Dietary Supplement Education for Warfighters

DoD Human Performance Resource Center

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Overview

• Introduction
• Definitions and Regulations
• Military Personnel and Supplements
• Safety Concerns
• Finding Science-Based Information
Introduction

• Military-specific guidelines are needed on how to use dietary supplements (DS).
• Currently, there are no integrated, service-wide policies to guide military personnel on how to use DS safely.
• This presentation will provide “must-know” information on DS to help you make informed decisions.
What is a Dietary Supplement and how is it regulated?
What is a Dietary Supplement?*

• Product containing one or more dietary ingredients intended to supplement the diet:
  – Macronutrients
  – Vitamins, minerals, amino acids
  – Herbs or other botanicals
  – “Other” dietary substances

*Adapted from the U.S. Dietary Supplement Health and Education Act of 1994
What is a Dietary Supplement?
(continued)

• Intended to be taken by mouth
• In the form of a capsule, powder, softgel, gelcap, tablet, liquid, etc.
• Not represented for use as conventional food
• Labeled as a dietary supplement
What is a Botanical?

• Plant or plant part valued for its medicinal or therapeutic properties, flavor, and/or scent.
• Herbs are a subset of botanicals.

Flaxseed  
*Linum usitatissimum*

St. John’s Wort  
*Hypericum perforatum*

Soybean  
*Glycine max*

Thyme  
*Thymus vulgaris*
Why do Military Personnel use Dietary Supplements?

**Demographics**
- Age
- Gender
- Duty assignment
- Education
- Ethnicity

**Motivations for use**
- Determine the selection of specific products

**Attitudes**
- Promote health and prevent illness
- Enhance physical/cognitive performance
- Increase strength and stamina
- Build muscle mass
- Boost energy
- Lose weight
# Regulation of DS, Foods, and Drugs in the United States

## Food Additives
- Subject to many laws and regulations closely monitored by the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and local agencies
- Mandatory inspections and incident reports

## Dietary Supplements
- Subject to limited pre-market review and no pre-market approval
- *No formulation standards*
- No product registration
- No approval of claims - Manufacturer is responsible for ensuring safety and compliance
- Mandatory reporting of adverse events

## Medical Drugs
- Subject to many laws and regulations that are closely monitored by the FDA, Drug Enforcement Agency (DEA), or other agencies
- Mandatory reporting of adverse events

*No formulation standards. However, manufacturers must follow current good manufacturing practices (cGMPs) - 21 CFR Part 111.*
Regulation of DS in the United States: Labels

• Most closely regulated part of a supplement
• Must conform to FDA standards
• Requires following information on labels:
  – Statement that it is a "supplement"
  – Name and place of business of manufacturer, packer, or distributor
  – Complete list of ingredients
  – Net contents of the product, e.g., number of pills
  – *Nutrition labeling (i.e., "Supplement Facts" panel)

*Except for some small-volume products or those produced by eligible small businesses
Label Requirements

- Statement of Identity
- Net quantity of contents: 60 CAPSULES
- Structure-function claim
- Directions: Take one capsule daily.
- Supplement Facts panel
- Other ingredients in descending order of predominance and by common name or proprietary blend.
- Name and place of business of manufacturer, packer or distributor. This is the address to write for more product information.
DS Claims

• **Claims on Labels**
  – Must be truthful
  – May not say the DS can be used to prevent, treat, or cure a disease or condition
  – Must have the following FDA disclaimer, if it has a structure/function claim:
    • "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease."

• **Claims on Brochures**
  – Claims on supplement labels and content of separate brochures and fliers are subject to FDA and Federal Trade Commission (FTC) oversight

Federal Trade Commission (FTC) regulates advertising for dietary supplements.
Regulation of DS in DoD

- Generally, if a supplement is not banned or recalled by the FDA, FTC, or DEA, it is not banned by DoD at large.
- DoD, each service, and each base/command/unit has the authority to issue guidance on specific supplements and/or categories of supplements.
- Check to see if your base/command/unit has a DS policy in effect.
Regulation of DS in the United States:
THE BOTTOM LINE

