photos of how you fuel your performance and be featured on our Facebook page!

[Two new dietary supplement reports](#)

[Dietary supplement module](#)

Earn continuing education credits (if eligible) for this two-hour online module.

#### Share This

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## THE EDGE YOU NEED FOR TOTAL FITNESS

HPRC's human performance optimization (HPO) website is for U.S. Warfighters, their families, and those in the field of HPO who support them. The goal is Total Force Fitness: Warfighters optimized to carry out their mission as safely and effectively as possible.

## Dietary Supplements Classification System

Make informed decisions about supplements with the Dietary Supplement Classification Table.

Click on the links below to jump to each section.

[Supplements by Class](#)

[Supplements by Zone](#)

## Dietary Supplements Classification System—Risks and Benefits

Before using any dietary supplement, a Warfighter—or anyone—should ask: “What are the potential benefits?” and “What are the risks associated?” And finally, “Are the potential benefits worth the risks?” This Dietary Supplements Classification Table was developed to assist healthy military personnel in making informed decisions about supplements. Benefit was ranked on a scale of low, moderate, or high potential benefit. Safety concern was similarly ranked on a scale of minimal, low, moderate, or high concern.

**For an alphabetical list of supplements, see here.**

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.		Risk (Safety Concerns)			
		Minimal	Low	Moderate	High
Potential Benefit	High	<u>1</u>	<u>2</u>	<u>7</u>	<u>9</u>
	Moderate	<u>3</u>	<u>4</u>	<u>8</u>	<u>10</u>
	Low	<u>5</u>	<u>6</u>	<u>11</u>	<u>12</u>

**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 "yellow zone," and 9-12 in the "red zone."**

Supplements by Zone		
Green Zone	Yellow Zone	Red Zone
<u>Branched-Chain Amino Acids</u>	<u>Antioxidants</u>	<u>Ephedra</u>
<u>Fish Oil/Omega-3 Fatty Acids</u>	<u>Beta-Alanine (B-Alanine)</u>	<u>Melatonin (for flight personnel)</u>
<u>Melatonin</u>	<u>*Caffeine</u>	<u>Bitter Orange (Synephrine)</u>
<u>Multivitamins &amp; Minerals</u>	<u>Chromium</u>	<u>Testosterone Precursors/Boosters and Anabolic Compounds</u>
<u>Probiotics</u>	<u>Coenzyme Q10</u>	<u>Weight-loss Supplements</u>
<u>Tyrosine</u>	<u>Creatine</u>	
<u>Vitamin B Complex</u>	<u>Glutamine</u>	

	<u>L-Arginine</u>	
	<u>L-Carnitine</u>	
	<u>Megavitamins &amp; Minerals</u>	
	<u>Quercetin</u>	
<b>Food-based Products</b>		
<u>Sports Bars</u>	<u>Protein Powder (including whey)</u>	<b>**Energy Shots</b>
<u>Sports Drinks</u>	<b>*Energy Drinks</b>	
<u>Sports Gels</u>		
<p>*Excessive consumption is potentially dangerous and could lead to side effects and/or adverse reactions.                  **Insufficient evidence to support a recommendation for use.  <b>Note: Supplements in bold appear in more than one zone.</b></p>		

## Supplements By Class

### Class 1 (Green Zone) Supplements

Class 1 (Green Zone) supplements are those that are most likely to provide performance benefits with the least likelihood of adverse effects.

### Class 2 (Green Zone) Supplements

Class 2 (Green Zone) dietary supplements that, like those in Class 1, have high potential of benefits. Their associated risks, while still low, are somewhat greater than for supplements in Class 1.

### Class 3 (Green Zone) Supplements

Class 3 supplements are in the Green Zone because, like Class 1 supplements, they have minimal likelihood of presenting adverse side effects. However, their proposed benefits have only moderate potential.

### Class 4 (Yellow Zone) Supplements

Class 4 supplements have low risk of adverse effects and only moderate potential benefits, placing them in the Yellow Zone.

### Class 5 (Yellow Zone) Supplements

Class 5 (Yellow Zone) supplements have minimal associated risks, but their potential for positive results is low, so you may want to consider the likelihood of benefits before taking any of these.

### Class 6 (Yellow Zone) Supplements

Class 6 supplements are in the Yellow Zone because, while their associated risks are still low, so are their potential benefits.

### Class 7 (Yellow Zone) Supplements

Class 7 (Yellow Zone) supplements are those that have the same high potential benefits as those in Classes 1 and 2, but they are accompanied by moderate risks of experiencing undesirable side effects. Although their positive effects may seem promising, take a close look at the possible risks.

#### Class 8 (Yellow Zone) Supplements

Class 8 supplements are still in the Yellow Zone, but their moderate likelihood of adverse effects is accompanied by only moderate potential for positive results.

#### Class 9 (Red Zone) Supplements

Class 9 dietary supplements are in the Red Zone because, although they have high potential of producing beneficial effects, they also have high potential of producing undesirable—even dangerous—side effects. Consider the risks very carefully before thinking about using these supplements.

#### Class 10 (Red Zone) Supplements

Class 10 (Red Zone) supplements present high risks of adverse side effects, yet they have only moderate potential for positive results. Carefully weigh the likelihood of getting what you want out of these versus the possibility of getting something you don't want.

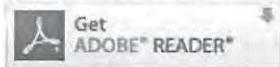
#### Class 11 (Red Zone) Supplements

Class 11 supplements present moderate safety concerns, as for Class 7 and 8 supplements, but they fall in the Red Zone because they are unlikely to provide any benefits.

#### Class 12 (Red Zone) Supplements

Class 12 supplements are as far into the Red Zone as possible: They have a low potential of any producing benefits and are highly likely to produce dangerous side effects.

Some documents are in a PDF format. Download Adobe Acrobat Reader [here](#).



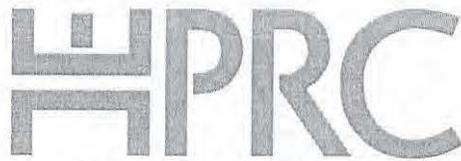
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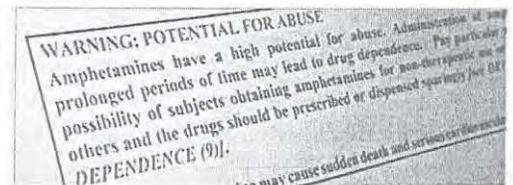
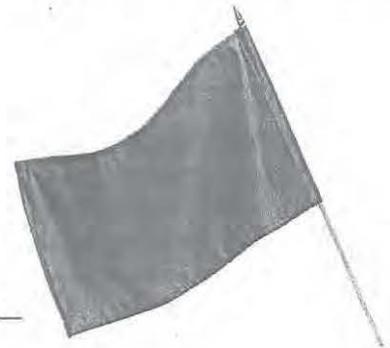
<http://hprc-online.org>

**DIETARY SUPPLEMENTS**

**RED FLAGS – WHAT YOU NEED TO KNOW TO STAY SAFE AND AVOID FRAUD**

Despite growing popularity among military personnel, many dietary supplements on the market are tainted and unsafe. If you are currently using or considering using a dietary supplement, ask yourself these RED FLAG questions to minimize your risk of consuming harmful products.

- Is it a high-risk dietary supplement? High-risk product categories include:**
  - Bodybuilding products
  - Diabetes products
  - Weight-loss products
  - Sexual enhancement products
- Does the supplement's product label have any of the claims below? These claims often indicate that the supplement may contain substances not on the ingredients list, prescription drug analogs, or banned substances.**
  - An alternative to (or claiming to have similar effects to) an FDA-approved drug—e.g., "All natural alternative to XYZ."
  - "Do not take if you have any medical condition, if you are taking any prescription medications, or if you are pregnant."
  - "May cause a positive result in a performance-enhancing drug test."
- If the supplement makes a claim about a dietary ingredient affecting normal body structure or function (e.g., "helps promote bone health"), is its product label missing the following statement?**
  - "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."
- Does the label:**
  - Claim to cure a wide range of unrelated diseases (e.g., cancer, AIDS, in addition to diabetes)?
  - Promise "quick fixes" (e.g., cure XYZ in seven days, lose weight in nine days, shrink tumors in one week, cure impotency in two weeks, etc.)?
- Does the label have:**
  - Text in a foreign language?
  - Directions or warnings that resemble FDA-approved drug products?
  - Claims that it is as effective as an FDA-approved drug?
  - Inadequate or absent safety warnings?
  - A black-box warning?
- Is the label missing a third-party certification label? Third-party verification programs evaluate and certify dietary supplements for purity and/or quality. Examples are:**
  - United States Pharmacopeia (USP)
  - NSF International
  - Informed-Choice, HFL Sport Science
  - ConsumerLab.com
  - Banned Substances Control Group (BSCG)



Sample FDA-approved black box warning label



- Is the product marketed with personal testimonials about amazing results from using the product?
- Did you receive solicitations (emails) offering products in the high-risk product categories?
- Is the product rated 7 or lower by the Natural Medicines Comprehensive Database (NMCD)? The NMCD rates commercial products based on safety, effectiveness, and quality. Each product gets a rating of 1-10 with 10 being the best and 1 being the worst.
- Does the product contain any of the ingredients below?

5-HTP (5-Hydroxytryptophan)	Canadian hemp	Gravel root
Aconite	Catnip	Greater Celandine
Adrenal extract	Cesium	Hawaiian baby woodrose
Aga (Aminita muscaria)	Chaparral	Heartleaf (Sida cordofolia)
Alkanna	Chenopodium oil	Hemp oil
American mistletoe	Clematis	Horny goat weed (Epimedium grandiflorum)
Apricot kernel	Clubmoss	Indian snakeroot (Rauwolfia)
Aristolochia	Colloidal Silver	Jaborandi
Beth Root	Coltsfoot	Jimson weed
Bitter Orange (Synephrine)	Comfrey	Kava
Bittersweet nightshade	Country Mallow	Laminaria
Bladderwrack	DMAA (1,3 dimethylamylamine)	Lobelia
Blue Cohosh	Dolomite	Pinellia ternata
Blue Flag	Ephedra	Salvia (Diviner's sage)
Butanediol (BD)	European mandrake	Usnea or Usnic acid
Buttercup	Germanium	Vinca rosea (madagascar periwinkle)
Calamus	Gamma-butyrolactone (GBL)	Wild indigo
Calotropis	GHB (Gamma hydroxybutyrate)	Yohimbe

If you answered “YES” to several of these questions, you may be consuming an unhealthy or harmful product! Be an informed consumer and choose wisely. However, remember that a supplement cannot replace regular exercise, medical drugs, or a healthy diet.

For additional alerts, click on the links below.

[Athlete Advisory - Methylhexanamine and Dietary Supplements](#)

[Athlete Guide to the 2011 Prohibited List](#)



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HTTP://HPRC-ONLINE.ORG

DIETARY SUPPLEMENTS

DIETARY SUPPLEMENTS/PRODUCTS CONTAINING DMAA

### Dietary Supplement Products Containing DMAA

On 12 April 2012, FDA posted "Q&A on DMAA in Dietary Supplements," in which they clearly stated that "Dietary supplements containing DMAA are illegal and FDA is doing everything within its authority to remove these products from the market." Since February 2012, HPRC has maintained a list of currently available commercial products that contain DMAA (listed on the product label or website by that or one of the other names that have been used synonymously; see below). The list is accurate as of the time of compiling, although some manufacturers have already modified their products to exclude DMAA or have removed their DMAA-containing products altogether, and we will continue to update this list as changes occur. The list likely does not include all products available. Some retailers still have stock of discontinued/reformulated products that contain DMAA, and newer, non-DMAA versions sometimes have the same product name. **So it is important to read ingredient labels carefully before using any product, especially those promoted for bodybuilding and weight loss (and party pills).**

Many manufacturers clearly identify the "geranium extract" or "geranium oil extract" in their products as 1,3-dimethylamylamine or one of its other equivalent chemical names. For those that do not, however, we have no way to determine whether the "geranium (oil) extract" identified on the label is a different—possibly natural—product or some form of synthetic DMAA. The only way to determine positively if a product does or does not contain DMAA is through laboratory testing, so HPRC recommends using only dietary supplements that have evidence of third-party testing by a reputable independent laboratory.

In checking labels, you need to know the numerous terms/synonyms for DMAA. The most common ones are 1,3-dimethylamylamine; methylhexanamine or MHA; dimethylpentylamine or DMP; 4-methylhexan-2-amine; Geranamine; and geranium oil, extract, or stems and leaves. Below is a list of various terms that could appear on a Supplement Facts label of a product containing DMAA:

- 1,3-dimethylamylamine
- 1,3-dimethylpentylamine
- 2-amino-4-methylhexane
- 2-hexanamine,4-methyl-(9Cl)
- 4-methyl-2-hexanamine
- 4-methyl-2-hexylamine
- 4-methylhexan-2-amine (IUPAC)
- C7H17N (chemical formula)
- CAS 105-41-9
- Crane's bill extract 200:1 (misnomer; not necessarily DMAA)
- dimethylamylamine (DMAA)
- dimethylpentylamine (DMP)
- DMAA
- Floradrene
- Forthan
- Forthane
- Fouramin
- Geranamine (Proviant™)
- GeranaX
- Geranium extract
- Geranium flower extract
- Geranium oil
- Geranium oil extract
- Geranium stems and leaves
- Metexaminum
- Methexaminum
- Methylhexanamine
- Methylhexanamine (MHA)
- Pelargonium (various)
- Pentylamine
- synthetic geranium

**NOTE: Dietary supplements containing DMAA have been placed on medical hold by the DoD due to concerns about related adverse health effects and are currently not for sale on military installations.**

⇒ HPRC periodically updates this list, so be sure to check back for newer versions.

