Guidance for Industry

Street Drug Alternatives

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I. INTRODUCTION

This guidance is intended for those persons who are manufacturing, marketing, or distributing alternatives to illicit street drugs. FDA considers any product that is promoted as a street drug alternative to be an unapproved new drug and a misbranded drug in violation of sections 505 and 502 of the Federal Food, Drug, and Cosmetic Act (the Act). Such violations may result in regulatory action, including seizure and injunction.

II. BACKGROUND

The Agency has become aware of the proliferation of various products that are being manufactured, marketed, or distributed as alternatives to illicit street drugs (*street drug alternatives*). FDA is concerned that these products are being abused by individuals, including minors, and pose a potential threat to the public health.

Street drug alternatives are generally labeled as containing botanicals, and some are also labeled as containing other ingredients, such as vitamins, minerals, or amino acids. They are marketed under a variety of brand names with claims implying that these products mimic the effects of controlled substances. Many of these products are promoted on the Internet and in counterculture magazines as alternatives to illicit street drugs such as MDMA (4-methyl-2, dimethoxyamphetamine), a methamphetamine analogue, also known as *ecstasy, XTC*, and *X*. Other examples of products whose names imply street drug alternative use are *e-Ludes, Hextacy,* and *Herbal Koke.*

These products are intended to be used for recreational purposes to effect psychological states (e.g., to get high, to promote euphoria, or to induce hallucinations) and have potential for abuse. FDA considers these street drug alternatives to be unapproved new drugs and misbranded drugs under sections 505 and 502 of the Act.

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[1]This guidance has been prepared by the Office of Compliance, Division of Labeling and Nonprescription Drug Compliance, in the Center for Drug Evaluation and Research (CDER), Food and Drug Administration. This guidance represents the Agency's current thinking on street drug alternatives. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

FDA is also aware that some of these street drug alternatives are being marketed as dietary supplements. FDA does not consider street drug alternatives to be dietary supplements. The term *dietary supplement* as defined in section 201(ff) of the Act means, inter alia, a product "intended to supplement the diet." While the Act does not elaborate on the meaning of this phrase, many congressional findings, set forth in the Dietary Supplement Health and Education Act of 1994, suggest that dietary supplements are intended to be used to augment the diet to promote health and reduce the risk of disease. FDA does not believe that street drug alternatives are intended to be used to augment the diet to promote health or reduce the risk of disease. Moreover, FDA considers the diet to be composed of usual food and drink that may be designed to meet specific nutritional requirements. Illicit street drugs are not food or drink, and neither they, nor alternative street drugs, can be said to supplement the diet. Rather, these products are intended to be used for recreational purposes to effect psychological states (e.g., to get high, to promote euphoria, or to induce hallucinations). Accordingly, street drug alternatives are not intended to supplement the diet and are not dietary supplements. This position is consistent with that set forth at 62 Fed. Reg. 30678, 30699-700 (June 4, 1997).

III. POLICY

FDA considers any product that is promoted as a street drug alternative to be an unapproved new drug and a misbranded drug in violation of sections 505 and 502 of the Federal Food, Drug, and Cosmetic Act. Such violations may result in regulatory action, including seizure and injunction