Table 1. Herbs containing caffeine commonly combined with ephedra in products marketed for weight loss or improved physical performance

Common Name	Botanical Name
Cocoa	*Theobroma cacao*
Coffee	*Coffea arabica*
Guarana	*Paullinia cupana*
Kola nut	*Cola acuminata* *Cola vera*
Maté leaf	*Ilex paraguayensis*
Tea (black, green, oolong)	*Camilla sinensis*

Table 2. Technical expert panel members

Name	Expertise	Institution
Awang, Dennis V. (PhD)	Natural product chemist	MediPlant Consulting Services
Benowitz, Neal (MD)	Psychiatry, pharmacology	UCSF
Farnsworth, Norman (PhD)	Pharmacognosy	University of Illinois at Chicago
Fielding, Roger (PhD)	Exercise	Boston University
Goldberger, Jeffrey (MD)	Cardiology	Northwestern Univ. Medical School
Heber, David (MD, PhD)	Weight loss	UCLA School of Medicine
Ko, Richard (PharmD, PhD)	Food and drug scientist	California Department of Health Services
Leung, Albert (PhD)	Pharmacognosy	AYSL Inc.
Mills, Simon (FNIMN)	Herbalist	Center for Complementary Medicine, Exeter, UK
Nestmann, Earle (PhD)	Toxicology	CANTOX Health Sciences, Canada

Table 3. Technical expert panel suggestions about data collection

Collection Item	Suggestions
Outcomes of interest when assessing efficacy	Weight = outcome for weight loss Long-term weight loss = at least six months Long-term exercise = at least 12 weeks Change the term "exercise enhancement" to "exercise capacity" VO2 max, metabolism, heart rate = intermediate outcomes for exercise capacity Power, strength, endurance = primary outcomes for exercise capacity
Subpopulations of interest	Age; gender; race; body composition/BMI; history of (Hx) hypertension; Hx asthma; Hx diabetes
Risk factors of interest in assessing possible harmful effects	Existing structural heart disease Renal function Use of other drugs, tobacco

Table 4. Measures used in assessing causality

Measure	Example
Temporal relationship	When the drug was consumed, dosage
De-challenge response	Do symptoms disappear when substance is removed?
Re-challenge response	Do symptoms appear again if substance is reintroduced?
Possibility of alternative explanation	Dehydration or consumption of other toxic substances
Prior reaction to same substance	
Dose response	
Objective evidence of adverse event	Witnesses or medical records
Previous conclusive reports	Has this same reaction happened when other persons consumed substance?
Definition of substance	

Table 5. Ephedra/ ephedrine search methodology

SEARCH NUMBER	#1A
Database searched and time period covered	MEDLINE Via PubMed 1965-2001
Search strategy	Ephedra AND (clinical trial OR clinical trials OR randomized controlled trials OR meta analysis OR meta-analysis OR review* OR Publication Type=Meta-Analysis OR Publication Type=Clinical Trial OR Publication Type=Review OR Publication Type=Randomized Controlled Trial)
Number of items retrieved	8
SEARCH NUMBER	#1B
Database searched and time period covered	EMBASE 1974-2001
Search strategy	Ephedra AND (clinical trial* OR randomi* OR review* OR metaanalys* OR meta analys* OR Document Type=Review)
Number of items retrieved	20
SEARCH NUMBER	#1C
Database searched and time period covered	BIOSIS 1969-2001
Search strategy	Ephedra AND (metaanal* OR meta anal* OR trial* OR review* in title or subject heading field OR Document Type=Review OR Document Type=Literature Review)
Number of items retrieved	15
SEARCH NUMBER	#1D
Database searched and time period covered	Allied & Complementary Medicine 1984-2001 MANTIS 1880-2000/Apr Cochrane Library – Controlled Clinical Trials Register Database (CCTR)
Search strategy	ephedra
Number of items retrieved	12
SEARCH NUMBER	#2A (performed 4/5/01)
Database searched and time period covered	MEDLINE via PubMed 1965-2001
Search strategy	ephedrine NOT ephedra AND (review OR meta analysis OR randomized controlled trials OR clinical trials OR Publication Type=Review OR Publication Type=Clinical Trial OR Publication Type=Randomized Controlled Trial OR Publication Type=Meta-Analysis)
Number of Items Retrieved	704
SEARCH NUMBER	#2B (performed 4/6/01)
Database searched and time period covered	EMBASE 1974-2001
Search strategy	ephedrine NOT ephedra AND (review* OR meta analys* OR metaanalys* OR random* OR trial*)
Number of items retrieved	1450

Note: *denotes truncated search term.