Product Name	Distributor or Manufacturer	Ingredient as on label/advertising
1,3 D Bomb	Total Body Nutrition USA	1,3 Dimethylamylamine
1,3 D Nox	Total Body Nutrition USA	Geranium Extract (1,3 Dimethylamylamine)
1,3 Dimethylamylamine	(various distributors & suppliers)	1,3 Dimethylamylamine
3-D Explosion	Generic LabZ	1,3-Dimethylamylamine (Geranium [Stem])
357 Xtreme Pre-Workout Fuel	Aviva Nutrition	1,3 Dimethylamylamine HCL
Absolute Pump	Peak Performance Innovations	1,3 Dimethylamylamine
ACE (Appetite Control and Energy) *	AMS Health Sciences	1,3-Dimethylpentylamine HCl
Addieup	Nature's Cures LLC	1,3 Dimethylamylamine
Adralin	CTD Labs	1,3-dimethylamylamine
AdrenHERlyn Cuts *	BlackMarket Labs	1,3-Dimethylamylamine HCl
AdreN.O.lyn Bulk *	BlackMarket Labs	1,3-Dimethylamylamine HCl
AdreN.O.lyn Cuts *	BlackMarket Labs	1,3-Dimethylamylamine HCl
Apple Tight	Muscle Fitness & More Inc.	Geranium oil extract
Atomizer	Aviva Nutrition	1,3-Dimethylamylamine
Avidex	United Health	Geranium Oil Extract
Black Widow *	Hi-Tech Pharmaceuticals LLC	1,3-Dimethylamylamine
Body Burn	Bodystrong	1,3-dimethylamylamine
Body Surge	Bodystrong	1,3-Dimethylamylamine
Clear Shot 3X Concentrate	E-Pharm Nutrition	Geranamine
CO <sup>2</sup> Xtreme Fat Burner	Extreme Sports Performance	1,3-Dimethylamylamine (Geranium Stem Oil)
Core Zap	Core Nutritionals	Geranium (1,3-Dimethylpentylamine)
Decimate	Cygen Laboratories	Geranium
DMAA Powder	(various)	1,3 Dimethylamylamine/DMAA
DynaPep Energy Micro-Shot	Emerging Products Development Group	2-Amino 4-Methyl Hexane HCL
E-Power	Natural Herbal Nutrition Supplement, Ltd.	Geranium oil extract
EPH 100	Delta Health Products	1,3 Dimethyl Amyl Amine
Ergolean AMP	E-Pharm Nutrition	Geranamine (1,3-dimethylamylamine)
Excel Extreme 4D	Excel Nutritional	Geranium Extract
Fastin-XR *	Hi-Tech Pharmaceuticals LLC	1,3-Dimethylamylamine
Fat Smack XR	Purus Labs	2-amino-4-methylhexane
Fitness Magic (formerly TriThin Magic)	TriUnity International	1,3-dimethylpentylamine (constituent from Geranium Flower)
FlashOver	Omega Sports	1,3-dimethylamylamine (from Geranium Oil)
Fruta Planta USA	AGL	4-Methylhexan-2-Amine HCL (Geranium extract leaves and stem)
Geranamine (powder and capsules)	Fusion Supplements	Proviant Technologies™ DMAA
Geranium Extract	Various	1,3-dimethylamylamine
Hell Fire EPH 150	Innovative Bio Labs	1,3 Dimethylamylamine HCL (geranium)
High Performance GF *	CNP Professional Sports Nutrition	1,3 Dimethylamylamine
Hyper Trim	Schwartz Laboratories	DMAA (1,3 Dimethylamylamine)
Hypercuts	CTD Labs	1,3-dimethylamylamine
Hyperdrine-OD	KiloSports Nutrition	1,3 Dimethylamylamine
HyperLean FX7	Nova Body Science	2-Amino-4-Methylhexane HCL (Geranium)
Infested	Xcel Sports Nutrition	Methylhexaneamine
Jack3d	USPlabs/NutraPlanet	1,3-Dimethylamylamine (Geranium [Stem])
JP8x Hardcore	Get Diesel Nutrition	DMAA (1,3-Dimethylpentylamine)

Product Name	Distributor or Manufacturer	Ingredient as on label/advertising
Lean 650	GenX Labs	Geranamine 91,3-Dimethylamylamine)
Lipodrene Hardcore *	Hi-Tech Pharmaceuticals LLC	1,3-Dimethylamylamine
Lipodrene Xtreme *	Hi-Tech Pharmaceuticals LLC	1,3-Dimethylamylamine HCl
Mass-Pump XXL	Powerlab Nutrition	Geranium Extract (1,3-Dimethylamylamine)
Matador Extreme Energy	BioFuxion Health Products, Inc.	2-amino-4-methylhexane
Mesomorph	APS Nutrition	Geranium Oil Extract (Geranaburn™)
Metabadrine	Legacy Nutritional Products	1,3 Dimethylamylamine
Muscle Marinade	Purus Labs	2-amino-4-methylhexane
Muscle Spike	Muscle Fortress	1,3 dimethylamylamine
N2-Amp	Need to Build Muscle Inc	1,3-Dimethylamylamine
Nitrox Silver Bullet	Xcel Sports Nutrition	1,3-Dimethylamylamine
NOX Pump	Dorian Yates Nutrition	geranamine
Noxipro	CTD Labs	1,3 Dimethylamylamine
Overdose ReduX	NRG-X Labs	Geranium Maculatum Extract [leaves and stems]
OxyELITE Pro	USFlabs	1,3-Dimethylamylamine (Geranium [Stem])
Phenadrine	APS Nutrition	1,3 dimethylamylamine
Plasmatic EP	Engineered Sports Technology (EST)	Geranium Root and Stem (Standardized)
Plexus Slim Accelerator	Plexus Worldwide Inc.	GeranaX
Razor8 Blast Powder (U.S.)	Allmax Nutrition	Geranium Maculatum (Cranes bill extract)
Red Stinger Black Label	NRG-X Labs	1,3-Dimethylamylamine (Geranium [Stem])
Rocket Fuel Capsules	Fusion Supplements	1,3 Dimethylamylamine
Seirogan Toi A	Taiko Pharmaceutical Co., Ltd.	Powdered Geranium Herb
Spirodrene	Engineered Sports Technology (EST)	GeraniPure™ (Geranium Root and Stem)
Suppress NT	Nutrition Alliance International (NSI)	1,3 dimethylamylamine
Technical Knockout Pre-Workout	KiloSports Nutrition	1,3-dimethylamine Hcl
Therm-O	BioFuxion Health Products, Inc.	2 Aminio-4 Methyl Hexane
ThunderSlim	(undetermined)	Geranium Extract
Tiger Claw DMAA	Kempo Nutrition	1,3-Dimethylamylamine (Geranium Oil Constitute)
Vaporizer XR	Aviva Nutrition	1,3 Dimethylamylamine HCL
Vaso Maize	Lift Labz	1,3-Dimethylamylamine
Velocity XT	Neogenix	1,3-Dimethylamylamine
White Lightning	APS Nutrition	Geranaburn (geranium oil extract)
Wyked	Taurus Nutrition	Geranium Oil Extract (4-Amino-Methyl Hexane)
Xyng Fuel 4 Life	Xyngular	geranium flower extract (1,3 dimethylpentylamine)
Youth Addict Torch'd	SavInd Inc.	Dimethylpentamine: Geranium Oil Constituent

#### DISCONTINUED/REFORMULATED PRODUCTS:

The following products either are no longer shown on the manufacturer's website (or website no longer exists), have been reformulated to exclude DMAA, or no longer list DMAA on the product label (indicating reformulation); some DMAA-containing product may still be available from stock held by retail suppliers. (We have made the assumption that the information on labels and websites is accurate, but only laboratory testing will confirm the absence of DMAA.)

1,3-DiMeth	Pharmapro	1,3 Dimethylamylamine HCL
1.M.R. (One More-Rep)	BPI Sports	(previously contained 1,3-Dimeth. – removed from recipe in summer 2011)
Adrena-G	Serious Nutrition Solutions (SNS)	1,3-Dimethylamylamine (1,3-DMAA)
AmphetaLean-Extreme	Beast Sports Nutrition	1,3-Dimethylamylamine HCL

Product Name	Distributor or Manufacturer	Ingredient as on label/advertising
<b>DISCONTINUED PRODUCTS (CONTINUED)</b>		
Anadraulic Pump	LG Sciences, LLC	Geranium Oil Extract #105-41-9
Anarchy	Vital Pharmaceuticals (VPX Sports)	Supra-Amine™ Apple Geranium (Pelargonium Odoratissimum)(Leaves)[Std. To 1,3 Dimethylpentylamine]
Anarchy Covalex	Vital Pharmaceuticals (VPX Sports)	Supra-Amine™ Apple Geranium (Pelargonium Odoratissimum)(Leaves)[Std. To 1,3 Dimethylpentylamine]
Appetite Control Formula	Smart City	DMAA (1,3-Dimethylamylamine)
Beta-Cret Extreme	ProMera Health	1,3 Dimethylamylamine (Geranium Oil)
Black Cats	Applied Nutraceuticals	1,3 Dimethylamylamine
Blood Rush Pump	Muscle Gauge Nutrition	1,3-Dimethylamylamine
Blue G Energy Stimulant	Utopia Wholesale/Legal Utopia	geranium oil, 1,3-dimethylamylamine
Cardio Cuts	NDS Nutrition	1,3-dimethylpentylamine HCl
Caution	Xtreme Caution Labs	1,3-Dimethylamylamine
Cerebral Success Brain Power	Cerebral Success	Geranamine (DMAA)
Charge ASF-Ephedra-Free	Labrada Nutrition	1,3-Dimethylpentylamine (constituent of geranium oil)
Charge Extreme Energy	Labrada Nutrition	1,3-Dimethylpentylamine (constituent of geranium oil)
Clear Shot	E-Pharm Nutrition	Dimethylpentylamine (constituent of Geranium oil)
Code Red	MuscleMeds Performance Technologies	1,3 dimethylamylamine (geranium) (stem)
Crack	Revolutions Nutrition	Geranium extract (extracted for 1,3-Dimethyl-amylamine)
CryoShock *	Neogenix	1,3-Dimethylamylamine
CTS360 Maximum	Complete Nutrition	1,3-Dimethylamylamine
Dexaprine	iForce Nutrition	1,3 Dimethylpentylamine
Dialed-In	Pride Nutrition	1,3-Dimethylamylamine (Geranium [Stem])
Dominate Extreme	Pride Nutrition	1,3-Dimethylamylamine (Geranium [Stem])
D Stunner	Betancourt Nutrition	1,3 Dimethylamylamine
E-911	LG Sciences, LLC	Geranium Oil Extract Cas# 105-41-9
Embrace XTREME	NDS Nutrition	1,3-dimethylpentylamine HCl
En-R-G	KDA Global, Inc.	1,3 dimethylpentylamine (active from Geranium flower)
Endoburn NT	BSN Inc.	1,3-Dimethylpentylamine (A Natural Constituent of Geranium Oil)
EPH-25 New Formula	Accelerated Sport Nutraceuticals (ASN)	1,3 dimethylamylamine
EphedFx *	Complete Nutrition Holdings Inc.	Geranium Extract (1,3-Dimethylamylamine)
ErgoBurn (previously AMP2)	ErgoPharm/E-Pharm/Ergogenix	Geranamine (constituent of geranium oil)
Finaflex Epi-V	Redefine Nutrition	2-amino-4 methylhexane
Finaflex Ignite 2	Redefine Nutrition	2-amino-4 methylhexane
Finaflex Methyl Ice	Redefine Nutrition	1,3 Dimethylamylamine
Finaflex N-O Ignite	Redefine Nutrition	1,3 Dimethylamylamine
Finaflex Pro Xanthine	Redefine Nutrition	2-amino-4 methylhexane
G6 Extreme Energy	Planet Nature Pty Ltd	Dimethylamylamine HCL
Geranium 20	SD Pharmaceuticals	1,3-Dimethylamylamine, which is also referred to as DMAA and Methylhexaneamine
Heat Accelerated	Magnum Nutraceuticals	Geranamine
Hemo-Rage Black	Nutrex Research (Nutrex Underground)	1,3-Dimethylamylamine HCL
Hemo-Rage Black Turbo Shot	Nutrex Research (Nutrex Underground)	Methylhexaneamine
Hemo-Rage Black Ultra Concentrate	Nutrex Research (Nutrex Underground)	Methylhexaneamine
Hemodrene	Nutrabolics	Geranium Extract (1,3-Dimethylamylamine)
Hemorush	Nutrabolics	Geranium Extract

Product Name	Distributor or Manufacturer	Ingredient as on label/advertising
<b>DISCONTINUED PRODUCTS (CONTINUED)</b>		
<b>HydroxyStim</b>	MuscleTech	Geranium extract (as Geranium robertianum) (aerial parts)
<b>Ignite Energy Boost</b>	Ignite Powder (ASN Distributors)	Geranium (1,3-Dimethylamylamine or Methylhexamine)
<b>Intensify XTREME</b>	NDS Nutrition	1,3-dimethylpentylamine HCl
<b>Launch</b>	SAN Nutrition	Geranium Oil Extract [Stem & Leaves - Stand to 1,3-DMPA1]
<b>Launch Full Impact 4350</b>	SAN Nutrition	Geranalean [Geranium Oil Extract][Std. to 1,3-DMPA]
<b>Lean EFX (includes Lean Shots)</b>	Fahrenheit Nutrition	1,3 Dimethylamylamine
<b>Lipo Extreme</b>	American Muscle Mass Optimization (AMMO) Labs	1,3-Dimethylamylamine
<b>Lipo-6 Black (all)</b>	Nutrex Research Underground	Methylhexaneamine
<b>Lipo-6 Black Ultra-Concentrate (all)</b>	Nutrex Research Underground	Methylhexaneamine
<b>LipoRUSH</b>	NDS Nutrition	1,3-dimethylpentylamine HCl
<b>Lipo-Sear *</b>	Empyrean Nutrition	Dimethylamylamine
<b>Massive Growth</b>	Muscle Gauge Nutrition	1,3-Dimethylamylamine (Geranium [Stem])
<b>Matrix Energy Mood Enhancing Energy Drink</b>	Innovative Body Enhancement (IBE)	Pelargonium graveolens extract (1, 3-dimethylpentylamine)
<b>Maximize Intense</b>	iForce Nutrition	1,3 Dimethylpentylamine
<b>Maximize V2</b>	iForce Nutrition	1,3 Dimethylpentylamine (Constituent of Geranium Oil)
<b>Methyl Fire</b>	GE Pharma	1,3 Dimethylamylamine (geranium (stem))
<b>MethylHex 4,2</b>	SEI Pharmaceuticals	4-methylhexan-2-amine HCL (geranium extract leaves and stem)
<b>MethylRush</b>	SEI Pharmaceuticals	4-methylhexan-2-amine HCL
<b>Motivate</b>	Anabolic Innovations	Geranamine (1,3-Dimethylamylamine)
<b>MyoRipped</b>	E Nutrition Research LLC	1,3 Dimethylamylamine
<b>N2KTS (Need To Kill That Shit)</b>	Need To Build Muscle Inc	1,3-Dimethylamylamine (Geranium)
<b>Napalm</b>	Muscle Warfare	1,3-Dimethylamylamine HCL
<b>Napalm Mini-Gun</b>	Muscle Warfare	1,3 Dimethylamylamine
<b>NeuroCore</b>	MuscleTech	Geranium extract (as Geranium robertianum) (aerial parts)
<b>Nitric Blast</b>	SNI	geranium extract
<b>NL-Octrain</b>	No Limits Lab	1,3-Dimethylamylamine HCl
<b>OverDose Powder</b>	NRG-X Labs	1,3-Dimethylamylamine - also known as Geranamine, Methylhexaneamine, or DMAA
<b>OxyECA</b>	Lecheek Nutrition	2-amino-4-methylhexane
<b>Phen 375 (Phentemine 375)</b>	RDK Global	1,3-Dimethylpentylamine HCL
<b>Phen-D/Phentramin-d</b>	Lazarus Labs	1,3 - Dimethyl-pentylamine-hydrochloride
<b>Phenphedrine</b>	Iovate Health Sciences/MuscleTech	1,3 dimethylamylamine
<b>Phenteramin</b>	Lazarus Labs	1,3 dimethylpentylamine
<b>PMD-ACG3</b>	NDS Nutrition	1,3-dimethylpentylamine HCl
<b>Predivite Extreme Energy *</b>	Health Technology Inc.	DMAA (1,3 dimethylpentylamine)
<b>PreSurge Unleashed</b>	Athletic Edge Nutrition	1,3-Dimethylamylamine HCL (Geranium)
<b>PumpFixx</b>	Advanced Muscle Science	Geranamine
<b>PWR Ultra-Concentrated Pre-Workout Revolution</b>	iSatori Technologies, LLC	1,3-dimethylpentylamine HCL
<b>Quake 10-0</b>	SciVation	1,3-Dimethylamylamine
<b>Rage Version X</b>	Active Nutrition Corporation (ANC)	Geranamine
<b>Rapid Action Energize 2-Way</b>	DR Distributors LLC	4-Methylhexan-2-Amine HCL
<b>Red Velvet</b>	Utopia Wholesale/Legal Utopia	geranium oil,BK 1,3-dimethylamylamine

