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## FDA Statement

### FOR IMMEDIATE RELEASE

Statement  
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### FDA Statement on Tenth Circuit's Ruling to Uphold FDA Decision Banning Dietary Supplements Containing Ephedrine Alkaloids

*Background: On Aug. 17, the U.S. Court of Appeals for the Tenth Circuit in Denver upheld the Food and Drug Administration's (FDA) final rule declaring all dietary supplements containing ephedrine alkaloids adulterated, and therefore illegal for marketing in the United States, reversing a decision by the District Court of Utah.*

The Tenth Circuit Court of Appeals' ruling demonstrates the soundness of FDA's decision to ban dietary supplements containing ephedrine alkaloids, consistent with the Dietary Supplement Health and Education Act (DSHEA) of 1994. The Tenth Circuit Court of Appeals also found that Congress clearly required FDA to conduct a risk-benefit analysis under DSHEA.

FDA conducted an exhaustive and highly resource-intensive evaluation of the relevant scientific data evidence on ephedrine alkaloids before issuing its final rule, which became effective in 2004. The court found that the 133,000-page administrative record compiled by FDA supports the agency's findings that dietary supplements containing ephedrine alkaloids pose an unreasonable risk of illness or injury to users, especially those suffering from heart disease and high blood pressure.

No dosage of dietary supplements containing ephedrine alkaloids is safe and the sale of these products in the United States is illegal and subject to FDA enforcement action.

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