Table 6. Ephedra/ ephedrine search methodology – additional databases

SEARCH NUMBER	#1A (performed 6/25/01)
Database searched and time period covered	International Pharmaceutical Abstracts - 1970-2001/May Pascal - 1973-2001/June Week 4 SciSearch (Archival File) - 1974-1989 SciSearch (Current File) - 1990-2001/June Week 4
Search strategy	ephedra OR ephedrine AND trial? OR review? OR rct? OR meta analys? OR metaanal?
Number of items retrieved	167
SEARCH NUMBER	#1B (performed 6/25/01)
Database searched and time period covered	International Pharmaceutical Abstracts - 1970-2001/May Pascal - 1973-2001/June Week 4 SciSearch (Archival File) - 1974-1989 SciSearch (Current File) - 1990-2001/June Week 4
Search strategy	ephedra(IN TITLE OR SUBJECT HEADING FIELDS) OR ephedrine (IN TITLE OR SUBJECT HEADING FIELDS) AND adverse OR side effect? OR efficacy OR fail? OR succeed? OR success? OR effective? OR toxic?
Number of items retrieved	330 (NOTE – RESULTS FROM SEARCH 1A WERE “NOTTED OUT” OF THESE SEARCH RESULTS)

Table 7. Categories of adverse events

Event Type
Death
Stroke (CVA)
Myocardial infarction (heart attack)
Cardiovascular other than MI
Neurological other than stroke
Endocrine
Psychiatric
Pulmonary
Renal/urinary
Musculoskeletal
Gastrointestinal
Hepatic
Rheumatologic
Dermatological
Acid-base/electrolytic disturbances
Pain
Withdrawal symptoms
Gynecological/obstetrical
Hematological
Immunological/allergic reaction
Other rare events
Not described

Table 8. Report reviewers

Reviewer	Affiliation
Dr. David Allison	University of Alabama at Birmingham
Dr. Arne Astrup	The Research Department of Human Nutrition The Royal Veterinary and Agricultural University, Denmark
Dr. Dennis Awang	Mediplant Consulting Services
Dr. Neal Benowitz	University San Francisco, Dept. of Med., SFGH, Clin. Pharm Div.
Dr. Heidi Blanck	Centers for Disease Control and Prevention, Division of Nutrition and Physical Activity, Chronic Disease Nutrition Branch
Dr. George Bray	Pennington Biomedical Research Center
Hon Dan Burton	U.S. Representative
Mr. John Cardaro	Council for Responsible Nutrition
Ms. Beth Clay	U.S. House of Representatives, Hon Dan Burton's Office
Hon Dick Durbin	U.S. Senator
Dr. Norman Farnsworth	Univ. of Illinois Med. Center
Dr. Roger Fielding	Boston University Dept. of Health Services
Dr. Gary Franklin	University of Washington
Dr. Curt Furberg	Wake Forest University
Dr. Frank Greenway	Pennington Biomedical Research Center
Prof. Bill Gurley	University of Arkansas School for Med. Sciences, College of Pharmacy
Dr. Christine Haller	University California San Francisco, Div of Clinical Pharmacology
Dr. Robert Hart	National Institute of Neurological Disorders and Stroke
Dr. David Heber	UCLA Center for Human Nutrition, Obesity and Nutrition
Dr. Steve Heymsfield	St. Luke's/Roosevelt Hospital
Mr. Loren Israelsen	Utah Natural Products Alliance
Dr. Steven Karch	Assistant Medical Examiner, San Francisco
Dr. Steve Kimmell	Chair, Ephedra Education Council Expert Panel
Dr. Richard Ko	California Dept. of Health Services, Food and Drug Branch
Dr. Albert Leung	AYSL
Dr. Lori Love	Food and Drug Administration
Mr. Michael McGuffin	President, American Herbal Products Association
Dr. Simon Mills	Center for Complementary Health Studies, University of Exeter
Dr. Earle Nestman	CANTOX
Dr. Paul Pentel	Hennepin County Medical Center, Div. of Toxicology, Dept. of Medicine
Mr. Paul Rubin	Patton Boggs
Mr. David Seckman	National Nutritional Foods
Mr. Wes Seigner	Hyman, Phelps, & McNamara
Hon Henry Waxman	U.S. Representative
Dr. Raymond Woosley	University of Arizona Health Sciences Center
Ms. Susan Yanovski	Obesity and Eating Disorder Program National Institute of Diabetes and Digestive and Kidney Diseases
Organizations	
National Center for Complementary and Alternative Medicine	
National Institute of Diabetes and Digestive and Kidney Diseases	
National Heart, Lung and Blood Institute	
Office of Dietary Supplements	
Center for Science in the Public Interest	
Public Citizen Health Research Group	

