AER's have not received an extensive clinical analysis by FDA.

7. CFSAN Market Review—FDA review covering the period August 1999 through March 2000 to determine whether there have been changes in the types of ephedrine alkaloid containing dietary supplement products available in the marketplace since the agency's review in 1995–1996.

Several parties have informed the agency that, since the issuance of the ephedrine alkaloids proposal, there is new usage data, and new scientific information, including clinical trials sponsored by manufacturers, that supports the safety of dietary supplements containing ephedrine alkaloids. FDA has not been provided this information to date and encourages interested persons to submit this information and any other information the submitter believes is relevant to assessing the safety of dietary supplements containing ephedrine alkaloids. FDA encourages interested persons to submit this information to this docket by May 18, 2000, so that it will be available to the public and the agency for review.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the availability. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. These documents and any received comments may be seen by interested persons at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Public Forum

A public forum for discussion of the documents being made available in this document will be held at a date and location to be announced. A contact person for the public forum will also be announced.

Written comments received in response to this document, and participation at the public forum, will assist the agency in determining appropriate next steps regarding dietary supplements containing ephedrine alkaloids.

Dated: March 30, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–8283 Filed 3–31–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1119]

Guidance for Industry on Street Drug Alternatives; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Street Drug Alternatives.'' The guidance is intended to inform industry and the public that 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 two sections of the Federal Food, Drug, and Cosmetic Act (the act). Such violations may result in regulatory action, including seizure and injunction.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: William Nychis, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7363.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Street Drug Alternatives.'' FDA is issuing this guidance in response to the proliferation of various products that are being manufactured, marketed, or distributed as alternatives to illicit street drugs. FDA is concerned that these products are being abused by individuals, including minors, and pose a potential threat to the public health.

These 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. These products are intended to be used for recreational purposes to effect psychological states.

This guidance is intended to inform industry and the public that 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 act (21 U.S.C. 355 and 352). Such violations may result in regulatory action, including seizure and injunction.

Moreover, FDA is also aware that some of these street drug alternatives are being promoted as dietary supplements. FDA does not consider street drug alternatives to be dietary supplements because they are not intended to supplement the diet.

This Level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The guidance is being implemented immediately without prior public comment because of the potential hazard to the public health. The 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.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 28, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–8110 Filed 3–31–00; 8:45 am]

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