Product Name	Distributor or Manufacturer	Ingredient as on label/advertising
<b>DISCONTINUED PRODUCTS (CONTINUED)</b>		
<b>RedLine Ultra Hardcore Capsules</b>	Vital Pharmaceuticals (VPX Sports)	Supra-Amine™ Apple Geranium (Pelargonium Odoratissimum) (Leaves)[Std. To 1,3 Dimethylpentylamine]
<b>RezoIution</b>	LG Sciences, LLC	geranamine (2-amino-4-methylhexane)
<b>Ripped Juice EX2</b>	Betancourt Nutrition	1,3-Dimethylpentylamine (Geranamine)
<b>Rocked</b>	Advanced Performulations Inc. (API)	1,3 Dimethylamylamine
<b>RoxyLean ECA</b>	BPI Sports	1,3-dimethylamine
<b>RUSH</b>	Stacker-2	1,3-Dimethylamylamine
<b>Ruthless *</b>	Science Defined Nutrition	1,3-Dimethylamylamine (Geranium root/stem)
<b>SlimMax Fat Burner &amp; Appetite Suppressant</b>	Pure Health Trends	1,3 Dimethylamylamine
<b>Speed V2</b>	LG Sciences	Geranium Oil Extract #105-41-9
<b>Speed Xtreme Ultra Concentrate</b>	Lecheek Nutrition	1,3-Dimethylamylamine
<b>Spirodex</b>	Gaspari Nutrition	“Geranium maculatum extract [leaves and stems] standardized for 4-methylhexan-2-amine content
<b>SSN Juice</b>	BIORhythm ADS	Geranium [Stem] (13-Dimethylamylamine)
<b>Stampede</b>	Anabolic Designs	Geranium Extract
<b>Stim-Force (powder and chewables)</b>	Labrada Nutrition	1,3-Dimethylpentylamine Hydrochloride
<b>StimulantX</b>	Anabolic Xtreme	Methylhexamine HCl (from salted Geranium oil isolate)
<b>Swagger</b>	MAN Sports	Geranastim(TM) (1,3-dimethylamylamine)
<b>The Curse (Magic Berry flavor only)</b>	Cobra Labs	1,3 Dimethylamylamine
<b>ThermbuteroL Hardcore</b>	SEI Pharmaceuticals	4-methylhexan-2-amine HCL (geranium extract leaves and stem)
<b>Thermofuse</b>	Muscle Warfare	1,3 Dimethylamylamine HCL
<b>ThermoGum</b>	ThermoGum LLC	Geranium Extract
<b>Thermosculpt Capsules</b>	Designed by Dean	2-amino-4-methylhexane
<b>Trim-Down</b>	Muscle Gauge Nutrition	1,3 Dimethylamylamine
<b>Ultimate Fighting Creatine HCl Serum *</b>	MMUSA	1,3-Dimethylamylamine Hydrochloride
<b>Ultra Concentrate Speed Xtreme</b>	Lecheek Nutrition	1,3 Dimethylamylamine
<b>Ultra-Thermo (for Women &amp; for Men) *</b>	MMUSA	1,3-Dimethylamylamine Hydrochloride
<b>V3 Weight Management Complex *</b>	Voyager Health Technologies	1,3-dimethylpentylamine HCl
<b>ViSi Weight Loss</b>	ViSi Global	Geranium Oil Extract
<b>Vyperize w/DMAA</b>	Professional Supplements	1,3-Dimethylamylamine
<b>X-Force</b>	Innovative Body Enhancement (IBE)	Methylhexaneamine (1, 3-dimethylpentylamine)
<b>XM3 Capsules</b>	Zija International, Inc.	Supra-Amine™ Apple Geranium (Pelargonium Odoratissimum)(Leaves)[Std. To 1,3 Dimethylpentylamine]
<b>XMam Extreme Moringa Caps</b>	Zija International, Inc.	1,3-dimethylpentylamine (active from geranium)
<b>Youth Addict Intense</b>	SavInd Inc.	1, 3-Dimethylpentylamine/Geranium Oil Extract
<b>Zenalean Pro</b>	Accelerated Sport Nutraceuticals (ASN)	Geranium Extract (1,3-Dimethylamylamine )

\* Change to list since previous update

(NOTE: Party pills represent a different category of DMAA-containing products; they are not considered dietary supplements, as they are marketed solely for recreational use, so we are no longer including them on this list. The use of DMAA in party pills led to its ban in New Zealand.)

The Natural Medicines Comprehensive Database (NMCD) also has a list of dietary supplements that contain DMAA. This user-friendly database is available for both Warfighters and healthcare professionals who have a “.mil” email address through links on the HPRC website. Choose the appropriate version and follow the instructions to create an account. To view NMCD’s list of products containing DMAA, log on, type “DMAA” in the keyword search box and then click on the link that says “View 276 Products Containing: DMAA (DIMETHYLAMYLAMINE).” Note that NMCD provides safety ratings for most of these dietary supplement products.

## The Dangers of **Energy Drinks** and Supplements

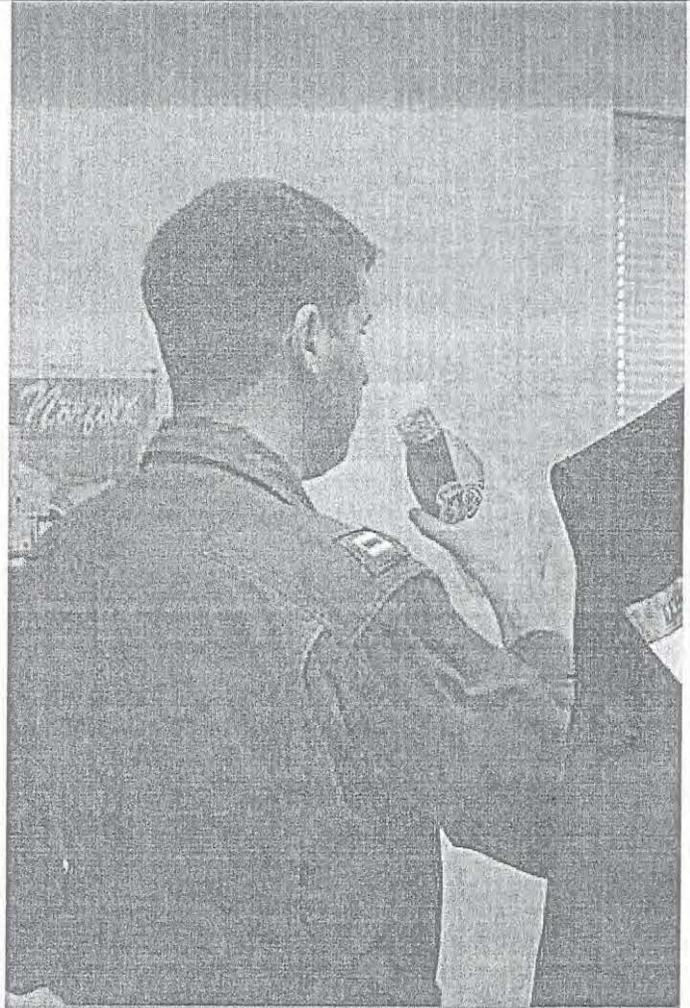
BY LCDR. T.E. SATHER MSC, CASP

**A**viators know that NATOPS prohibits the use of over-the-counter medications, and that you must get approval from your flight surgeon to use nutritional supplements. There is a very good reason for this: You just don't know what is in these drinks. Nutritional supplements and their derivatives (like energy drinks) are not regulated by the Food and Drug Administration (FDA) — unlike medications, soft drinks, and even tap water, which are tightly regulated to ensure safety and purity.

America has become a culture of instant gratification. We expect results almost immediately and nothing is fast enough. We are turning to stimulants, painkillers and anti-anxiety meds to help launch ourselves through the endless daily to-do lists. In today's culture, better living through chemistry is now the norm.

What happens when we get tired, as many of us do, on a daily basis? We turn to some type of energy booster — a cup of coffee, tea or even a high-tech energy drink.

Energy drinks promise to give you wings, to boost you through "that 2:30 p.m. feeling," to be a remedy for a poor diet, and to provide athletic prowess like never before. Energy drinks promise a lot.



Many people assume that natural products are safe and do not have side effects. This is far from the truth. Natural products can be as toxic as synthetic ones.

This trend toward stimulant drinks seems to be a natural evolution of our love for and, in some cases, dependence on caffeine. But, energy drinks go beyond the effects of simple caffeine. They add additional stimulants derived from vitamins, herbs, and amino acids to create a more intense energy boost or rush.

Teens and young adults, both athletes and non-athletes, consume energy drinks at an alarming rate. Energy drinks, including small "shot" products, are readily available in grocery stores, convenience stores and a variety of other places. They are advertised to enhance energy, increase focus and improve athletic performance with catchy slogans such as, "Bigger,

better, faster and stronger.” They are scientifically formulated to provide an incredible energy boost. Products now come in gum form and energy chews, claiming to pack as much caffeine as a cup of coffee. There are over 600 brands of energy beverages on the market with a wide variety of ingredients. However, most are just slightly different concoctions of the same stock ingredients.

As advertised, energy drinks will give you a boost of energy. They deliver high concentrations of caffeine and other stimulants to give the drinker a rush of energy. They contain huge quantities of sugar, caffeine, the amino acid taurine and B vitamins. Some of the newer beverages are throwing in powerful herbal compounds such as yohimbine hydrochloride and evo-diamine (EVO). Some nutritionists believe these are more powerful (and maybe dangerous) stimulants than caffeine. Some products are so potent that an eight-ounce can contains four times the caffeine per ounce as a traditional energy drink. Some ingredients, at least those that are monitored and regulated by the FDA, can contain 800 times more than the recommended daily allowance (RDA). Energy drinks may also contain a huge variety of natural, exotic ingredients like guarana, green-tea extract, yerba mate, bitter orange (synephrine or octopamine), vinpocetine, 5-hydroxyl tryptophan, methylphenylethylamine (5-HTP) and ginseng.

A large number of supplemental products have dubious value, content and quality. Independent tests have found that some products are contaminated with unwanted, potentially harmful ingredients such as heavy metals, pesticides, bacteria and prescription drugs. The purity, potency and identity of a supplement may also vary by manufacturer and from product to product. The makers of energy drinks are under no legal obligation to disclose the source of any natural supplement. Because their product lines are classified as nutritional supplements, they are not bound by the same level of regulation and oversight as soda or juice companies.

Researchers do not know the exact effects of all the ingredients in energy drinks when used in combination with one another. It is the combination of the ingredients, the concentration, and the speed of ingestion that make energy drinks dangerous. Almost all the studies done on energy drinks have involved relatively small sample sizes of young, healthy individuals and yield little evidence of short-term ill effects. We need studies with larger sample sizes using methods to determine

whether long-term use of energy drinks will translate into negative effects.

There are many documented accounts where emergency room physicians describe cases of seizures, delusions, heart problems and kidney or liver damage in people who had downed one or more of these nonalcoholic energy drinks. Caffeine-associated deaths have been documented. Because of this evidence the American Association of Poison Control Center created a new category to track these cases. According to the Poison Control Center, from October 2010 to February 2011, there were more than 1,000 energy-drink overdoses; mostly children and young adults, with the average consumption of between 3 to 8 cans (although one individual consumed 80 cans).

**Q. What's the best single method to improve energy levels and increase the ability to concentrate?**

**A. Get an extra 60 to 90 minutes of sleep each night.**

There is a great variety of energy drinks on the market with different “energy blends” routed to enhance your energy level. The primary ingredients are usually caffeine, L-Taurine, glucuronolactone, and B Vitamins. Some of the more common ingredients include guarana, ginseng, L-Carnitine, inositol, choline, creatine, ginkgo biloba, milk thistle, and an assortment of vitamins.

Many energy drinks include a list of ingredients without quantity as part of a “proprietary blend,” by which only the total amount of the blend is listed. Many of the ingredients may be added for marketing purposes. Most ingredients are far below an optimal or even therapeutic dose that would elicit an effect. Some ingredients, like sugar, cause no harm and are treated like a food. Others, like most of the vitamins, are just excreted from the body in the urine. However, this is not true of all ingredients.

The biggest danger of consuming energy drinks has to do with caffeine, which is the most frequently used psychoactive drug in the world. Caffeine and its relatives theophylline (in tea) and theobromine (in chocolate) heighten our alertness. Caffeine can also

be “hidden” in herbs such as guarana (1 gram of guarana has about 40 mg of caffeine). Doses over 250 mgs consumed over a short period of time can trigger a condition called “caffeine intoxication.” This is a clinical syndrome which is marked by nervousness, anxiety, restlessness, insomnia, gastrointestinal upset, tremors, rapid heartbeat, restlessness and pacing. Some people may also experience euphoria and muscle twitches. Caffeine in extremely large doses can be deadly. Caffeine poisoning or reports of caffeine intoxication are no longer uncommon in the U.S. Caffeine-poisoning cases have increased significantly over the last few years. Fatal overdoses would require drinking 30 to 60 cups of coffee in one morning.

The caffeine content of energy drinks varies. While the FDA limits the caffeine content in soda to 71 milligrams per 12-ounce serving, energy drinks are not bound by these limits. A 12-ounce serving of a popular energy drink has 107 milligrams of caffeine, compared with 34 to 38 milligrams for the same amount of soda. Some energy drinks may contain more than 400 milligrams of caffeine.