Table 9. Weight loss trial inclusion results

Disposition of trials	**Number of Trials**
Total retained in meta-analysis	20
Total dropped from meta-analysis	24
Reasons for dropping trials from meta-analysis:	
Duration of treatment less than eight weeks	18
Ephedrine dose did not vary between study arms	1
Cross-over study without data available prior to the cross-over point	1
Insufficient statistics	3
Inappropriate outcome (weight gain)	1

Table 10. Ephedrine versus placebo

Trial	Total n	Effect Size	95% CI
Jensen[88]	17	-1.52	(-2.75, -0.29)
Lumholtz[94]	32	-1.03	(-1.78, -0.29)
Moheb[84]	64	-0.49	(-0.98, 0.01)
Pasquali[85]	19	0.00	(-0.93, 0.93)
Pasquali[85]	24	-0.42	(-1.23, 0.39)
Quaade[86]	70	-0.17	(-0.64, 0.30)
Pooled Random Effect Estimate		-0.50[1]	(-0.85, -0.15)

[1]Chi-squared test of heterogeneity p-value = 0.185

Table 11. Publication bias tests

Trials	Adjusted Rank Correlation Test p-value	Regression Asymmetry Test p-value
Ephedrine vs. placebo	0.45	0.82
Ephedrine + caffeine vs. placebo	0.30	0.12
Ephedrine + caffeine vs. ephedrine alone	N.C.	N.C.
Ephedrine vs. another weight loss therapy	N.C.	N.C.
Ephedra + herbs containing caffeine vs. placebo	0.73	0.23

N.C. = not calculated due to the small number of trials available.

Table 12. Ephedrine + caffeine versus placebo

Trial	Total n	Effect Size	95% CI
Astrup[111]	12	-0.72	(-1.88, 0.45)
Buemann[92]	32	-0.55	(-1.26, 0.16)
Daly[103]	24	-0.65	(-1.47, 0.18)
Jensen[88]	18	-1.84	(-3.10, -0.57)
Kalman[96]	25	-0.46	(-1.25, 0.34)
Kettle[90]	77	-0.40	(-0.85, 0.05)
Malchow-Moll[87]	69	-1.14	(-1.65, -0.63)
Moheb[84]	96	-0.76	(-1.20, -0.32)
Molnar[112]	29	-1.35	(-2.16, -0.54)
Quaade[86]	70	-0.50	(-0.98, -0.03)
Roed[95]	94	-1.38	(-1.83, -0.92)
Van Mil[91]	32	-1.00	(-1.74, -0.27)
Pooled Random Effect Estimate		-0.85[1]	(-1.08, -0.61)

[1]Chi-squared test of heterogeneity p-value = 0.073

Table 13. Ephedrine + caffeine versus ephedrine

Trial	Total n	Effect Size	95% CI
Jensen[88]	27	-0.32	(-1.07, 0.44)
Moheb[84]	96	-0.27	(-0.70, 0.15)
Quaade[86]	70	-0.36	(-0.83, 0.11)
Pooled Random Effect Estimate		-0.31[1]	(-0.60, -0.02)

[1]Chi-squared test of heterogeneity p-value = 0.966

Table 14. Ephedrine versus another active weight loss therapy

Trial	Total n	Effect Size	95% CI
Breum[113]	81	-0.29	(-0.73, 0.15)
Malchow-Moll[87]	70	0.08	(-0.36, 0.53)

Table 15. Ephedra versus placebo

Trial	Total n	Effect Size	95% CI
Donikyan[114]	154	-0.69	(-1.02, -0.37)

Table 16. Ephedra + herbs containing caffeine versus placebo

Trial	Total n	Effect Size	95% CI
Boozer[115]	48	-1.07	(-1.67, -0.46)
Boozer[89]	83	-0.63	(-1.07, -0.18)
Colker[93]	26	-0.87	(-1.68, -0.06)
Greenway[116]	30	-0.92	(-1.69, -0.15)
Pooled Random Effect Estimate		-0.81[1]	(-1.12, -0.51)

[1]Chi-squared test of heterogeneity p-value = 0.689

Table 17. Meta-regression results

Comparison Versus Placebo	Pooled Monthly Weight Loss Versus Placebo (lbs)	95% CI	p-value for Test Versus Ephedra + Herbs Containing Caffeine
Ephedrine	-1.3	(-2.1, -0.43)	0.17
Ephedra + herbs containing caffeine	-2.1	(-2.8, -1.3)	N.C.
Ephedrine + caffeine	-2.2	(-2.8, -1.7)	0.75

N.C. = Not calculated as this is the comparison group.