• FDA has “post-market” responsibility to ensure compliance with regulations.
• DS do not require pre-market approval.
• There is no guarantee of quality, purity, composition, safety, or effectiveness of dietary supplements.
• Many DS contain banned or harmful substances not declared on the label.
Making Informed Decisions on DS Products

• RECOMMENDATION: Shop for products with seals from third-party verification programs.
• They evaluate and certify DS for quality.
• Examples are:
  – United States Pharmacopeia (USP)
  – NSF International
  – Informed-Choice, HFL Sport Science
  – ConsumerLab.com
Safety Concerns

Tainted Dietary Supplements
Beware of Tainted DS

- Supplements with hidden drugs & ingredients
- Potentially dangerous ingredients include:
  - Approved prescription drug ingredients and their analogs
  - Drugs banned by the FDA for safety reasons
  - Controlled substances such as anabolic steroids
  - Untested/unstudied new active drug ingredients
Health Hazards of Tainted DS

- Contain undeclared ingredients
- Sometimes contain 3-4x recommended dose
- Claim to be “natural” or “herbal”
- Contain untested and unstudied ingredients
- Interact with other medications
- Possible side effects
- Consumer perception that more is better
Red Flags to watch for

- High-risk category products:
  - Bodybuilding products
  - Sexual enhancement products
  - Weight-loss products
  - Diabetes products
Red Flags to watch for

• Claims on labels such as:
  – “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.”
  – An alternative to (or claiming to have similar effects to) an FDA-approved drug—e.g., “All natural alternative to XYZ.”

These claims often indicate that the supplement may contain substances not on the ingredients list, prescription drug analogs, or banned substances.
Red Flags to watch for

• Claims about the supplement curing a wide range of unrelated diseases (e.g., cancer, AIDS, in addition to diabetes)

• Labels missing the statement below if supplement claims to affect normal body structure or function (e.g., “helps promote bone health”)
  – “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.”

• Supplements promising “quick fixes” (e.g., to cure XYZ in seven days, lose weight in nine days, shrink tumors in one week, cure impotency in two weeks, etc.)
Red Flags to watch for

• Labels that 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

• Supplements not verified by a third-party verification program. Some third-party verification programs are:
  – United States Pharmacopeia (USP)
  – NSF International
  – Informed-Choice, HFL Sport Science
  – ConsumerLab.com
Red Flags to watch for

• Solicitations (e-mails) offering products in the high-risk product categories
• Directions and warnings that resemble FDA-approved drug products
• Inadequate or absent safety warnings
• Product marketed with personal testimonials about amazing results from using the product
• Products 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.
Red Flags to watch for

- Products that contain any of these problematic ingredients...

5-HTP
(5-Hydroxytryptophan)
Aconite
Adrenal extract
Aga
(Amanita muscaria)
Alkanna
American mistletoe
Apricot kernel
Aristolochia
Beth Root
Bitter Orange

(Synephrine)
Bittersweet nightshade
Bladderwrack
Blue Cohosh
Blue Flag
Butanediol (BD)
Buttercup
Calamus
Calotropis
Canadian hemp
Catnip
Cesium

Chaparral
Chenopodium oil
Clematis
Clubmoss
Colloidal Silver
Coltsfoot
Comfrey
Country Mallow
Coltsfoot
Comfrey
Country Mallow
Red Flags to watch for

- Products that contain any of these problematic ingredients…

- DMAA (1,3 dimethylamylamine)
- Dolomite
- Ephedra
- European mandrake
- Germanium
- Gamma-butyrolactone (GBL)
- GHB (Gamma hydroxybutyrate)
- Gravel root
- Greater Celandine
- Hawaiian baby woodrose
- Heartleaf (Sida cordofolia)
- Hemp oil
- Horny goat weed (Epimedium grandiflorum)
- Indian snakeroot (Rauwolfia)
- Jaborandi
- Jimson weed
- Kava

- Laminaria
- Lobelia
- Pinellia ternata
- Salvia (Diviner's sage)
- Usnea or Usnic acid
- Vinca rosea (madagascar periwinkle)
- Wild indigo
- Yohimbe
Additional Safety Concerns

- **Lack of science-based information**
  - Lack of studies in military-like environments

- **Excess protein intake**
  - Consuming protein shakes, bars, and powders may result in excessive intake of protein

- **Excess nutrient intake**
  - Using more than one supplement may result in too much of one ingredient

- **Stacking**
  - Taking multiple ingredients together to increase effects of selected ingredients
Additional Safety Concerns

• Proprietary Ingredients
  – Actual ingredients and their amounts typically are not provided.