The adage “All things in moderation” holds true for most of the ingredients in energy drinks. Unfortunately, the temptation to outdo the competition has led the manufacturers of energy products to disregard the topic of health and safety when creating their formulas, which has resulted in more and more potent and dangerous mixtures.

Because energy drinks contain high levels of caffeine and other stimulant ingredients, athletes should avoid putting their health at risk by consuming such products. When these stimulants are combined into one beverage, they can reveal an undiagnosed cardiac abnormality or instigate a serious cardiovascular response. Athletes, parents, coaches, teachers and trainers should be informed of the potential harm of these products.

What about energy drinks and aviators?

Research is limited on the effects of energy drinks on a pilot. A study done at Oklahoma State University looked at reaction times. OSU researchers divided a group of 30 student pilots into two groups and asked each to complete a series of flight exercises on two separate days. Thirty minutes before takeoff, one group drank a 16 ounce energy drink and the other group drank a placebo. The groups switched drinks

on the second day of exercises. The results were startling, especially if you’re a flight instructor.

Student pilots (civilian) who consumed energy drinks before flying had a harder time maintaining straight and level flight. They also were about 10 seconds slower to return their aircraft to the proper position after executing a complex turn, and were five seconds slower to complete an emergency checklist (and less accurate at completing the EPs) than those drinking the placebo. Eighty-seven percent of the students who consumed energy drinks had a larger number of flight errors than they did after consuming the placebo.

Why did this happen? It is theorized that the caffeine, taurine, sugar, and various other stimulants make it difficult for the pilot to perform multiple tasks simultaneously. The study also showed an almost cavalier attitude to the use of these drinks, even though 67 percent of the participating flight students agree that energy drinks have a negative effect on collegiate flight students’ ability to fly an aircraft. The study showed that 57 percent of student pilots surveyed routinely consumed these drinks between one to three times a week and 60 percent of them reported that they consumed energy drinks the same day they piloted an aircraft. The same percentage of respondents also had observed other student pilots consuming energy drinks the same day they piloted an aircraft.

While the idea of slamming down an energy drink before a flight may help a pilot or aircrew stay awake or to energize them during a long flight, research says this may not be in everyone’s best interest. What’s the best single method to improve energy levels, increase the ability to concentrate, sharpen memory, strengthen the immune system, and decreases people’s risk of being killed in accidents? The answer may surprise you. Researchers have discovered that getting an extra 60 to 90 minutes of sleep each night will do just that.

While many people argue that they get by just fine on very little sleep, they also find themselves reaching for a little boost as that “2:30 tired feeling” takes hold once again.

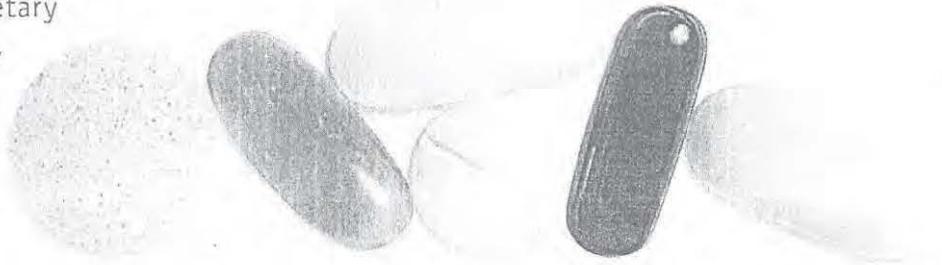
The bottom line is, while in a flight status, energy drinks are a no go!

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# FDA 101: Dietary Supplements

The law defines dietary supplements in part as products taken by mouth that contain a "dietary ingredient." Dietary ingredients include vitamins, minerals, amino acids, and herbs or botanicals, as well as other substances that can be used to supplement the diet.



Dietary supplements come in many forms, including tablets, capsules, powders, energy bars, and liquids. These products are available in stores throughout the United States, as well as on the Internet. They are labeled as dietary supplements and include among others

- vitamin and mineral products
- "botanical" or herbal products—These come in many forms and may include plant materials, algae, microscopic fungi, or a combination of these materials.
- amino acid products—Amino acids are known as the building blocks of proteins and play a role in metabolism.

- enzyme supplements—Enzymes are complex proteins that speed up biochemical reactions.

People use dietary supplements for a wide assortment of reasons. Some seek to compensate for diets, medical conditions, or eating habits that limit the intake of essential vitamins and nutrients. Other people look to them to boost energy or to get a good night's sleep. Postmenopausal women consider using them to counter a sudden drop in estrogen levels.

### Talk with a Health Care Professional

The Food and Drug Administration (FDA) suggests that you consult with

a health care professional before using any dietary supplement. Many supplements contain ingredients that have strong biological effects, and such products may not be safe in all people.

If you have certain health conditions and take these products, you may be putting yourself at risk. Your health care professional can discuss with you whether it is safe for you to take a particular product and whether the product is appropriate for your needs. Here is some general advice:

- Dietary supplements are not intended to treat, diagnose, cure, or alleviate the effects of diseases. They cannot completely prevent

*FDA suggests that you consult with a health care professional before using any dietary supplement.*

*Using supplements improperly can be harmful. Taking a combination of supplements, using these products together with medicine, or substituting them in place of prescribed medicines could lead to harmful, even life-threatening, results.*

diseases, as some vaccines can. However, some supplements are useful in reducing the risk of certain diseases and are authorized to make label claims about these uses. For example, folic acid supplements may make a claim about reducing the risk of birth defects of the brain and spinal cord.

- **Using supplements improperly can be harmful.** Taking a combination of supplements, using these products together with medicine, or substituting them in place of prescribed medicines could lead to harmful, even life-threatening, results.
- **Some supplements can have unwanted effects before, during, or after surgery.** For example, bleeding is a potential side effect risk of garlic, ginkgo biloba, ginseng, and Vitamin E. In addition, kava and valerian act as sedatives and can increase the effects of anesthetics and other medications used during surgery. Before surgery, you should inform your health care professional about all the supplements you use.

**How Are Supplements Regulated?**

You should know the following if you are considering using a dietary supplement.

- Federal law requires that every dietary supplement be labeled as such, either with the term "dietary supplement" or with a term that substitutes a description of the

product's dietary ingredient(s) for the word "dietary" (e.g., "herbal supplement" or "calcium supplement").

- Federal law does not require dietary supplements to be proven safe to FDA's satisfaction before they are marketed.
- For most claims made in the labeling of dietary supplements, the law does not require the manufacturer or seller to prove to FDA's satisfaction that the claim is accurate or truthful before it appears on the product.
- In general, FDA's role with a dietary supplement product begins after the product enters the marketplace. That is usually the agency's first opportunity to take action against a product that presents a significant or unreasonable risk of illness or injury, or that is otherwise adulterated or misbranded.
- Dietary supplement advertising, including ads broadcast on radio and television, falls under the jurisdiction of the Federal Trade Commission.
- Once a dietary supplement is on the market, FDA has certain safety monitoring responsibilities. These include monitoring mandatory reporting of serious adverse events by dietary supplement firms and voluntary adverse event reporting by consumers and health care professionals. As its resources permit, FDA also reviews product labels and other product information, such as package inserts, accompa-

nying literature, and Internet promotion.

- Dietary supplement firms must report to FDA any serious adverse events that are reported to them by consumers or health care professionals.
- Dietary supplement manufacturers do not have to get the agency's approval before producing or selling these products.
- It is not legal to market a dietary supplement product as a treatment or cure for a specific disease, or to alleviate the symptoms of a disease.
- There are limitations to FDA oversight of claims in dietary supplement labeling. For example, FDA reviews substantiation for claims as resources permit.

**Are Supplements Safe?**

Many dietary supplements have clean safety histories. For example, millions of Americans responsibly consume multi-vitamins and experience no ill effects.

Some dietary supplements have been shown to be beneficial for certain health conditions. For example, the use of folic acid supplements by women of childbearing age who may become pregnant reduces the risk of some birth defects.

Another example is the crystalline form of vitamin B12, which is beneficial in people over age 50 who often have a reduced ability to absorb naturally occurring vitamin B12. But further study is needed for some other

*Some ingredients and products can be harmful when consumed in high amounts, when taken for a long time, or when used in combination with certain other drugs, substances, or foods.*

dietary supplements.

Some supplements have had to be recalled because of proven or potential harmful effects. Reasons for these recalls include

- microbiological, pesticide, and heavy metal contamination
- absence of a dietary ingredient claimed to be in the product
- the presence of more or less than the amount of the dietary ingredient claimed on the label

In addition, unscrupulous manufacturers have tried to sell bogus products that should not be on the market at all.

Before taking a dietary supplement, make sure that the supplement is safe for you and appropriate for the intended purpose.

**Be a Safe and Informed Consumer**

- Let your health care professional advise you on sorting reliable information from questionable information.
- Contact the manufacturer for information about the product you intend to use.
- Be aware that some supplement ingredients, including nutrients and plant components, can be toxic. Also, some ingredients and products can be harmful when consumed in high amounts, when taken for a long time, or when used in combination with certain other drugs, substances, or foods.
- Do not self-diagnose any health condition. Work with health care

professionals to determine how best to achieve optimal health.

- Do not substitute a dietary supplement for a prescription medicine or therapy, or for the variety of foods important to a healthful diet.
- Do not assume that the term “natural” in relation to a product ensures that the product is wholesome or safe.
- Be wary of hype and headlines. Sound health advice is generally based upon research over time, not a single study.
- Learn to spot false claims. If something sounds too good to be true, it probably is.

**Report Problems**

Adverse effects with dietary supplements should be reported to FDA as soon as possible. If you experience such an adverse effect, contact or see your health care professional immediately. Both of you are then encouraged to report this problem to FDA. For information on how to do this, go to [www.cfsan.fda.gov/~dms/ds-rept.html](http://www.cfsan.fda.gov/~dms/ds-rept.html).

Adverse effects can also be reported to the product’s manufacturer or distributor through the address or phone number listed on the product’s label. Dietary supplement firms are required to forward reports they receive about serious adverse effects to FDA within 15 days.

For a general, nonserious complaint or concern about dietary supplements, contact your local FDA District Office ([www.cfsan.fda.gov/~dms/district.html](http://www.cfsan.fda.gov/~dms/district.html)).

This article appears on FDA’s Consumer Health Information Web page ([www.fda.gov/consumer](http://www.fda.gov/consumer)), which features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at [www.fda.gov/consumer/consumerenews.html](http://www.fda.gov/consumer/consumerenews.html).

**For More Information**

Protect Your Health  
Joint FDA/WebMD resource  
[www.webmd.com/fda](http://www.webmd.com/fda)

Fortify Your Knowledge About Vitamins  
[www.fda.gov/consumer/updates/vitamins111907.html](http://www.fda.gov/consumer/updates/vitamins111907.html)

Tips for the Savvy Supplement User: Making Informed Decisions  
[www.fda.gov/fdac/features/2002/202\\_supp.html](http://www.fda.gov/fdac/features/2002/202_supp.html)

Overview of Dietary Supplements  
[www.cfsan.fda.gov/~dms/ds-oview.html#what](http://www.cfsan.fda.gov/~dms/ds-oview.html#what)

Food Labeling and Nutrition  
[www.cfsan.fda.gov/label.html](http://www.cfsan.fda.gov/label.html)

Final Rule Promotes Safe Use of Dietary Supplements  
[www.fda.gov/consumer/updates/dietarysupps062207.html](http://www.fda.gov/consumer/updates/dietarysupps062207.html)

### **3.7 Self-Medication (over-the-counter):**

Definition of over-the-counter self-medication

Description of the most common over-the-counter medications

Pharmacological effects of the most common over-the-counter medications

Symptoms, signs and performance effects of the most common over-the-counter medications

Aviation accident investigation and post-mortem toxicological testing

FAA regulations concerning the use of over-the-counter medications

## **SECTION II, 3.7 SELF-MEDICATION (OVER THE COUNTER)**

Non prescription medications are medicines that the patient can obtain or purchase that can be used to treat a condition that does not require authorization by a physician or licensed medical practitioner.

### DEFINITION OF OVER THE COUNTER SELF-MEDICATIONS

“Over the Counter” medications (OTCs) are legal, non-prescription substances taken for the relief of discomforting symptoms that may be in capsule, tablet, powder or liquid form. This could also include topical agents as well as agents that use a dermal delivery system (i.e. patch). In the Physicians Desk Reference for non prescription drugs (NP/PDR) and dietary supplements there are over 100 categories of medications that one can be obtained without a prescription. These, according to the NP/PDR treat conditions ranging from acne to wart care preparations. Also included in the NP/PDR are dietary supplements as well as diagnostics (i.e. pregnancy). Therefore, a person sometimes not only has the ability to treat but, in some cases, confirm a diagnosis that, heretofore, could only be made under the direction of a physician or licensed medical caretaker.

### DESCRIPTION OF THE MOST COMMON OVER THE COUNTER MEDICATIONS

Some of the more common over the counter (OTC) medications would include:

Analgesics: This would include Non-steroidal anti-inflammatory drugs (NSAID) such as Ibuprofen, aspirin, and acetaminophen

Cold and flu preparations which fall into categories such as antihistamines, decongestants, and cough preparations

Bowel, or gastrointestinal agents such as laxatives and anti-diarrheals.

Appetite suppressants, often in the sympathomimetic category of stimulants, such as phenylpropanolamine (PPA), were recently taken off the market due to reported adverse reactions, and ephedra, a similar agent, is currently coming under scrutiny for its deleterious effects on the user, and in some cases, abuser.

Sleeping aids generally have low dose antihistamines in them

Stimulants such as caffeine

Dietary supplements, including agents such as amino acids, vitamins, herbal and mineral/vitamin combinations.

## PHARMACOLOGIC EFFECTS OF THE MOST COMMON OVER THE COUNTER MEDICATIONS

### ANALGESICS:

Aspirin: Produces analgesia by an ill defined effect on the hypothalamus and by blocking pain peripherally, which may involve prostoglandin synthesis via inhibition of cyclo-oxygenase enzyme. This inhibition may also have an effect on inflammatory mediators as well. The antipyretic action is by the effect on hypothalamic heat regulating centers to produce peripheral vasodilatation, increasing peripheral blood supply and promote sweating, thus cooling.

Acetaminophen: Mechanism and site of action though to be related to inhibition of prostaglandin synthesis in the CNS, thus elevating the pain threshold. Antipyretic action through increased heat dissipation through sweating and vasodilatation.

Ibuprofen: Mechanism unknown. Probably through inhibition of prostaglandin synthesis.

### COLD/FLU PREPERATIONS:

Antihistamine: H1-receptor antagonist. Competes for the H1 receptor sites on smooth muscle of the bronchi, GI tract, uterus and large blood vessels by binding to cellular receptors and to suppress histamine induced allergic symptoms, though it does not prevent histamine release. Antiemetic/antivertigo/antidyskinetic most probably acts via central antimuscarinic actions. The mechanism of sedative action is unknown.

