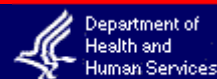


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July 17, 2008

**Guidance for Industry****Final Rule Declaring Dietary Supplements  
Containing Ephedrine  
Alkaloids Adulterated Because They Present  
an Unreasonable Risk****Small Entity Compliance Guide**

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*Additional copies are available from:*  
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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition (CFSAN)  
July 17, 2008**

**Guidance for Industry<sup>(1)</sup>****Final Rule Declaring Dietary Supplements**

# Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

## I. Introduction

On February 11, 2004, FDA published in the Federal Register a final rule that established a regulation declaring dietary supplements containing ephedrine alkaloids adulterated under the Federal Food, Drug, and Cosmetic Act because they present an unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in labeling, under ordinary conditions of use (69 FR 6787). The final rule became effective on April 12, 2004. FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121). This guidance document restates in plain language the legal requirements set forth in 21 CFR 119.1 concerning dietary supplements containing ephedrine alkaloids. This regulation is binding and has the full force and effect of law.

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## II. Questions and Answers

1. What does the regulation state about the legal status of dietary supplements containing ephedrine alkaloids?

The regulation states that dietary supplements that contain ephedrine alkaloids are adulterated under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(f)(1)(A)). It is illegal to market an adulterated dietary supplement.

2. What is the basis for concluding that dietary supplements containing ephedrine alkaloids are adulterated?

Dietary supplements that contain ephedrine alkaloids present an unreasonable risk of illness

or injury under conditions of use recommended or suggested in the labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use (21 CFR 119.1).

3. What scientific evaluation did FDA rely upon when issuing the final regulation on dietary supplements containing ephedrine alkaloids?

FDA took this action based upon the well-known pharmacology of ephedrine alkaloids, the peer-reviewed scientific literature on the effects of ephedrine alkaloids, and the adverse events reported to have occurred in individuals following consumption of dietary supplements containing ephedrine alkaloids (69 FR at 6788).

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<sup>(1)</sup>This guidance has been prepared by the Division of Dietary Supplement Programs in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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