Table 18. Exercise trials by Bell and colleagues

Reference	Compounds	Type of Exercise	Results
Bell, Jacobs & Zamecnik[128]	Placebo 1 mg/kg Ephedrine 5 mg/kg Caffeine 1mg/kg Ephedrine + 5 mg/kg Caffeine (E+C)	Cycle ergometer trials to exhaustion	E+C significantly increased time to exhaustion compared to placebo. Heart rate during exercise was significantly increased for E+C, caffeine arms.
Bell & Jacobs[130]	Placebo 75 mg Ephedrine + 375 mg Caffeine (E+C)	Canadian Forces Warrior Test - 3.2 km run wearing 11 kg equipment	E+C trial run times were significantly faster than control and placebo trials.
Bell, Jacobs, McLellan, Miyazakie, and Sabiston[131]	Placebo 1 mg/kg Ephedrine + 5 mg/kg Caffeine (E+C)	Treadmill walking at 50% VO2 peak, 40 degrees celsius climate, 30% relative humidity	E+C did not significantly change tolerance times when compared to placebo. E+C did not affect skin or rectal temperature, sweat rate, or sensation of thermal comfort.
Bell, Jacobs, McLellan & Zamecnik[129]	Placebo 5 mg/kg Caffeine + 0.8 mg/kg Ephedrine 4 mg/kg Caffeine + 1 mg/kg Ephedrine 4 mg/kg Caffeine + 0.8 mg/kg Ephedrine	Cycle ergometer trials to exhaustion at 85% VO2 peak	A lower dose of E+C resulted in ergogenic effect similar in magnitude to those reported previously with a higher dose, with fewer side effects.
Pasternak, Jacobs & Bell[132]	Placebo 0.8 mg/kg Ephedrine 4 mg/kg Caffeine 0.8mg/kg Ephedrine + 4 mg/kg Caffeine (E+C)	Three supersets of leg press & bench press, to exhaustion	Ephedrine, E+C increased muscular endurance, but only in the first set. Systolic blood pressure was increase with ephedrine, E+C.
Bell, Jacobs & Ellerington[133]	Placebo 1 mg/kg Ephedrine 5 mg/kg Caffeine 1 mg/kg Ephedrine + 5 mg/kg Caffeine (E+C)	Two different cycle ergometer tests, one was to exhaustion at 125% VO2 peak	Ephedrine improved performance during Wingate test of anaerobic power. Caffeine increased time to exhaustion in second test.

Table 19. Summary table of meta-analysis of adverse events reported controlled trials

Adverse Events	# of Trials	Placebo		Intervention Groups		Pooled OR 95% CI
		# Adverse Events	Sample Size	# Adverse Events	Sample Size	
Psychiatric symptoms	8	16	273	59	351	3.64 (1.91, 7.31)
Autonomic hyperactivity	13	39	365	138	587	3.37 (2.19, 5.31)
Palpitations	11	18	386	51	563	2.29 (1.27, 4.32)
Hypertension	5	3	257	7	305	2.19 (0.49,13.34)
Upper gastrointestinal symptoms	10	46	432	88	568	2.15 (1.39, 3.38)
Headache	5	8	123	16	185	1.64 (0.62, 4.68)
Tachycardia	1	0	45	6	90	N.R.

N.R. = not reported.

Table 20. Summary table of other of adverse events reported in controlled trials

Other Adverse Events	# of Trials	Placebo		Intervention Groups	
		# Adverse Events	Sample Size	# Adverse Events	Sample Size
Bundle branch block	1	0	33	0	49
Concentration difficulties	5	17	257	18	391
Constipation	5	8	139	15	215
Diarrhea	3	3	81	3	114
Dry mouth	5	4	111	22	174
Fatigue, weakness	2	4	49	6	64
Postural hypotension	1	1	45	4	90
Syncope	1	0	45	1	90
Ventricular events	1	3	84	3	83

Table 21. Distribution of adverse events in the FDA file according to the Excel spreadsheet

Data Type	Event				
	Death	**Stroke**	**MI**	**Other**	**Total**
Available data	71 (5.3%)*	54 (4.0%)	33 (2.5%)	1,186 (88.2%)	1,344 (100%)
Data dated after Sept. 30, 2001	17 (12.4%)	15 (10.9%)	5 (3.7%)	100 (73.0%)	137 (100%)
Unavailable data	4 (1.9%)	18 (8.4%)	9 (4.2%)	183 (85.5%)	214 (100%)
Total	92 (5.4%)	87 (5.1%)	47 (2.8%)	1,469 (86.7%)	1,695 (100%)

*Number of events (row percent).
Chi-squared test of independence p-value < 0.001.
Note: summary data were available for AERs beyond Sept 30, 2001. Detailed, redacted records were only available for AERs up through Sept 30, 2001.