Decongestants: adrenergic; stimulates the adrenergic receptors of the respiratory mucosa to produce vasoconstriction, shrinkage of nasal mucosa, reduction of tissue hyperemia and edema. Relaxation of bronchial smooth muscle may result from direct stimulation of the  $\beta$ -adrenergic receptors. CNS stimulation may occur.

### BOWEL PREPARATIONS:

Laxatives: (Magnesium salt): An antiulcer agent, it neutralizes gastric acid, decreasing the direct acid irritant effect. This increases the pH leading to pepsin inactivation. The laxative effect is by increasing the osmotic gradient in the gut thus drawing in water, causing distention which, in turn, stimulates peristalsis and bowel evacuation.

Anti-diarrheal: (Hydrated magnesium aluminum silicate): Though its action is unknown, it is thought to be related to absorbing large numbers of bacteria and toxins thus reducing water loss in the GI tract.

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**APPETITE SUPPRESANTS:** (Dexatrim) Ephedra stem /caffeine et al. This is an adrenergic agent with direct and indirect –acting sympathomimetic effect. It may cause stimulation as well as vasoconstriction from the  $\alpha$ -adrenergic effects adding to the pressor effects, in addition to cardiac stimulation.

**SLEEPING AIDS:** Cimetadine, diphenhydramine (See antihistamines, above)

**STIMULANTS:** (Caffeine): Xanthine derivative. It increases the levels of CAMP by inhibiting phosphodiesterase which can stimulate all levels of CNS. It increases contractile force and decreases skeletal muscle fatigue.

### SYMPTOMS, SIGNS AND PERFORMANCE EFFECTS OF THE MOST COMMON OVER THE COUNTER MEDICATIONS

ANALGESICS	Aspirin	Tinnitus, nausea, stomach ulceration
	Acetaminophen	Hepatic toxicity in large or chronic doses
	Ibuprofen	Upset GI tract, itching, dizziness, water retention
COLDS/FLU	Antihistamines	Sedation, dizziness, rash, GI upset, impaired coordination blurred vision, dryness
	Decongestants	XS stimulation, palpitations, dizziness, urinary difficulty
BOWEL PREP	Laxatives	Unexpected bowel activity, especially at altitude
	Anti-diarrheals	Drowsiness. Depression, blurred vision
APPETITE SUPPRESANTS	Acutrim, Dexatrim	XS stimulation, dizziness, palpitations
SLEEPING AIDS	Nyrol, Sominex	Prolonged drowsiness, blurred vision (antihist)
STIMULANTS	Caffeine	Tremors, palpitations, headache, tremors

### AVIATION AND ACCIDENT INVESTIGATION AND POST MORTEM TOXICOLOGICAL TESTING

A [retrospective] study of accidental non-commercial aircraft fatalities was performed on the case files of the Office of the Medical Examiner of Metropolitan Dade County in Miami, FL, U.S.A., between the years 1977 through 1983. A total of 57 cases were collected and analyzed as to the age of the A study of accidental non-commercial aircraft fatalities was performed on the case files of the Office of the Medical Examiner of Metropolitan Dade County in Miami, FL, U.S.A., between the years 1977 through 1983. A total of 57 cases were collected and analyzed as to the age of the victim, the race and sex of the victim, the cause of death, the blood alcohol content at autopsy, the drugs detected at autopsy, the type of aircraft, the occupant role, the risk factor responsible for

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the crash, the time of the fatality, and the nature of usage of the aircraft. Essentially, these 57 cases comprised 1.2% of the non-vehicular accidental fatalities during the period. The age of distribution is relatively evenly distributed from age 16 to 65 years with white males predominating. Multiple injuries were the most common cause of death although conflagration injuries (e.g., smoke inhalation, burns) were frequent. The victims were sober and free of drugs in the majority of cases. Most fatalities occurred in a single engine plane with the victim, the pilot, flying for private reasons in the afternoon or evening hours. The most common identifiable risk factor was human error (e.g., judgement), rather than mechanical or plane failure.

Toxicological findings in all military aircraft fatalities investigated by the Division of Forensic Toxicology at the Armed Forces Institute of Pathology from 1986-1990 are presented. Carbon monoxide saturation levels greater than 10% were found in 4% of the 535 cases where appropriate specimens were collected. Positive ethanol findings were more indicative of postmortem formation than antemortem consumption. In only 1 case was an abused drug (cannabinoids in a passenger) detected. Other drugs identified included nicotine, chloroquine and over-the-counter analgesic agents, antihistamines and sympathomimetic drugs.

In a series of 2326 deaths (in 1983) there were 314 positive drug tests found. The most often found was aspirin (109), acetaminophen (61), ethanol (51), and diphenhydramine (1).

FAA REGULATIONS CONCERNING THE USE OF OVER THE COUNTER MEDICATIONS

<u>NONPRESCRIPTION DRUG</u>	<u>PRESCRIPTION DRUG</u>	<u>ILLCIT DRUG</u>
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Antacids		
	Amphetamines	Amphetamines
	Anticoagulants	
	Antidepressants	
Antihistaminic	Antihistaminic	
	Antihypertensive	
	Antiviral	
	Anxiolytics	
	Barbiturate	
Aspirin	Aspirin	
		Cocaine
	Contraceptives	
	Cyclic hormones	
	Desensitization injections	
		Hallucinogens
	Hypnotics	
	Hypoglycemic drugs	
Ibuprofen	Ibuprofen	
	Insulin	
		Marijuana
	Mood ameliorating	
Motion sickness	Motion sickness	
	Mydriatic	
	Naproxen	
	Narcotics	
Opioids	Opioids	
	Oral hypoglycemic	
Phenylephrine	Phenylephrine	
	Psychoactive	
	Sedative	
	Steroid	
Stimulant	Stimulant	
	Sucralfates	
	Tranquilizers	
	Warfarin	

The drugs/medications are those listed in the Guide for Aviation Medical Examiners. Each category will be discussed in the appropriate section.

SUMMARY OF ALL DRUGS

NAME OF DRUG	FAA GUIDE FOR AVIATION MEDICAL	PAGE CITATION: AME GUIDE
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	EXAMINER	
Antacids	ND	51
Amphetamines	DIS	28, 66, 71
Anticoagulants	MPC/ DFR	22, 27, 49
Antidepressants	DIS	70
Antihistaminic	MPC see footnote below*	22
Antihypertensive	MPC see footnote below**	22, 27, 95
Antiviral	MPC/ DFR	22
Anxiolytics	DIS	22, 28, 86, 70, 71
Aspirin	ND see footnote re: dipyramidole	27, 58
Barbiturate	DIS or DFR	22
Cocaine	DIS	28, 66, 71
Contraceptives	ND	55
Cyclic hormones	ND	55
Desensitization injections	ND	25
Experimental drugs	DFR	22
Hallucinogens	DIS	28, 66, 70, 71
Hypnotics	DIS	28, 66
Hypoglycemic	MPC/ DFR	3, 22, 28, 72, 75, 98
Ibuprofen	Tolerated? No side effects?	58
Illegal substances	DIS	28
Insulin	DIS	3, 28, 72, 75, 98
Investigational	DFR	22
Marijuana	DIS	28, 71
Mood ameliorating	DIS, DFR	22
Motion sickness	DFR	22, 29
Mydriatic	EX Not recommended for exam	40, 92
Naproxen	Tolerated? No side effects?	58
Narcotics	DIS	22
Opioids	DIS	28, 66, 71
Oral Hypoglycemic	MPC/ DFR	3, 74
Phenylephrine HCl	EX: May be used in ENT exam	36
Psychoactive	DIS	28, 66, 71
Psychotropic	DIS	68, 70
Sedative	DIS	28, 66, 70, 71
Steroid	MPC/DFR	22
Stimulant	DIS	66
Sucralfates	ND Tolerated? No side effects?	51
Substance, abuse/depend	DIS	3, 28, 30, 31, 66, 67, 71, 72,
Tranquilizers	DIS	22, 70
Warfarin	MPC/ DFR	49

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DIS=DISQUALIFYING

ND=NOT-DISQUALIFYING (Medication well tolerated? No side effects?)

DFR=DEFER TO FAA

EX=USED IN EXAMINATION

MPC/DFR=MAY PRECLUDE CERTIFICATION (DEFER)

ANTIHYPERTENSIVES: Diuretics,  $\alpha$ -adrenergic blocking agents,  $\beta$ -adrenergic blocking agents, Calcium channel blocking agents, ACE inhibitors, direct vasodilators. This assumes the medicine is well tolerated and does not produce side effects.

\*\*ANTIHISTAMINES: Loratidine, Astemizole or Fexofenadine not disqualifying assuming that the medication is well tolerated and does not produce side effects.

\*\*\*ASPRIN (Dipyridamole, a coronary vasodilator and platelet aggregate inhibitor, may not be disqualifying

According to one of the FAA's publications which offers the following advice and recommendations:

READ and follow label directions for use of **all** medications

If the label warns of side-effects, do **NOT** fly until twice the recommended dosing interval has passed. For example, if the label says "take every 4-6 hours" then wait at least 12 hours!

Remember, the condition you are treating may be as disqualifying as the medication itself.

When in doubt, ask your physician or Aviation Medical Examiner.

As a pilot, you are responsible for your own personal "pre-flight." Be wary of any illness that requires medicine to make you feel better.

If an illness is serious enough to require medication it is also serious enough to prevent you from flying.

Do not fly if you have a cold, changes in atmospheric pressures with changes in altitude could cause serious ear and sinus problems.

Avoid mixing decongestants and caffeine

Beware of medications that use alcohol as a base for the ingredients

**IN SUMMARY: IF IN DOUBT, ERR ON THE SIDE OF CAUTION! TO QUOTE THE WISE PILOTS OF YESTERYEAR, "TIS BETTER TO BE A LIVE CHICKEN, THAN A DEAD DUCK!"**

## Miscellaneous Pharmaco-active Substances and Nutritional Supplements: Education and Policy for Aircrew members

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### GENERAL DIETARY SUPPLEMENTAL ADVICE

Congress defined the term "dietary supplement" in the Dietary Supplement Health and Education Act (DSHEA) of 1994. A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandular extracts, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders. They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Whatever their form may be, DSHEA places dietary supplements in a special category under the general umbrella of "foods," not drugs, and requires that every supplement be labeled a dietary supplement. *This Act, passed during the Clinton administration, shifted the burden to the FDA to prove that dietary supplements pose a significant or unreasonable risk rather than have the manufacturers bear the responsibility to establish the safety of the products they sell. A dangerous loophole considering many of the "supplements" have known pharmacoeactive properties and the fact the FDA often has few or inadequate data to evaluate, unless a group of investigators decides to independently conduct studies. Dr. Kessler from the Yale University School of Medicine has said, "Without a systematic review of safety and an adequate data base on safety, the American public remains at risk."*

#### Points to Remember:

- Harmful effects often associated with use in very high doses or in non-standard manner
- The U.S.P. notation indicated that a manufacturer has followed standards established by the US Pharmacopoeia, and without it one is essentially playing "Russian Roulette" with respect to bottle contents
- Just because it might be "natural" doesn't mean it is safe
- Many may have beneficial effects in some users when used in moderation
- No method to test for most substances by urine or blood tests
- Flight Surgeons and other medical providers must be armed with "tools" to make informed decisions
- Aviators must be confident of accurate and informed counsel
- This list will require revision at least annually
- Must compel flight surgeons to discuss and document use of supplements at least annually.  
**\*\*Should be specific questions about nutritional supplements on SF/medical history form.**
- **Forms referring to "Medication" should be revised to read "medications or supplements"**
- Education
- Flight Surgeons, dietitians, and healthcare providers engaged in care of special operational personnel should be offered educational blocks covering dietary supplements
- Possible venues include:
  - Flight Surgeon Primary Course
  - Entry level training

- Continuing Education
- Studies may include performance enhancement qualities, specific aerospace effects (e.g. effects on G-tolerance), or literature base study of overall health effects
- As no current venue for aeromedical research into this area currently exists, cooperative study with civil and sister services may be considered
- FDA desires to have many recommendations regarding supplements by 2010.

**Resources that may be helpful:**

-U.S. Army Center for Health Promotion and Preventive Medicine

<http://chppm-www.apgea.army.mil/dhpw>

-The Center for Food Safety and Applied Nutrition

<http://vm.cfsan.fda.gov>

-Office of Dietary Supplements: <http://ods.od.nih.gov>

-US Air Force <http://www.brooks.af.mil/af/altmed/HOMEFRAME.htm>

## **POLICY FOR SUPPLEMENTS AND VARIOUS PHARMACO-ACTIVE OTC ITEMS: CLASS A, B, and C**

### **CLASS A Substances for Class I, II, and III personnel (Use requires only documentation at annual physical)**

Substances for which there is strong evidence of safety and/or efficacy. Limitations on quantity and type of supplement shall be discussed *and documented* at time of annual physical according to the below.

#### **1. Sports drinks without creatine, ephedra, herbal supplements:**

Background: Sport drinks not containing any of the compounds listed in Class B or Class C (i.e. ephedra, herbal compounds, glycerol, and creatine) and containing only a mixture of carbohydrates, vitamins, and minerals, are allowed. These have been shown to help performance of continuous activity lasting longer than 90 minutes. However, they are not necessary if water is available. They are absorbed faster than water because of the added sugar and electrolytes and have added sodium, which stimulates thirst, stimulates drinking, and helps retain water.

Educating the aircrew member about the type of safe and allowable sports drinks is essential. *Many sports drinks found at fitness centers and nutrition stores contain ephedra alkaloids (Class C) which have been strongly associated with adverse cardiovascular and central nervous system events including:*

- Seizures
- Strokes
- Hypertension
- Arrhythmias
- Myocardial infarction
- Death

Sports drinks containing caffeine are allowed, but should be strongly discouraged for their propensity to dehydrate and increase blood pressure and heart rate to potentially dangerous levels during exercise.

Use in Aircrew: *Sport drinks found in nutritional stores, gyms and other sources containing only carbohydrates, various mixtures of proteins, minerals/electrolytes and no compounds in Class B or C are allowed.*

#### **2. Protein Supplementation (form of shakes, capsules, nutrition bars):**

Background: A considerable amount of research has evaluated dietary protein needs of athletes. Although there is some debate, most studies indicate that in order to maintain protein balance during intense resistance and/or endurance training, athletes should ingest approximately 1.3 to 1.8 g protein per kg body mass per day. Athletes training at high-altitude may need as much as 2.2 g protein per kg per day in order to maintain protein balance. This protein intake is about 1.5 to 2 times the recommended dietary allowance (RDA) for the normal adult. In most instances an iso-energetic diet

can provide the required protein, but athletes who maintain hypo-energetic diets do not ingest enough quality protein in their diet, and/or train at altitude where they may be susceptible to protein malnutrition. In theory, this state could slow tissue growth and/or recovery from training.

