



**Reporting  
Prescription Drugs,  
Over-the-Counter  
Medications, and  
Dietary Supplements**

**Human Reliability Program**

**U.S. Department of Energy  
Office of Health, Safety and Security  
Office of Departmental Personnel Security**

Contents of this brochure are based on 10 CFR Part 712, Human Reliability Program; however, the information presented herein in no way supersedes or has precedence over the provisions of that regulation as published or amended.

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## Introduction

Some prescription drugs, over-the-counter medications, dietary supplements, and combinations of these substances can affect the reliable performance of Human Reliability Program (HRP) duties. To identify potential concerns caused by these substances, the HRP requires that all HRP-certified individuals notify the site occupational medical director (SOMD), the designated physician, or the designated psychologist of any physical or mental condition requiring medication or treatment. The HRP occupational health professionals evaluate the condition, treatment, and prescribed medication with regard to the individual's duties identified in the job task analysis to ensure that safe and reliable performance of HRP duties is not compromised. This policy has been clarified to include reporting the use of certain over-the-counter (OTC) medications. Reporting is required if:

- The label or container of the product carries the following warnings or cautions: (1) may cause drowsiness, dizziness, excitability; or (2) use caution when driving a motor vehicle or operating machinery;
- The individual has a preexisting condition that is listed on the medication's warning label; or
- The individual is unsure of possible side effects.

Additionally, it is recommended that all medications be reported because of potential side effects and possible interactions between prescription drugs, OTC medications, and dietary supplements. This ensures that the occupational health office is aware of the use and can evaluate those side effects or interactions that can cause a reliability concern.

The reporting requirement and recommendation were established because HRP-certified individuals have access to very sensitive materials and information as they perform their duties. The potential consequences of an unsafe or unreliable worker are serious, and it is important to ensure that the use of prescription drugs, OTC medications, and dietary supplements does not pose reliability, safety, or health concerns.

## Prescription drugs

Prescription drugs are regulated by the Food and Drug Administration (FDA) because they are not safe to use except under the supervision of a health care practitioner. They may be potentially toxic,

have other harmful effects, or the means by which they are administered may require medical supervision.

Prescription drug use is of particular concern in HRP-certified individuals because these medications could become addictive or have serious side effects that could impair reliability. The pharmacy labels and package inserts contain information regarding dosage, possible side effects, and drug interactions that the occupational health provider must know. It is helpful to have the prescription container on hand when making a report.

## Over-the-counter medications

Over-the-counter (OTC) medications are those that are available to consumers without a prescription. There are more than 80 therapeutic categories of OTC medications, with uses ranging from acne to weight control. As with prescription drugs, the FDA oversees OTC medications to ensure that they are properly labeled and beneficial. OTC medications generally have these characteristics:

- Their benefits outweigh their risks
- The potential for misuse and abuse is low
- Consumers can use them for self-diagnosed conditions
- They can be adequately labeled
- Supervision of health care practitioners is not needed for the safe and effective use of the product

Because some OTC medications can cause impaired reliability, labels should be carefully examined for any warnings or cautions. Any OTC medication that has a label warning such as “may cause drowsiness, dizziness, excitability” or “use caution when driving a motor vehicle or operating machinery” must be reported to the SOMD, the designated physician, or the designated psychologist. You should also report if you have a pre-existing condition that is indicated on the label, are taking other prescription drugs, OTC medications, or dietary supplements, or if you are unsure of the possible effects.

## Dietary supplements

A dietary supplement is any product intended to supplement the diet that contains one or more dietary ingredients and is taken by mouth as a pill, capsule, tablet, or liquid. Examples of dietary supplements are vitamins, minerals, herbs or other botanicals, amino acids, and other substances or

components. The National Institutes of Health Office of Dietary Supplements reports that in 2004 Americans purchased \$20.3 billion in dietary supplements. Daily use was reported by 52 percent of the U. S. population, and many had been taking the supplements for many years.

### **Vitamins and minerals**

Humans must get vitamins and minerals from food because their bodies do not make them. It should be noted that a standard multivitamin supplement with minerals cannot compensate for an unhealthy diet. It provides some of the vitamins known to maintain health, but that is a small fraction of what is included in a well-balanced diet. The Harvard School of Public Health calls taking a daily multivitamin “a sort of nutritional safety net.”