Table 22. Evidence table of case reports - Death

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Death 11/03/1999 21 yo Male Ephedra FDA Case (13914)	Hydroxycut 10.0 mg <6 hours; < 48 hours Ripped Fuel Unknown Not described; not described	Autopsy conducted: Yes	Sentinel event
Death 09/26/2000 22 yo Female Ephedra FDA Case (14390)	Slacker II Unknown Not described; 14-60 days (acute)	Autopsy conducted: Yes	Sentinel event
Death 30 yo Female Ephedrine FDA Case (3275432)	MiniTabs 250.0 mg Not described; >60 days (chronic)	Autopsy conducted: Yes	Sentinel event
Death 33 yo Male Ephedrine FDA Case (3289590)	Max Brand Two-Way 150.0 mg Not described; Not described	Autopsy conducted: Yes	Sentinel event
Death 28 yo Male Ephedrine Literature Case (348)	Insufficient information Unknown <24 hours; >60 days (chronic)	Autopsy conducted: Yes	Sentinel event
Death 05/19/1994 36 yo Female Ephedra FDA Case (9508)	Nature's Nutrition-Formula One Unknown Not described; >60 days (chronic)	Autopsy conducted: Yes	Possible sentinel event
Death 03/09/1995 32 yo Male Ephedra FDA Case (10276)	Nature's Nutrition-Formula One Unknown Not described; >60 days (chronic)	Autopsy conducted: Yes	Possible sentinel event

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Deaths (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Death 07/25/1997 38 yo Male Ephedra FDA Case (12485)	Ripped Fuel 43.2 mg <6 hours; >60 days (chronic)	Autopsy conducted: Yes	Possible sentinel event
Death 12/19/1997 21 yo Male Ephedra FDA Case (12722)	Thermogenics Plus 23.1 mg Not described; Not described	Autopsy conducted: Yes	Possible sentinel event
Death 04/11/1998 15 yo Female Ephedra FDA Case (12843)	Ripped Fuel 40.0 mg <6 hours; Not described	Autopsy conducted: Yes	Possible sentinel event
Death 08/03/1999 26 yo Male Ephedra FDA Case (13906)	Ripped Fuel Unknown Not described; 2-13 days (acute)	Autopsy conducted: Yes	Possible sentinel event
Death 02/16/2000 26 yo Female Ephedra FDA Case (14019)	Diet Fuel 26.6 mg Not described; >60 days (chronic)	Autopsy conducted: Yes	Possible sentinel event
Death 01/09/2001 35 yo Male Ephedra FDA Case (14638)	Hydroxycut 20.0 mg 6-24 hours; 2-13 days	Autopsy conducted: Yes	Possible sentinel event
Death 23 yo Male Ephedra Literature Case (258)	Ripped Fuel 50.0 mg Not described; >60 days (chronic)	Autopsy conducted: Yes	Possible sentinel event

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Deaths (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Death 42 yo Male Ephedrine Literature Case (44)	Street drug (“speed”) 306.0 mg Not described; >60 days (chronic)	Autopsy conducted: Yes	Possible sentinel event
Death 84 yo Female Ephedrine Literature Case (44)	Unknown Unknown Not described; Not described	Autopsy conducted: Yes	Possible sentinel event
Death Literature Case Ephedrine 44 yo Male (224)	Insufficient information Unknown <24 hours; 14-60 days (acute)	Autopsy conducted: Yes	Possible sentinel event
Death 31 yo Female Ephedrine FDA Case (313104)	Ephedrine Unknown <6 hours; <48 hours	Autopsy conducted: No	Intraoperative ephedrine
Death 30 yo Female Literature Case (17)	Insufficient information Unknown Not described; Not described	Autopsy conducted: Yes	Suicide
Death 19 yo Female Literature Case (96)	Insufficient information Unknown <6 hours; Not described	Autopsy conducted: Yes	Suicide
Death 21 yo Male Literature Case (96)	Insufficient information Unknown <6 hours; Not described	Autopsy conducted: Yes	Suicide
Death 06/11/1999 24 yo Male Ephedra FDA Case (13672)	Ripped Fuel Unknown <6 hours; < 48 hours	Autopsy conducted: Yes	Probably not related
Death 40 yo Male Ephedrine FDA Case (1859087)	Max Alert Not described Not described	Autopsy conducted: No	Probably not related