*On the other hand, ingesting more protein than necessary to maintain protein balance during training (e.g., > 1.8 g/kg/d) does not promote greater gains in strength or fat-free mass. These findings indicate that athletes typically do not need to supplement their normal diets with protein, provided they ingest enough quality protein to maintain protein balance. Excessive amounts of protein intake can cause nausea, vomiting, and ultimately death in adults.*

**Use in Aircrew:** *Aircrew may supplement their diet with supplemental protein in the form of protein shakes, protein bars, or capsules, provided that the protein supplement does not contain supplements listed under Class C (creatine, ephedra, herbals, steroids) and the TOTAL amount of protein the aircrew member consumes does not exceed 2 times the RDA value (1.58g/kg or .72 g/lb per day). Physicians must take into account the amount of protein coming from normal dietary sources (usually 12-15% of total calories comes from protein).*

### 3. Vitamins/Minerals:

**Background:** "Healthy adult men and healthy adult non-pregnant, non-lactating women consuming a usual, varied diet do not need vitamin supplements. Infants may need dietary supplements at given times, as may pregnant and lactating women. Occasionally, vitamin supplements may be useful for people with unusual lifestyles or modified diets, including certain weight reduction regimens and strict vegetarian diets."-*The American Medical Association*. Healthy children and adults should obtain adequate nutrient intakes from dietary sources. *Meeting nutrient needs by choosing a variety of foods in moderation, rather than supplementation, reduces the potential risk of both nutrient deficiencies and nutrient excesses.* Individual recommendations regarding supplements and diets should come from physicians and registered dietitians. Nutrients are potentially toxic when ingested in sufficiently large amounts. Safe intake levels vary widely from nutrient to nutrient and may vary with age and health of the individual. In addition, high dosage vitamin and mineral supplements can interfere with normal metabolism of other nutrients and with the therapeutic effects of certain drugs. The Recommended Daily Allowances represent the best currently available assessment of safe and adequate intakes, and serve as the basis for the U.S. Recommended Daily Allowances shown on many product labels. There are no demonstrated benefits of self supplementation beyond these allowances." *The American Institute of Nutrition, The American Society for Clinical Nutrition, The American Dietetic Association, and The National Council Against Health Fraud.* "A large percentage of people in the United States take dietary supplements, but not necessarily because of nutrient needs. The adverse effects of large doses of certain nutrients (e.g., vitamin A) are well documented. There are no documented reports that daily multiple vitamin-mineral supplements equaling no more than the RDA for a particular nutrient are either beneficial or harmful for the general population. The potential risks or benefits of the long-term use of small doses of supplements have not been systematically examined." *Committee on Diet and Health, National Academy of Sciences, National Research Council.*

**NOTE:** The best advice is to obtain vitamins and minerals by eating a wide variety of foods. If an individual chooses to take a multivitamin-multimineral supplement, a balanced diet also should be consumed. This is because there is inadequate knowledge as to all of the essential nutrients needed by adults — all required nutrients may not be present in the supplement. Many multivitamin-multimineral supplements containing 100 percent U.S. RDA levels are on the market. The consumption of this level of supplement will not be harmful to health and may or may not be helpful. Taking high doses (1gram) of Vitamin C does not appear to prevent URI's in healthy subjects but may shorten the duration of the common cold to a small extent.

***Use in Aircrew:*** Educate the aircrew member. If a healthy adult wants to take a vitamin/mineral supplement, that supplement shall be a once-a-day multivitamin-multimineral from a USP labeled bottle.

#### 4. Tonic Water:

**Background:** Cinchonism is the well-known syndrome of quinine overdose involving disturbances of vision, hearing, and balance, which has occasional importance in aviation pathology, usually related to ingestion of tonic water. Ordinary social drinking of tonic water may lead to appreciable amounts of quinine in the body, although the levels are far lower than those commonly used in the treatment of malaria. The Armed Forces Institute of Pathology (AFIP) in Washington, DC, found levels of 0.2mg/L in pilots in 3 fatal accidents in which positional cues seemed to be important. AFIP results show that commercial tonic water can contain 5.5-6.8 mg/dl. In the late eighties and early nineties, the Surgeon General of the Army medically restricted regular users of tonic water from flying and advised all aviators not to use it. Army aircrew members were restricted from flying for 72 hours after ingestion of tonic water. It has been suggested that a chronic low-dose intake of quinine may accumulate in the endolymph of the human vestibular system and this accumulation could produce vestibular effects equivalent to a unilateral labyrinthectomy (see "The Bite of Jesuits' Bark", Aviation Space and Environmental Medicine, July, 1989).

***Use in Aircrew:*** Educate the aircrew member about the risks associated with drinking tonic water regularly. Drinking more than three 12oz drinks per day (36 oz total) of tonic water is not authorized. Because tonic water is not classified as a supplement, it is important to ask at annual physical examinations if the aircrew member drinks tonic water.

**CLASS B Supplements for Class I, II, III (Use Not prohibited but information required)**

These are substances for which evidence of risk is minimal.

**For all Class B supplements:** Use requires consultation with flight surgeon and documentation of use in medical record. In addition, must have documented in medical record that specific guidelines of dosages, risks, benefits, and side effects were discussed with the aircrew member. Supplements with the “USP” label are highly encouraged. Additional documentation needed is listed below for various supplements. Overall, the importance of educating the aircrew member with some of the background information given below cannot be overstated.

**1. Glucosamine with or without chondroitin:**

**Background:** Glucosamine (with or without chondroitin) may have some beneficial effect on osteoarthritis, and studies up to 3 yrs in duration have found no more adverse effects than with placebo, but most physicians are skeptical. Whether glucosamine offers any advantages over better-established drugs such as acetaminophen, traditional NSAIDS, or selective COX-2 inhibitors remains to be determined. As with other dietary supplements, the quality and purity of the ingredients may vary (The Medical Letter, Vol. 43, Dec 20, 2001). American college of Rheumatology states it is too early to recommend its usage for osteoarthritis. NIH-sponsored randomized controlled trial ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)) is currently in progress. Because of concerns regarding infectious contamination of chondroitin (a derivative of shark cartilage), glucosamine sulfate or glucosamine hydrochloride is recommended over glucosamine/chondroitin combinations.

**Use in Aircrew:** *Aircrew member must be evaluated by the flight surgeon and diagnosis of osteoarthritis established. Educate the aircrew member about the questions regarding the efficacy of these compounds vs. traditional anti-inflammatories and the lack of evidence demonstrating a structural modifying relationship. Dosage must not exceed 1500mg per day.*

**Grounding:** 24 hour local grounding after first dose.

**Waiver:** Not required

**2. Saw Palmetto (*Serenoa repens*):**

**Background:** A standardized liposterolic (fat-soluble) saw palmetto berry extract has demonstrated numerous pharmacological effects relating to its primary clinical application in the treatment of benign prostatic hyperplasia (BPH), a disorder caused by accumulation of testosterone in the prostate where a conversion to dihydrotestosterone (DHT) takes place. The primary therapeutic action of saw palmetto extract in the treatment of BPH is thought to be a result of inhibition in the intraprostatic conversion of testosterone to DHT and inhibition of its intracellular binding and transport. However, more recent research has suggested other mechanisms including anti-estrogenic and receptor site-binding effects. In the United States, between 50 to 60% of men between the ages of 40 and 59 years have BPH. This disorder is characterized by increased urinary frequency, nighttime awakening to empty the bladder, and reduced force and caliber of urination. These major symptoms have been shown to be significantly improved in over a dozen double blind, placebo-controlled clinical trials. In one of the larger studies involving 110 patients with BPH, impressive clinical results were reported. Nocturia

decreased by over 45%, flow rate (ml/s) increased by over 50%, and post-micturition residue (ml) decreased by 42% in the group receiving the serenoa extract. In contrast, those on placebo showed no significant improvement in nocturia or flow rate, and post-micturition residual actually worsened. Significant improvements were also noted in self-rating by the patients and global rating by the physicians. Of the 50 treated subjects completing the 30-day study, physicians rated 14 greatly improved, 31 improved, and only five unchanged or worsened. In contrast, no subjects in the placebo group had greatly improved, 16 showed some improvement, and 28 remained unchanged or worsened. No significant side-effects have been reported in the clinical trials of the saw palmetto berry extract or with saw palmetto berry ingestion. Long-term studies (3 years) have also failed to show any significant adverse effects other than gastric irritation.

***Use in Aircrew: Provided the aircrew member has been evaluated by the urologist who recommends the use of saw palmetto, the dosage for the liposterolic extract of saw palmetto berries (containing 85–95% fatty acids and sterols) is 160 mg twice daily. A similar dose using fluid extracts and tinctures is not authorized.***

***Grounding: 24 hours after first dose***

***Waiver: Not required.***

**CLASS C Supplements (Not authorized for use by any aviation personnel)**

Dietary supplements, nutritional supplements, and other preparations *containing* the following incapacitating/dangerous substances shall not be used by aviation personnel. Many of these substances have either (1) proven to be hazardous or (2) have not been proven to be safe with no clear proven benefit

- Personnel taking these substances should be removed from aviation duty for a minimum of 24 hours after the last dose of the substance.

**Herbal Supplements:**

- **Aconitum napellus (wolfsbane)**
- Adonis vernalis (Pheasant's eye)
- Atropa belladonna (Deadly Nightshade)\*
- Cantharanthus roseum (Periwinkle)
- Chelidonium majus (Celandine)
- Conium maculatum (Hemlock)
- Convallaria majalis (Lilly of the Valley)
- Corynanthe yohimbe (Yohimbe bark)
- Cystisus scoparius (Broom)
- Datura stramonium (Jimson weed)\*
- Datura stramonium (Thorn Apple)
- Digitalis lanata (Yellow foxglove)
- Digitalis purpurea (Purple Foxglove)
- Ephedra species (Ephedra)
- Exchscholzia californiica (California Poppy)
- GHB (Gamma Hydroxy Butyrate ) or GBL (Gamma-Butyrolactone) (may be known as Renewtrent, Revivarant, Blue Nitro, GH Revitalizer, Gamma G, Remforce)
- Humulus lupulus (Hops)
- Hyoscyamus niger (Henbane)\*
- Hypericum Perforatum (St. Johns Wort)
- Lactuca virosa (Wild lettuce)
- Lycopodium serratum (Jin Bu Huan)
- Mandragora officinarum (Mandrake)
- Myristica fragrans (Nutmeg)in large quantities
- Papaver somniferum (Opium poppy)
- Passiflora incarnata (Passion flower)
- Piper methysticum (Kava-Kava)
- Psilocybe semilanceata (magic mushrooms)
- Rauwolfia serpentina (Indian snakeroot)
- Rauwolfia serpentina (Indian Snakeroot)
- Scilla maritima (White Squill)
- Scopolia carniolica (Scopolia)\*

- Scutellaria laterifolia (Skullcap)
- Strophanthus kombe (Strophanthus)
- Urginea maritima (Squill)
- Valeriana officinalis (Valerian)

Dietary Supplements, Nutritional Supplements, and other preparations *containing* the following *potentially* harmful substances shall not be used by personnel in above categories.

- Personnel taking these substances should be removed from aviation duty for a minimum of 24 hours after the last dose of the substance.

**Anabolic Steroids:**

- \*Zeranol
- \*Testosterone (Malogen, Malogex, Delatestryl)
- \*Stanozolol (Winstrol, Stromba)
- \*Oxymetholone (Anadrol, Anapolon 50, Adroyd)
- \*Oxandrolone (Anavar)
- \*Norethandrolone (Nilevar)
- \*Nandrolone (Durabolin, Deca-Durabolin, Kabolin, Nandroboic)
- \*Methyltestosterone (Android, Estratest, Metandren, Virilon, Oreton Methyl, Testred)
- \*Methandrostenolone (Dianabol)
- \*Metenolone (Primobolan, Primonabol-Depot)
- \*Metandienone (Danabol, Dianabol)
- \*Mesterolone (Androviron, Proviron)
- \*Human Chorionic Gonadotrophin
- \*Growth Hormone
- \*Fluoxymesterone (Android F, Halotestin, Ora-Testryl and Ultradren)
- \*Dihydrotestosterone (Stanolone)
- \*DHEA
- \*Dehydrochlormethyl Testosterone (Turinabol)
- \*Danocrine
- \*Danazol
- \*Clostebol (Steranabol)
- \*Clenbuterol
- \*Boldenone (Equipoise)
- \*Bolasterone (Vebonol)
- \*Androstendione (Androsten and others)

**Glandular Extracts:**

- Teucrium spp. (Germander)
- Testicular extracts

- *Symphytum officinale* (Comfrey)
- *Senecio* spp (thread leafed groundsel and Life root)
- *Larria tridentata* (chaparral)
- Aortic extracts
- Adrenal Extract

**Other Compounds:**

- **Pangamic Acid (Vitamin B15)**
- *Echinacea* species
- Creatine
- Amino Acid Supplements (Anabolic and Branched Chain), Beta-Hydroxy-Beta Methylbutyrate (HMB)
- Coenzyme Q (CoQ10), Choline, L-Carnitine, Chromium Picolinate, Phosphate salts, vanadyl sulfate
- Glycerol
- Any supplement not listed in this policy is considered Class C, until further research indicates otherwise

**Background on Class C Supplements**

**Plant Products (Herbs)**

- *Psychiatric effects*
  - **Sedation**
    - Some substances used in “medicinal” doses (exceeding sprinkled on spices) are known to have sedative properties.
    - Their effects may be additive with other over the counter or prescription agents with sedative properties.
    - The duration of action is unpredictable
    - Research into their effects on specific areas of concentration and tracking tasks is lacking.
    - **Plant products known or likely to be sedatives:**
      - *Valeriana officinalis* (Valerian)
      - *Rauwolfia serpentina* (Indian snakeroot)
      - *Atropa belladonna* (Deadly Nightshade)\*
      - *Chelidonium majus* (Celandine)
      - *Humulus lupulus* (Hops)
      - *Conium maculatum* (Hemlock)
      - *Lycopodium serratum* (Jin Bu Huan)
      - *Papaver somniferum* (Opium poppy)
      - *Passiflora incarnata* (Passion flower)
      - *Scutellaria laterifolia* (Skullcap)
      - *Lactuca virosa* (Wild lettuce)
      - *Aconitum napellus* (wolfsbane)
      - *Hyoscyamus niger* (Henbane)\*