### **Herbal remedies**

Herbal remedies are alternative substances derived from plants. Many herbal remedies have been used for thousands of years and are becoming increasingly popular to both treat existing illness and prevent maladies such as high blood pressure. Some popular herbal remedies are *Echinacea*, St John’s wort, *Ginkgo biloba*, goldenseal, and ginseng. Although widely used, herbal remedies may not be effective or safe. In addition, they can interfere with prescription drugs, produce erroneous laboratory results, and adversely affect your health and wellbeing.

### **Evaluating dietary supplements**

Dietary supplements may help to ensure that you get adequate amounts of essential nutrients or to promote optimal health and performance if you do not consume a variety of foods. However, dietary supplements are not intended to treat, diagnose, mitigate, prevent, or cure disease. In some cases, dietary supplements may have unwanted effects, especially if they are taken before surgery or if you have certain health conditions. Combining them with other dietary supplements, OTC medications, or prescription drugs, can also create unwanted effects.

If you take dietary supplements, caution is advised for several reasons:

- The preparation may be expensive but ineffective
- The label may not accurately list ingredients
- The contents may be adulterated with other potentially dangerous pharmaceuticals
- The ingredients may cause dangerous interactions with prescription drugs, OTC medications, or other supplements, reinforcing or antagonizing their actions.

### **Regulating dietary supplements**

Many assume that dietary supplements are safe to use because they are made from natural ingredients and sold without prescriptions. It should be noted, however, that manufacturers are

responsible for making sure their products are safe before they go to market. They are also responsible for determining that the claims on their labels are accurate and truthful.

This means that dietary supplement products are not reviewed by the government before they are marketed. After the product reaches the market, the FDA must prove that a product is not safe before it can restrict its use or remove it from the market. Similarly, the FDA must first prove that claims on marketed dietary supplement products are false and misleading before they take action against the product manufacturer.

### **Dietary supplements and the HRP**

Some dietary supplements, such as glucosamine, do not seem to have ill effects; others, such as the herb ephedra, can cause serious conditions. Other safety issues include contaminants and adulterations. Many dietary supplements contain active ingredients that have strong biological effects, and their safety is not always ensured in all users. Additionally, some interfere with prescription drugs. As with OTC medications, dietary supplements should be discussed with the medical department to determine if any adverse reaction or interactions could occur.

### **In summary**

Both prescription drugs and OTC medications are carefully regulated by the Food and Drug Administration. Before they are made available to the public, they must be tested to ensure that they are safe and that they work. Dietary supplements, however, are regulated differently. Their ingredients, safety, and appropriateness for a particular condition are not ensured before they are marketed.

Using dietary supplements and OTC medications without medical evaluation can be harmful in some cases. HRP-certified individuals should not attempt to self-diagnose any health condition. Instead, they should work with their primary health care provider to determine how best to achieve optimal health, and should always check with that health care provider before taking an OTC medication or dietary supplement, especially when combining them with or substituting them for food or prescription drugs.

Because it is vitally important to ensure that HRP-certified individuals are reliable, they are required to immediately report use of prescription drugs to the SOMD, designated physician, or designated psychologist. OTC drugs are required to be reported if they carry a warning label, warn of a contraindicated preexisting condition, or if the individual is unsure of the side effects. To evaluate side effects, interactions, and contraindications, it is additionally recommended that any dietary supplement or OTC medication be reported. The facility occupational medical office will evaluate

the report as it relates to HRP duties and job requirements and make a recommendation regarding performance of HRP duties.

Remember that the goals of the occupational medical department are promoting workplace safety and health, preventing occupational injuries, and providing needed information regarding personal wellness. By providing information that can help them achieve these goals, HRP-certified individuals actively contribute to their own health and to the safety and security of the facility in performing its mission.



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by  
Center for Human Reliability Studies  
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Oak Ridge Institute for Science and Education  
P. O. Box 117/MS-50 ■ Oak Ridge, TN 37831-0117  
CHRS@ORISE.ORAU.gov  
<http://orise.orau.gov/nsem/chrs.htm>  
Voice: 865.576.2208 ■ FAX 865.576.7903  
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