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Deaths (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Death Not described yo Male Ephedrine FDA Case (1902493)	Unknown Not described Not described	Autopsy conducted: Yes	Probably not related
Death 30 yo Male Ephedrine FDA Case (3491515)	Insufficient information Unknown Not described; Not described	Autopsy conducted: Yes	Probably not related
Death 29 yo Male Ephedrine FDA Case (3772362)	Insufficient information Unknown Not described; Not described	Autopsy conducted: Yes	Probably not related
Death 03/10/1994 23 yo Male Ephedra FDA Case (9188)	Cybergenics Body Builder Unknown Not described; 14-60 days (acute)	Autopsy conducted: No	Insufficient information
Death 06/09/1994 44 yo Male Ephedra FDA Case (9327)	Asian Herbal High Energy Unknown Not described; >60 days (chronic)	Autopsy conducted: No	Insufficient information
Death 06/14/1994 43 yo Female Ephedra FDA Case (9395)	Nature's Nutrition-Formula One Unknown Not described; 14-60 days (acute) Nature Nutritional Complex 1 Unknown Not described; Not described	Autopsy conducted: No	Insufficient information
Death 06/20/1994 36 yo Female Ephedra FDA Case (9473)	Nature's Nutrition-Formula One Unknown Not described; >60 days (chronic)	Autopsy conducted: No	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Deaths (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Death 05/24/1994 43 yo Female Ephedra FDA Case (9506)	Nature's Nutrition-Formula One Unknown Not described; >60 days (chronic)	Autopsy conducted: No	Insufficient information
Death 09/07/1994 45 yo Male Ephedra FDA Case (9864)	Nature's Nutrition-Formula One Unknown Not described; 14-60 days (acute)	Autopsy conducted: Yes	Insufficient information
Death 04/07/1995 26 yo Male Ephedra FDA Case (10104)	Natural Trim Unknown Not described; 14-60 days (acute)	Autopsy conducted: Yes	Insufficient information
Death 01/12/1993 43 yo Male Ephedra FDA Case (10251)	Omnitrition Herbal Tea 39.0 mg Not described; >60 days (chronic)	Autopsy conducted: Yes	Insufficient information
Death 06/14/1995 61 yo Female Ephedra FDA Case (10296)	New Image Plus Unknown >24 hours; 14-60 days (acute)	Autopsy conducted: No	Insufficient information
Death 12/19/1994 20 yo Male Ephedra FDA Case (10448)	Cybertrim Unknown Not described; Not described	Autopsy conducted: Yes	Insufficient information
Death 03/15/1995 17 yo Female Ephedra FDA Case (10849)	Unknown E'ola Product Unknown Not described; Not described	Autopsy conducted: No	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Deaths (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Death 03/14/1996 20 yo Male Ephedra FDA Case (10862)	The Equillizer- Part B Unknown <6 hours; < 48 hours	Autopsy conducted: No	Insufficient information
Death 04/08/1996 67 yo Male Ephedra FDA Case (10902)	Quickshot Unknown Not described; 2-13 days	Autopsy conducted: No	Insufficient information
Death 04/12/1996 29 yo Female Ephedra FDA Case (11018)	Omni-Trim (Omni-Trim Int'l) Unknown Not described; 14-60 days (acute)	Autopsy conducted: No	Insufficient information
Death 02/16/1996 64 yo Female Ephedra FDA Case (11060)	Nature's Nutrition-Formula One Unknown >24 hours; >60 days (chronic)	Autopsy conducted: No	Insufficient information
Death 05/20/1996 Not described yo Male Ephedra FDA Case (11134)	Ripped Fuel 60.0 mg Not described; >60 days (chronic)	Autopsy conducted: Yes	Insufficient information
Death 05/13/1996 37 yo Male Ephedra FDA Case (11248)	Nature's Nutrition-Formula One 42.4 mg Not described; >60 days (chronic) Equillizer Fast Start Unknown >24 hours; >60 days (chronic) Not described Unknown Not described; Not described	Autopsy conducted: No	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Deaths (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Death 07/11/1996 59 yo Male Ephedra FDA Case (11307)	Herbalife Original Green 26.4 mg Not described; 14-60 days (acute)	Autopsy conducted: No	Insufficient information
Death 06/25/1996 34 yo Female Ephedra FDA Case (11417)	Herbalife Original Green Unknown Not described; Not described	Autopsy conducted: No	Insufficient information
Death 07/23/1996 27 yo Male Ephedra FDA Case (11441)	Ripped Fuel 51.4 mg Not described; >60 days (chronic)	Autopsy conducted: No	Insufficient information
Death 07/12/1996 24 yo Male Ephedra FDA Case (11444)	Cybergenic super anti-fatigue 3.3 mg Not described; 14-60 days (acute)	Autopsy conducted: No	Insufficient information
Death 10/07/1996 56 yo Female Ephedra FDA Case (11721)	Easy Trim Unknown Not described; Not described	Autopsy conducted: No	Insufficient information
Death 08/25/1997 32 yo Female Ephedra FDA Case (12506)	Escalation Unknown Not described; Not described	Autopsy conducted: Yes	Insufficient information
Death 10/06/1997 0 yo Female Ephedra FDA Case (12594)	Ripped Fuel 20.0 mg Not described; >60 days (chronic)	Autopsy conducted: No	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Deaths (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Death 12/19/1997 22 yo Male Ephedra FDA Case (12720)	Ripped Fuel Unknown >24 hours; Not described	Autopsy conducted: Yes	Did not meet temporal relationship criterion
Death 04/23/1998 34 yo Male Ephedra FDA Case (12859)	Herbalife Original Green 42.0 mg Not described; 14-60 days (acute)	Autopsy conducted: No	Insufficient information