- *Datura stramonium* (*Jimson weed*)\*
- *Scopolia carniolica* (*Scopolia*)\*
  - \*anticholinergic actions
- **Synthetic Agents known or likely to be sedatives**
  - *GHB* (*Gamma Hydroxy Butyrate*)
    - *Renewtinent, Revivarant, Blue Nitro, GH Revitalizer, Gamma G, Remforce*
    - Is a CNS depressant associated with several deaths especially if used with ETOH
      - Pure form experimentally used for some sleep disturbances (controlled drug)
    - Marketed as agent to enhance fitness, reduce stress and enhance sex drive
      - Precursor agents (GBL) marketed openly (although illegally in most states)
    - FDA has issued do not use warnings.
- **Hallucinations**
  - Some plants, sometimes smoked to release high concentrations of volatile oils, are capable of causing hallucinations or altered sensorium
  - These are not widely marketed by mainstream companies, but are often available through other sources
  - **Plant products known or suspected to cause hallucinations or altered sensorium:**
    - *Psilocybe semilanceata* (*magic mushrooms*)
    - *Exchscholzia californiica* (*California Poppy*)
    - *Piper methysticum* (*Kava-Kava*)
    - *Mandragora officinarum* (*Mandrake*)
    - *Myristica fragrans* (*Nutmeg*) in large quantities
    - *Cantharanthus roseum* (*Periwinkle*)
    - *Datura stramonium* (*Thorn Apple*)
    - *Corynanthe yohimbe* (*Yohimbe bark*)
- **Cardiovascular effects**
  - **Cardiac glycosides**
    - Cardiac glycosides may precipitate dysrhythmias; especially when found in association with electrolyte abnormalities such as would occur with poor hydration status (*digitalis* family).
  - **Plant products known to contain cardiac glycosides or cardioactive substances**
    - *Digitalis purpurea* (*Purple Foxglove*)
    - *Urginea maritima* (*Squill*)
    - *Cystisus scoparius* (*Broom*)
    - *Convallaria majalis* (*Lilly of the Valley*)
    - *Adonis vernalis* (*Pheasant's eye*)
    - *Strophanthus kombe* (*Strophanthus*)
    - *Scilla maritima* (*White Squill*)
    - *Digitalis lanata* (*Yellow foxglove*)
- **Vasoactive substances**
  - **Stimulant (s)**

- Contain powerful sympathomimetic agents that directly stimulate the heart and blood vessels.
  - Have been implicated in deaths due to stroke or heart attack attributed to massive increases in pulse and blood pressure, and have been responsible for mission failure due to palpitations.
  - **Substances known to be potent cardiovascular stimulants**
    - *Ephedra species (Ephedra)*
  - **Hypotensive Agent(s)**
    - These plants elaborate substances that relax blood vessels lowering blood pressure.
      - Such products would potentially affect Gz tolerance
  - Plant products known to contain substances with cardiovascular activity:
    - *Rauwolfia serpentina (Indian Snakeroot)*
- **Specific Therapies Felt To Pose A Risk to Overall Health:**
- **Liver Toxins**
    - **Pyrollizidine Alkaloids**
      - A number of plants elaborate pyrollizidine alkaloids, known to cause harm to the liver
      - Such damage is often irreversible, and may result in permanent disability or death.
      - Reaction to these alkaloids is poorly understood, and may not be totally dependent on dose
    - **Substances known or believed to be toxic to the liver**
      - *Senecio spp (thread leafed groundsel and Life root)*
      - *Larria tridentata (chaparral)*
      - *Symphytum officinale (Comfrey)*
      - *Teucrium spp. (Germander)*
  - **Anabolic Steroids-**
    - Many synthetic agents are currently available as dietary supplements. Most are steroids marketed for body builders. Adverse effects of anabolic steroid use include behavioral changes, testicular atrophy and reduced sperm production, gynecomastia, and baldness.
    - Long-term effects include increased atherogenesis; increased risk of stroke or heart attack due to increased platelet aggregation, and direct damage to the heart and liver
  - **Glandular Extracts**
    - Background: A wide variety of animal tissues have been processed to provide various health effects primarily related to their retained hormone effects.
      - Content of these extracts may be lost during digestion
      - Some appear to retain their biological activity although to what degree is unpredictable
      - All carry with them some risk of infectious transmission (especially prions and viruses)
    - **Commonly used glandular extracts include**
      - *Adrenal Extracts*
      - *Testicular extracts*
      - *Aortic extracts*
  - **Other Compounds (Pangamic Acid or Vitamin B15)**

Background: Although claiming to be a vitamin, this is not a true vitamin and is a mixture of a calcium compound and gluconate. It may contain a variety of compounds. There is no evidence to support the claim that it improves endurance and several of the compounds marketed under this name are potentially hazardous.

- **Echinacea products**

Background: Several well-documented reports of allergic skin reactions and anaphylaxis are associated with these plant products. There is no convincing evidence that echinacea decreases the severity or shortens the duration of upper respiratory infections and the purity and potency is highly variable as with other dietary supplements. In the studies where a significant effect was seen, there are several concerns over the method in which the studies were conducted.

- **Creatine**

Background: Although creatine came onto the scene as a performance promoter for the physically active individual, there are **several questions about performance gains and safety that preclude it being authorized for general use in aircrew at this time.** The benefits of supplementation on performance are limited to specific types of activities. Preliminary information suggests that high-intensity, short duration activities may benefit from creatine supplementation. Some examples include weight training, baseball, sprinting, throwing, jumping, football, and soccer. However, only people with low levels of muscle creatine will benefit from creatine supplementation. Testimonial reports imply that creatine supplementation can cause nausea, vomiting, diarrhea, kidney and liver problems, high blood pressure, and muscle cramps/strains/pulls, and no safety for long-term use has been shown. As a testimony to its medicinal properties, creatine supplementation has been carefully prescribed in the medical community and used with success in various mitochondrial and neuromuscular disorders to increase muscle function and strength.

France actually forbids the sale of any products containing creatine, and Italy allows its use but only under the strict supervision of a physician and only for certain pathological conditions. Furthermore, because of poor manufacturing processes and lack of stringent quality control here in the US, various contaminants present in creatine products (such as dicyandiamide, creatinine, etc.) may pose a health risk and also preclude recommendation at this time. **Creatine should always be avoided by those who seek to lose weight while exercising heavily in hot and humid conditions.** Preliminary findings indicate that creatine supplements may selectively reduce plasma volume, which impairs the capacity to sweat and thus decrease the ability to maintain a normal body temperature during exercise in hot, steamy conditions. **In contrast to high-intensity or anaerobic activities, creatine supplementation does not improve, and may even worsen, endurance performance.** One study found that marathon runners had poorer performances after creatine loading. There is one consistent side effect of creatine supplementation - a small weight gain, most likely from water accumulation, and the effect of this in the aviation environment has not been studied. Future studies need to address some practical issues. These issues include development of safe and effective programs to maximize muscle creatine accumulation and to maintain elevated creatine stores, determination of long term side effects of creatine supplementation, and assessment of its effects in women and the elderly. In time, as more studies focus on long term safety issues and quality issues are addressed by the FDA, a safe

recommendation on use and dosages might be possible. As mentioned above, the one promising area at this time is the use of creatine supplementation to restore muscle function in patients with muscle loss and specific types of nerve and muscle diseases. Creatine "loading" (20-30 grams/day) has been a common practice among a variety of athletes. More recent research indicates, however, that much smaller doses of creatine (3 to 5 grams daily or 1 pound of beef) in excess of the usual intake of 2 grams are equally effective in elevating muscle creatine and phosphocreatine.

- **Amino Acid Supplements (Anabolic and Branched Chain), Beta-Hydroxy-Beta Methylbutyrate (HMB)**

Background: There is some evidence from clinical populations that certain amino acids (e.g., arginine, histidine, lysine, methionine, ornithine, and phenylalanine) may stimulate the release of growth hormone, insulin, and/or glucocorticoids and thereby promote anabolic processes. However, there is little evidence that supplementation of these amino acids provides ergogenic benefit for athletes. Branched-chain amino acids and glutamine have been hypothesized to affect central fatigue and exercise-induced immune suppression, but their ergogenic value during prolonged exercise is equivocal at present. Furthermore, published studies of safety have not fully taken account of chronic consumption by healthy subjects of all age groups. Side effects seen with intake of individual amino acids were mostly neurological in nature.

Because glutamine is metabolized to glutamate and ammonia, both of which have neurological effects, psychological and behavioral testing may be appropriate if adverse effects are suspected in any patient. Human studies are inconclusive about the effectiveness of HMB, a breakdown of leucine, and more research is needed.

- **Coenzyme Q (CoQ10), Choline, L-Carnitine, Chromium Picolinate, Phosphate salts, vanadyl sulfate**

Background: Carnitine is involved in the metabolism of fats and is prevalent in a variety of animal products. It is claimed to increase aerobic power and energy level as well as decrease body fat. Some performance benefit is seen with repeated, very intense exercise, but there is no evidence it decreases body fat. The body generally makes adequate amounts. Choline is a constituent of cell membranes and is promoted to decrease body fat, delay fatigue and promote faster recovery. There is NO evidence it improves performance or reduces body fat. Supplements may cause diarrhea, foul smelling intestinal gas, and may cause a "fishy" body odor. Choline is found in egg yolks and meats, and deficiencies are very uncommon. Coenzyme Q, or CoQ10, is an enzyme component found in the mitochondria of cells. It is a potent antioxidant and is claimed to increase energy and cardiac performance. NO benefits have been reported in athletes. It has been used with therapeutic success in patients with heart disease to increase oxygen utilization and exercise performance and has also been shown to increase submaximal and maximal exercise capacities in sedentary men. With regards to chromium picolinate, phosphate salts, and vanadyl sulfate, research is either ambiguous or inadequate to support performance enhancement. Long term safety cannot be assumed or expected. Because of this, and the lack of proven benefits, they are not authorized at this time.

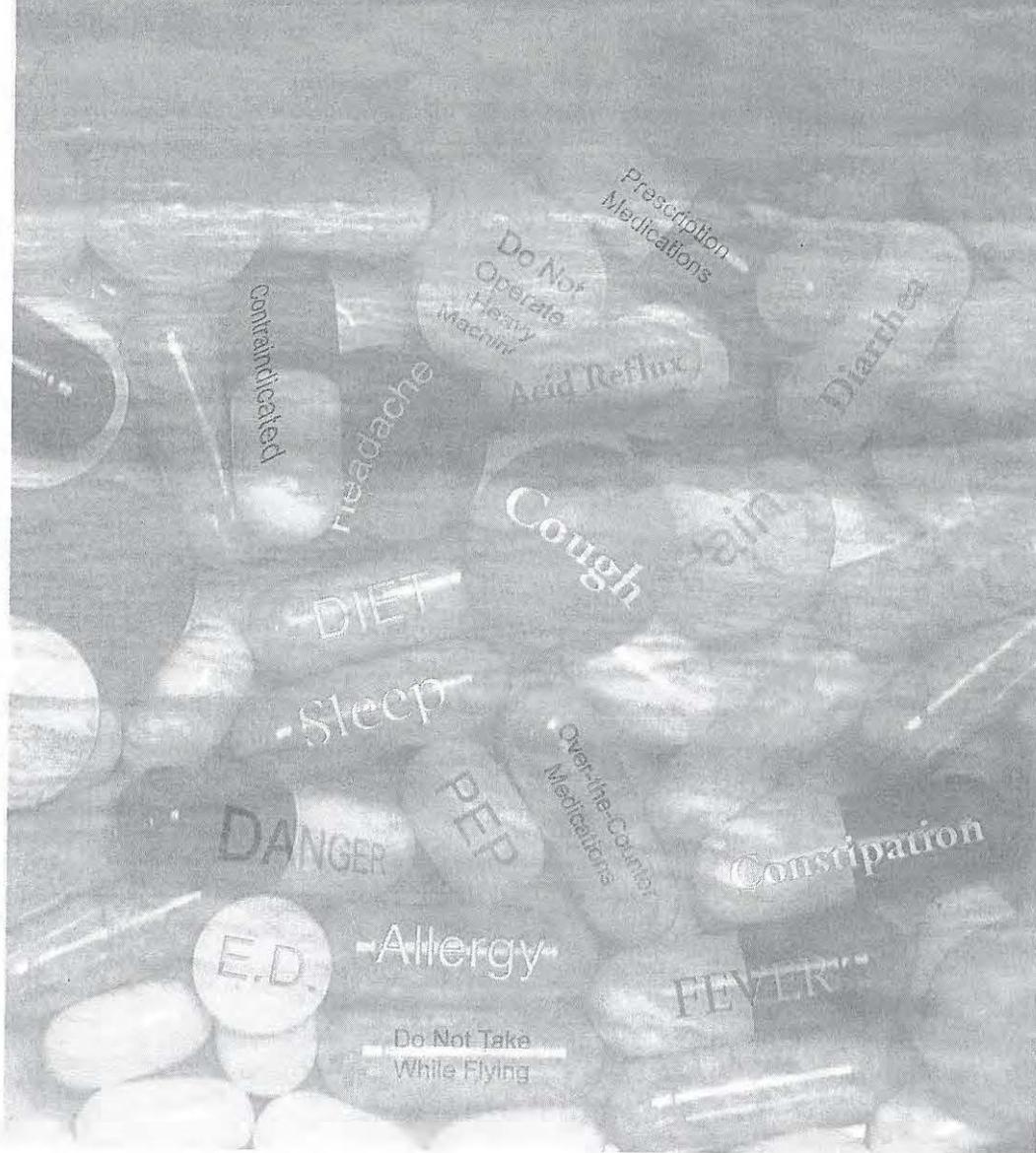
- **Glycerol**

Background: Some studies have shown glycerol to be an effective ergogenic aid. Most of these have methodological problems. Data and reviews from USARIEM (US Army Research Institute of Environmental Medicine) do not support the use of glycerol as an ergogenic aid (see Latzka and Sawka, Can J Appl Physiol, 25 (6): 536-545, 2000). More importantly, the clinical use of oral glycerol in reducing intraocular pressure and other medical anomalies (0.25-2g/kg) is effective because, although acute glycerol administration results in increased total body water (hyperhydration), it then turns into a potent osmotic dehydrating agent. This can be potentially dangerous in the post-exertion period as diuresis coupled with exercise dehydration could produce volume/ electrolyte abnormalities. Also, at doses around 1g/kg, many people experience nausea/vomiting from glycerol.



Federal Aviation  
Administration

## Medications and Flying



### Does this story sound familiar?

It's Sunday morning, the last day of a three-day trip. You have four hours of flying ahead of you to get back home, but something about the air conditioner last night has left you with stuffy nose and sinuses this morning. You know from your training and experience that flying with congested upper airways is not a good thing. As it turns out, one of the others on the trip has some new over-the-counter sinus pills that are "guaranteed" to unstop your breathing passages and let you fly without any worries about the congestion. *Should you take the medication?*

### Another scenario

You and your spouse are on the second leg of a five-leg, cross-country flight. While visiting relatives, you stayed up late at the party they threw in your honor, ate too much, and the next morning your stomach feels sort of queasy. Your spouse, a non-pilot, offers you a common motion-sickness pill prescribed by her doctor. Should you take the medication?

