DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington, DC

Dear Health Care Professional Colleague:

We are alerting you about a dietary supplement product that we believe presents a serious public health risk. Lipokinetix, distributed by Syntrax Innovations, Inc., has been implicated in several cases of serious liver injury. The Food and Drug Administration (FDA) has received reports of at least six persons who developed acute hepatitis and/or liver failure while using Lipokinetix. The injuries reported to FDA occurred in persons between 20 and 32 years of age. No other cause for liver disease was identified. In all cases, no preexisting medical condition that would predispose the consumer to liver injury was identified. Onset of liver injury was observed between 2 weeks and 3 months of starting Lipokinetix.

Lipokinetix has been promoted for weight loss by 'mimicking exercise' and supporting 'an increased metabolic rate'. The product contains norephedrine (also known as phenylpropanolamine or PPA), caffeine, yohimbine, diiodothyronine, and sodium usniate.

FDA has issued a consumer warning advising consumers to stop using this product and to consult their physician if they are experiencing symptoms possibly associated with this product, particularly nausea, weakness or fatigue, fever, abdominal pain, or any change in skin color.

We urge you to review your cases of hepatitis in order to determine if any may be related to the use of dietary supplements in these patients. Adverse events associated with the use of dietary supplements should be reported as soon as possible to FDA's MedWatch program by telephone (1-800-332-1088) or internet (http://www.fda.gov/medwatch).

Thank you for your efforts and cooperation in addressing this potentially serious public health issue. For additional information, see http://www.cfsan.fda.gov.

Sincerely yours,

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and Dietary Supplements
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