Death 04/24/1998 46 yo Male Ephedra FDA Case (12871)	Diet Fuel 20.1 mg Not described; Not described	Autopsy conducted: No	Insufficient information
Death 07/11/1998 43 yo Male Ephedra FDA Case (13021)	Ripped Fuel 63.6 mg Not described; >60 days (chronic)	Autopsy conducted: No	Insufficient information
Death 09/16/1998 37 yo Female Ephedra FDA Case (13096)	Metabolife 356 Unknown Not described; 2-13 days	Autopsy conducted: Yes	Insufficient information
Death 10/08/1998 49 yo Female Ephedra FDA Case (13127)	Thin Tabs Unknown Not described; Not described	Autopsy conducted: Yes	Insufficient information
Death 02/27/1999 18 yo Male Ephedra FDA Case (13380)	Ultimate Orange Unknown <6 hours; Not described	Autopsy conducted: No	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Deaths (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Death 05/19/1999 49 yo Male Ephedra FDA Case (13634)	Metabolife 356 60.0 mg Not described; < 48 hours	Autopsy conducted: No	Insufficient information
Death 06/04/1999 40 yo Female Ephedra FDA Case (13706)	Metabolife 356 72.0 mg >24 hours; 14-60 days (acute)	Autopsy conducted: Yes	Did not meet temporal relationship criterion
Death 06/30/1999 37 yo Female Ephedra FDA Case (13762)	Thermadrene Unknown Not described; Not described	Autopsy conducted: No	Insufficient information
Death 08/06/1999 59 yo Female Ephedra FDA Case (13802)	Metabolife 356 Unknown Not described; Not described	Autopsy conducted: No	Insufficient information
Death 08/03/1999 37 yo Male Ephedra FDA Case (13806)	Metabolife 356 Unknown <6 hours; 2-13 days	Autopsy conducted: Yes	Insufficient information
Death 10/06/1999 42 yo Female Ephedra FDA Case (13901)	Herbalife Original Green Unknown Not described; 14-60 days (acute)	Autopsy conducted: Yes	Insufficient information
Death 10/13/1999 62 yo Female Ephedra FDA Case (13993)	Metabolife 356 Unknown Not described; Not described	Autopsy conducted: No	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Deaths (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Death 04/04/2000 29 yo Female Ephedra FDA Case (14113)	Metabolife 356 Unknown >24 hours; >60 days (chronic) Omnitrition Herbal Tea Unknown Not described; 14-60 days (acute) Not described Unknown Not described; Not described	Autopsy conducted: Yes	Did not meet temporal relationship criterion
Death 08/10/2000 32 yo Female Ephedra FDA Case (14323)	Metabolift 60.0 mg Not described; 2-13 days	Autopsy conducted: Yes	Insufficient information
Death 08/31/2000 46 yo Female Ephedra FDA Case (14347)	Metabomax 72.0 mg Not described; 2-13 days	Autopsy conducted: No	Insufficient information
Death 09/14/2000 40 yo Female Ephedra FDA Case (14370)	Metabolife 356 Unknown Not described; 14-60 days (acute)	Autopsy conducted: No	Insufficient information
Death 03/28/2000 56 yo Male Ephedra FDA Case (14465)	Thermogen Plus Liquid 72.0 mg Not described; 2-13 days	Autopsy conducted: Yes	Insufficient information
Death 10/16/2000 46 yo Female Ephedra FDA Case (14470)	Up Your Gas 34.2 mg Not described; Not described	Autopsy conducted: Not described	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Deaths (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Death 11/14/2000 39 yo Male Ephedra FDA Case (14498)	Xenadrine 40.0 mg Not described; >60 days (chronic)	Autopsy conducted: Yes	Insufficient information
Death 11/18/2000 45 yo Female Ephedra FDA Case (14509)	Metabolife 356 24.0 mg >24 hours; 2-13 days	Autopsy conducted: No	Insufficient information
Death 12/06/2000 49 yo Female Ephedra FDA Case (14561)	Diet 2X Unknown Not described; 14-60 days (acute)	Autopsy conducted: No	Insufficient information
Death 12/24/2000 40 yo Male Ephedra FDA Case (14585)	Metabolife 356 72.0 mg Not described; >60 days (chronic)	Autopsy conducted: Yes	Insufficient information
Death 03/18/2001 28 yo Female Ephedra FDA Case (14747)	Mini Thin 75.0 mg Not described; >60 days (chronic) Yellow Jacket Unknown Not described; >60 days (chronic)	Autopsy conducted: Yes	Insufficient information
Death 03/29/2001 31 yo Female Ephedra FDA Case (14808)	Metabolife 356 Unknown Not described; >60 days (chronic)	Autopsy conducted: Yes	Insufficient information
Death 3 yo Male Ephedrine FDA Case (1772115)	Ephedrine Unknown <6 hours; < 48 hours	Autopsy conducted: No	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Deaths (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Death 99 yo Male Ephedrine FDA Case (1874879)	Unknown Not described Not described	Autopsy conducted: Yes	Insufficient information
Death 30 yo Female Ephedrine FDA Case (3135225)	MiniTabs Unknown Not described; Not described	Autopsy conducted: Yes	Insufficient information
Death 46 yo Male Ephedrine FDA Case (3173538)	Mini 2 Way Action Unknown Not described; >60 days (chronic)	Autopsy conducted: Yes	Insufficient information
Death 32 yo Female Ephedrine FDA Case (3551127)	Metabolift Unknown <6 hours; Not described	Autopsy conducted: N/A	Insufficient information
Death 99 yo Female Ephedrine FDA Case (3623625)	Diet 2X Unknown Not described; 14-60 days (acute)	Autopsy conducted: No	Insufficient information
Death 44 yo Female Ephedrine FDA Case (3768335)	Unknown Not described Not described; >60 days (chronic)	Autopsy conducted: No	Insufficient information
Death 20 yo Male Literature Case (462)	Ultimate Xphoria Unknown <6 hours; < 48 Hours	Autopsy conducted: Not described	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – MI