### Get the facts

Just like any other decision (equipment, weather, etc.) that you must make when you fly, you should know all the facts before you can answer this question. There are several things that you need to know and take into account before you make the go/no-go decision. Add these to your check list:

First, **consider the underlying condition that you are treating.** What will be the consequences if the medication doesn't work or if it wears off before the flight is over? A good general rule to follow is not to fly if you must depend on the medication to keep the flight safe. In other words, if the untreated condition is one that would prevent safe flying, then you shouldn't fly until the condition improves — whether you take the medication or not.

Second, you must **consider your reaction to the medication.** There are two broad categories of medication reactions. One is a unique reaction based on an individual's biological make-up. Most people don't have such reactions but anyone can, given the right medication. Because of this, you should NEVER fly after taking any medication that you have not taken before. It is not until after you have taken the medication that you will find out whether you have this uncommon and unexpected reaction to the medication.

Third, **consider the potential for adverse reactions**, or side effects — unwanted reactions to medications. This type of reaction is quite common, and the manufacturer of the medication lists these on the label. You **MUST** carefully read all labeling. If you don't have access to the label, then don't fly while using the medication.

Look for such key words such as lightheadedness, dizziness, drowsiness, or visual disturbance. If these side effects are listed or if the label contains a warning about operating motor vehicles or machinery, then you should not fly while using the medication.

Side effects can occur at any time, so even if you've taken the same medication in the past without experiencing side effects, they could still occur the next time. For this reason, you must never fly after taking a medication with any of the above-noted side effects.

### **Common side-effects of frequently used medications**

If you must take over-the-counter medications,

- Read and follow the label directions.
- If the label warns of significant side effects, do not fly after taking the medication until at least two dosing intervals have passed. For example, if the directions say to take the medication every 6 hours, wait until at least 12 hours after the last dose to fly.
- Remember that you should not fly if the underlying condition that you are treating would make you unsafe if the medication fails to work.
- Never fly after taking a new medication for the first time.
- As with alcohol, medications may impair your ability to fly—even though you feel fine.
- If you have questions about a medication, ask your aviation medical examiner.
- When in doubt, don't fly.

*Common side-effects of frequently used medications*

Problem	Type of Medication	Example	Potential side effects
Colds, congestion, and allergies	- Decongestant - Antihistamine	Pseudoephedrine (Sudaphed®) Diphenhydramine Benadryl®	Palpitations, jitteriness, anxiety, drowsiness
Cough	- Cough suppressant	Dextromethorphan (Robitussin DM®)	Dizziness, drowsiness
Fever	- Antipyretic	Aspirin	Ringing in ears, upset stomach
Pain	- Analgesic	Ibuprofen (Motrin®)	Dizziness, upset stomach
Nausea / Vomiting	- Antinauseant	Dimenhydrinate (Dramamine®)	Drowsiness
Diarrhea	- Antidiarrheal	Loperamide (Imodium®)	Drowsiness
Acid reflux	- Antacid	Ranitidine (Zantac®)	Headache, nausea
Constipation	- Laxative	Various	Abdominal cramping, diarrhea
Overweight	- Diet pill	Ephedrine (Ephedra)	Palpitations, jitteriness, anxiety, heart attack, stroke
Insomnia	- Sleeping pills	Diphenhydramine (Tylenol PM®)	Prolonged drowsiness and impairment of reaction times

## Prescription Medications

When your treating physician prescribes a medication for you, be sure to ask about possible side effects and the safety of using the medication while flying. Since most of their patients are not pilots, many physicians don't think about the special needs of pilots when they prescribe medication. You must also discuss the medical condition that is being treated. You may want to ask your physician to contact your aviation medical examiner to discuss the implications of flying with the medical condition and the medication.

When your pharmacy fills the prescription, let the pharmacist know that you are a pilot. Pharmacists are experts in medication side effects and can often provide advice that supplements the information that your physician gives you. The pharmacist will provide you with written information about your medication. You should treat this just like the label of an over-the-counter medication mentioned above. Read, understand, and follow the information and instructions that are given with the medication. Never hesitate to discuss possible problems with your physician, pharmacist, or aviation medical examiner.

## The Bottom Line

*What you must remember about medications*

### **Sometimes...**

...you will develop a medical condition that is not safe to fly with.

Whether you take a medication for the condition or not, you should wait to fly until the condition is either gone or significantly improved.

...you will have an ongoing (chronic) medical condition that your physician has prescribed a medication to treat. You should discuss the medical condition and treatment with your physician, pharmacist, and aviation medical examiner and make your flying decision based on their advice.

...you will have a medical condition that makes you uncomfortable but does not impair your ability to safely fly. If flying is very important, you may take either over-the-counter medications or prescription medications — within the guidelines suggested above.

Flying is important for many reasons. Not one of these reasons, however, is worth risking your life or the lives of those around you. Treat all medications with caution, and you'll be around to become one of the "old" pilots.

## MEDICAL FACTS FOR PILOTS

Publication OK05-0005

Written by:

Steve Carpenter, MD

Prepared by:

Federal Aviation Administration Civil Aerospace Medical Institute  
Aerospace Medical Education Division

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Number	Title
AM-400-94/2	Alcohol and Flying: A Deadly Combination
AM-400-95/2	Altitude Decompression Sickness
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AM-400-03/2	Deep Vein Thrombosis and Travel
AM-400-91/1	Hypoxia: The Higher You Fly, the Less Air...
AM-400-98/3	Hearing and Noise in Aviation
AM-400-97/1	Introduction to Human Factors in Aviation
AM-400-92/1	Over the Counter Medications and Flying
AM-400-98/2	Pilot Vision
AM-400-95/1	Smoke!
AM-400-00/1	Spatial Disorientation: Visual Illusions
AM-400-03/1	Spatial Disorientation: Why You Shouldn't Fly By the Seat of Your Pants
AM-400-01/1	Physiological Training Courses for Civil Aviation Pilots
AM-400-05/1	Sunglasses for Pilots: Beyond the Image

To view these pilot and passenger safety brochures, visit the

Federal Aviation Administration's Web site

[www.faa.gov/pilots/safety/pilotsafetybrochures](http://www.faa.gov/pilots/safety/pilotsafetybrochures)

### Physiological Training Classes for Pilots

If you are interested in taking a one-day aviation physiological training course with altitude chamber and vertigo demonstrations or a one-day survival course, learn about how to sign up for these courses that are offered at 14 locations across the U.S. by visiting this FAA Web site:

[www.faa.gov/pilots/training/airman\\_education/](http://www.faa.gov/pilots/training/airman_education/)

For more pilot and traveler safety information, see: [www.faa.gov/pilots/safety](http://www.faa.gov/pilots/safety)

OK05-0005

# Over-the-Counter Medications and *Flying.*

Maybe You Shouldn't . . .

FROM FAA PUBLICATION AM-400-92/1

A commonly held belief is that medicine cures all that ails. Whether medicine is prescribed by a doctor or is an over-the-counter medication (OTC) that you have selected, as a pilot you must consider the effect it will have on your performance.

When you are given a prescription, your doctor explains the possible side-effects of the medication you are about to take. Your pharmacist also outlines them when filling the prescription.

However, when you treat yourself with a nonprescription medication, you become your own doctor and pharmacist. Therefore, you must inform yourself of the possible adverse reactions that you might encounter. The following will help you understand some of the basics that you will need to successfully accomplish this task.

OTCs are any legal, nonprescription substance taken for the relief of discomforting symptoms. This substance may be in the form of capsules, tablets, powders, or liquids.

When you are not feeling well, your best action is to ground yourself and wait until you have recovered before resuming your pilot duties. There may be times, however, when you feel that you must fly and will be tempted to doctor yourself with OTCs. At these times it is good to remember that the OTCs only hide your symptoms for a while. They do not



*. . . when you  
treat yourself  
with a  
nonprescription  
medication,  
you become  
your own  
doctor and  
pharmacist.*

usually "cure" the condition, and you will not be at peak physical performance while you fly.

There are two main areas of concern about unwanted reactions to medications.

- Allergy is a rare and unpredictable reaction to a substance. If you know that you are allergic to something, you should carefully read the list of ingredients of any OTC to assure that none of the substance is included in its formulation.

- Possible unexpected side-effects can take many forms, including drowsiness, impairment of judgment, upset stomach or bowels, disturbance of vision, or even itching. Any of these could cause an impairment that might lead to incapacitation while flying.

Decongestants and caffeine (contained in coffee, tea, cola, chocolate) are both strong stimulants in some individuals. Mixed together, they can make you "hyperactive." Note also that some cough syrups contain a decongestant.

## **SUMMARY ADVICE**

READ and follow label directions for use of medication.

If the label warns of side-effects, do not fly until twice the recommended dosing interval has passed. SO, if the label says, "take every 4-6 hours," then wait at least 12 hours to fly.

Remember that the condition you are treating may be as disqualifying as the medication.

When in doubt, ask your physician or Aviation Medical Examiner for advice.



U.S. Department of Transportation  
Federal Aviation Administration



# OVER THE COUNTER MEDICATIONS AND FLYING



**MAYBE YOU SHOULDN'T...**

As a pilot, you are responsible for your own personal "pre-flight." Be wary of any illness that requires medicine to make you feel better.

If an illness is serious enough to require medication, it is also serious enough to prevent you from flying.

Do not fly if you have a cold —changes in atmospheric pressures with changes in altitude could cause serious ear and sinus problems.

Avoid mixing decongestants and caffeine.

Beware of medications that use alcohol as a base for the ingredients.

The above article can be found at <http://www.cami.jccbi.gov/AAM-400A/400aotc.html>. At this site you will also find a list of common OTCs listing the type/name of the medication, side-effects of the medication, and interactions the OTC may have with other medications. We have not included the current chart due to the fact that the FAA will be revising the medications brochure to include information about newer pharmaceutical products. They plan to publish a new brochure later this year. You can view this revised chart at the above website as well.



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#### 8.3.2.3.1 Nutritional Supplements

A nutritional supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The ingredients in these products may include vitamins, minerals, herbs or other botanicals, amino acids, protein, and substances such as enzymes, organ tissues, glandular extracts, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders, and food bars. Use of nutritional/dietary and other OTC supplements/products by flight personnel except those approved by BUMED is prohibited. Harmful effects are often associated when used in very high doses or in non-standard manner and virtually none are tested or assured safe in the aviation environment. The term "natural" does not mean it is safe. FSs shall be consulted to assist with making informed decisions regarding nutritional supplements. The use of nutritional supplements of all types shall be reported to the FS and recorded during every periodic physical examination or physical health assessment (PHA). See also policy in paragraph 8.3.2.5.a(6) for further information.

#### 8.3.2.5 Drugs

Drugs are defined as any chemical that when taken into the body causes a physiological response. All flight and support personnel shall be provided appropriate information by a command drug abuse education program.

a. Legal drugs are those medically prescribed or legally purchased for treatment of illness. Guidance and flight restrictions are provided in the Naval Aerospace Medical Institute's (NAMI) on-line Aeromedical Reference and Waiver Guide at

<http://www.med.navy.mil/sites/navmedmpte/nomi/nami/arwg>.

(1) Prescription drugs – Taking drugs prescribed by competent medical authority shall be considered sufficient cause for recommendation of grounding unless their use is specifically approved by an FS, or a waiver for specific drug use has been granted by CHNAVPERS or the CMC. Consideration shall be given to the removal of ground support personnel from critical duties, for the duration of the drug effects, if appropriate. Medicines such as antihistamines, antibiotics, narcotic pain relievers, etc., obtained by prescription for short term use to treat a self-limited condition, shall be discarded if all are not used during the period of medication. Unused quantities of performance maintenance drugs (amphetamines or sleeping pills) shall be returned to the FS or medical clinic for purposes of strict accountability.

(2) Over-the-counter (OTC) drugs – Because of the possibility of adverse side effects and unpredictable reactions, the use of OTC drugs by flight personnel is prohibited unless specifically approved by an FS. Ground support personnel shall be briefed on the hazards of self-medication and should be discouraged from using such drugs.

(3) Alcohol – The well-recognized effects of excessive alcohol consumption are detrimental to safe operations (i.e., intoxication and hangover). Consumption of any type of alcohol is prohibited within 12 hours of any mission brief or flight planning. Adherence to the letter of this

rule does not guarantee a crewmember will be free from the effects of alcohol after a period of 12 hours. Alcohol can adversely affect the vestibular system for as long as 48 hours even when blood alcohol content is zero. Special caution should be exercised when flying at night, over water, or in IMC. In addition to abstaining from alcohol for 12 hours prior to mission brief or flight planning, flightcrews shall ensure that they are free of hangover effects prior to flight. Detectable blood alcohol or symptomatic hangover shall be cause for grounding of flight personnel and the restriction of the activities of aviation ground personnel.

(4) Tobacco – Smoking has been shown to cause lung disease and impair night vision, dark adaptation, and increase susceptibility to hypoxia. Smoking is hazardous to nonsmokers, as the effects occur whether smoke is inhaled directly or secondarily. Persons desiring to smoke shall show due consideration for the desires of nonsmokers in the vicinity and abstain from smoking if asked. Further guidance on smoking is contained in paragraph 7.1.9 of this instruction.

(5) Caffeine – Excessive intake of caffeine from coffee, tea, cola, etc., can cause excitability, sleeplessness, loss of concentration, decreased awareness, and dehydration. Caffeine intake of 450 mg per day (3 to 4 cups of drip coffee) is the recommended maximum intake. Caffeine use when managed appropriately, can aid in maximizing performance during long sorties or periods of sustained operations, however, the caffeine effect is maximized in individuals who are not habituated to its effects as regular users.

(6) Nutritional/Dietary and other OTC Supplements and Products – The use of nutritional/dietary and other OTC supplements/products by flight personnel except those approved by BUMED is prohibited. Guidance and restrictions are provided in the NAMI on-line Aeromedical Reference and Waiver Guide at

<http://www.med.navy.mil/sites/navmedmpte/nomi/nami/arwg>.

b. The use of illicit drugs is prohibited.

## Supplements Information Packet

Naval Safety Center

Updated 5/7/2013

Ms. Kelsey Leo

### **Additional Resources**

#### *Searchable Database:*

- <http://cards-pws.od.nih.gov/cards/ProxyServlet?objectHandle=Search&actionHandle=getSearchFields&nextPage=jsp/search/searchMain.jsp>
- <http://dietarysupplementdatabase.usda.nih.gov/>
- <http://nccam.nih.gov/health/herbsataglance.htm>
- [http://www.nlm.nih.gov/medlineplus/druginfo/herb\\_All.html](http://www.nlm.nih.gov/medlineplus/druginfo/herb_All.html)
- <http://www.nlm.nih.gov/medlineplus/overthecountermedicines.html>