• Multiple-ingredient products
  – Some products contain several ingredients, which may or may not be listed on the label.
Common sense tells us that popping a pill alone does not build muscles. In reality, individuals must use skills, disciplined physical training, personal effort, and good nutrition to realize their full potential.
Guidelines for Evaluating Dietary Supplements
Guidelines for Evaluating DS

- What is in it?
- Does the label conform to FDA rules?
- Is it the right stuff?
- Is it safe?
- Does it make sense?
- Does it work?
- Does it reach its target?
- What other sources exist?
- Why take it?
Guidelines for Evaluating DS

• What is in it?
  – What does DS contain? Are there multiple ingredients?

• Does label conform to FDA rules?
  – Does product label state that it is a "supplement"?
    Name and place of manufacturer/packer/distributor?
    A complete list of ingredients?

• Is it the right stuff?
  – Is the active ingredient of the same quality/quantity as the one used in studies showing effectiveness?
Guidelines for Evaluating DS

• Is it safe?
  – Have credible professional organizations expressed concerns?

• Does it make sense?
  – Is the claim consistent with current knowledge of exercise physiology and nutrition?

• Does it work?
  – What effect does it have on performance and what is the evidence for this? What is the recommended dose?
Guidelines for Evaluating DS

- **Does it reach its target?**
  - Are there differences in bioavailability* between dietary and supplemental sources?

- **What other sources exist?**
  - Is it a dietary ingredient? What are the sources? Does it come naturally in food?

- **Why take it?**
  - Supplements cannot take the place of training or overall dietary adequacy.

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*Bioavailability: How much of the supplement you've taken is actually received by the body once it is ingested, digested, and distributed into the bloodstream?
Finding Information on DS Safety or Effectiveness

Examples of credible resources:

- Human Performance Resource Center
- Natural Medicines Comprehensive Database
- Office of Dietary Supplements
- U.S. Food and Drug Administration
- PubMed

Search engines:

- Google Scholar
- WorldCat
DoD Dietary Supplement Classification System

• Classifies DS for DoD service members based on expected risk and potential benefit

• Located at:
  – [http://hprc-online.org/dietary-supplements/dietary-supplement-classification-system-1#.UDP8no4Qh5g](http://hprc-online.org/dietary-supplements/dietary-supplement-classification-system-1#.UDP8no4Qh5g)
  – Accompanying monographs contain information on:
    – Dose range/upper limit
    – Putative benefits
    – Military performance and survivability
    – Medication interactions
    – Withdrawal effects
    – And more…
# Dietary Supplement Risk Matrix

## Safety

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<th>Benefit</th>
<th>&lt; Minimal Concern</th>
<th>Low Concern</th>
<th>Moderate Concern</th>
<th>High Concern</th>
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<tr>
<td>High Potential</td>
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<td>2</td>
<td>7</td>
<td>9</td>
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<tr>
<td>Moderate Potential</td>
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<tr>
<td>Low Potential</td>
<td>5</td>
<td>6</td>
<td>11</td>
<td>12</td>
</tr>
</tbody>
</table>
• DS cannot offset the unfavorable effects of poor food choices.
• Be an informed consumer and know:
  – How DS are regulated.
  – What third-party verification programs are.
  – Potential safety concerns and health hazards.
  – Which DS product categories are high risk.
• Use reliable, science-based resources to stay informed.
References and Resources

• Human Performance Resource Center
• Natural Medicines Comprehensive Database
• Nutrition Standards and Education. Army Regulation 40–25 BUMEDINST 10110.6. AFI 44-141.
• Office of Dietary Supplements
• US Food and Drug Administration