APPENDIX A

Ephedra Timeline

1993  FDA begins receiving reports of adverse events allegedly associated with ephedra.


July 27, 1995  FDA proposes an amendment for stronger regulation of ephedrine in over-the-counter drugs.

Oct. 11-12, 1995  FDA convenes the Ephedra Working Group to review adverse event reports (AERs) and take public comments on the safety of dietary supplements containing ephedra.

Aug. 27-28, 1996  FDA Food Advisory Committee meets to review new evidence. A majority of the committee recommends banning dietary supplements containing ephedrine alkaloids.

June 4, 1997  FDA proposes rules to restrict the dosage of ephedra in dietary supplements, to prohibit supplements from ephedra from being combined with other stimulants, and to mandate warnings on dietary supplements with ephedra.

Sept. 1998  House Committee on Science asks the General Accounting Office (GAO) to look into FDA’s process in issuing the June 4, 1997 NPRM.

May 27, 1999  The House Committee on Government Reform holds hearing, entitled “How Accurate is the FDA’s Monitoring of Supplements Like Ephedra?”

July 1999  GAO report concludes that adverse event reports pertaining to dietary supplements containing ephedra did not provide sufficient evidence to impose restrictions on ephedra.

April 3, 2000  The FDA withdraws substantial portions of its NPRM on dietary supplements and releases additional adverse event reports allegedly caused by ephedra.

Aug. 8-9, 2000  The Department of Health and Human Service’s (HHS) Office of Women’s Health hosts a meeting entitled Safety of Dietary Supplements Containing Ephedrine Alkaloids.

Oct. 9, 2001  Ephedrine Alkaloid Consumer Protection Act (H.R. 3066) and Dietary Supplement Information Act (H.R. 3065) are both introduced by Representative Susan Davis. Neither bill makes it past the committee stage.

June 14, 2002  HHS announces plans for additional research on the safety of ephedra.

July 25, 2002  The House Committee on Government Reform holds a hearing entitled “Diet, Physical Activity, Dietary Supplements, Lifestyle and Health.”
July 31, 2002  The Senate Committee on Governmental Affairs’ subcommittee on Government Management, Restructuring and the District of Columbia holds a hearing entitled “When Diets Turn Deadly: Consumer Safety and Weight Loss Supplements.”

Oct. 7-8, 2002  The FDA stops imports of certain Dutch products containing ephedra and sends inspectors to the U.S. firm distributing the products. Then-Secretary of HHS Tommy Thompson asks the FDA to examine scientific research and recommend a strong mandatory warning label for products with ephedra.

February 2003  RAND report, identifying 21 “sentinel events” associated with ephedra products, is released.

Feb. 12, 2003  Representative Susan Davis reintroduces the Ephedrine Alkaloid Consumer Protection Act (H.R. 725) and the Dietary Supplement Information Act (H.R. 724). Again, neither bill makes it out of committee.

Feb. 17, 2003  Baltimore Orioles pitcher Steve Bechler dies from organ failure due to heatstroke during spring training in Florida. The medical examiner attributes his death to his use of dietary supplements containing ephedra.

Feb. 25, 2003  Representative Darlene Hooley introduces H.Con.Res. 52, which would have expressed the sense of the House of Representatives that major sports organizations should ban dietary supplements containing ephedra and ephedra use. The bill does not make it out of committee.

Feb. 28, 2003  Over 1600 adverse events associated with ephedra use have been reported.

March 4, 2003  Representative John Sweeney introduces the Ephedra Public Protection Act (H.R. 1075). The bill does not make it out of committee.

March 5, 2003  The FDA reopens its 1997 rule on dietary supplements containing ephedra and asks for comments on health consequences of ephedra use.


Oct. 28, 2003  Representative Susan Davis introduces the Dietary Supplement Access and Awareness Act, H.R. 3377. This bill did not make it out of committee.

Nov. 6, 2003  Representative Susan Davis and Senator Dick Durbin introduce H.Res. 435 and S.Res. 260 respectively, which collectively would have expressed the sense of Congress that the Secretary of HHS should take action to ban dietary supplements containing ephedrine alkaloids. Neither resolution makes it past the committee stage.

Dec. 30, 2003  FDA issues a press release announcing its plans to prohibit the sale of dietary supplements containing ephedra. FDA also sends a letter to 60 dietary supplement manufacturers warning them of possible enforcement actions.

Feb. 11, 2004  The FDA uses authority under DSHEA to issue a final rule banning the sale of dietary supplements containing ephedra.
April 12, 2004  Ephedra ban becomes effective after the 60 days allowed under the Congressional Review Act, and passes without congressional objection. The U.S. District Court for the District of New Jersey does not grant a temporary restraining order that would have stopped the ephedra ban.

August 4, 2004  The U.S. District Court for the District of New Jersey declines petitioner’s request in *NVE, Inc.* to receive evidence outside of the administrative record.

April 14, 2005  A federal district court in Utah overturns the FDA ban in *Nutraceuticals*.

June 30, 2005  Representative Susan Davis introduced the Dietary Supplement Access and Awareness Act, H.R. 3156. This bill does not make it out of committee.

February 7, 2006  The Third Circuit denies NVE’s interlocutory appeal, remanding the proceeding to the New Jersey district court.

Aug. 17, 2006  On appeal, the U.S. Court of Appeals for the Tenth Circuit upholds the FDA final rule banning ephedra in *Nutraceuticals*.

Oct. 6, 2006  In a per curiam decision, the U.S. Court of Appeals for the Tenth Circuit denies Nutraceutical Corp.’s petition for rehearing.

Dec. 2006  Congress passes the Dietary Supplement and Nonprescription Drug Consumer Protection Act, and the President signs it into law.

Jan. 3, 2007  Nutraceutical Corporation files a Petition for a Writ of Certiorari with the U.S. Supreme Court asking the Court to review the Tenth Circuit’s decision that reinstated the FDA ban on dietary supplements containing ephedra.