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation of Etiology	RAND Classification
MI 03/20/1995 45 yo Male Ephedra FDA Case (10024)	Nature's Nutrition-Formula One Unknown <6 hours; 2-13 days	Angiography: Yes	Sentinel event
MI 23 yo Female Ephedrine FDA Case (3446357)	Midnight Ecstacy Unknown <6 hours; < 48 hours	Angiography: Yes	Sentinel event
MI 30 yo Male Ephedra Literature Case (244)	Ma huang Unknown <24 hours; Not described	Angiography: Yes	Sentinel event
MI 19 yo Male Ephedra Literature Case (516)	Dymetradine Xtreme 48.0 . <6 hours; Not described	Angiography: Yes	Sentinel event
MI 35 yo Female Ephedrine Literature Case (224)	Product unknown Unknown <24 hours; 14-60 days (acute)	Angiography: Yes	Sentinel event
MI 04/22/1994 37 yo Male Ephedra FDA Case (9372)	E'ola Amp II Pro Drops Unknown <6 hours; 2-13 days	Angiography: Yes	Possible sentinel event Note that this product was removed from the market- it contained illegal doses of ephedrine.
MI 05/23/1994 54 yo Male Ephedra FDA Case (9504)	Nature's Nutrition-Formula One Unknown 6-24 hours; >60 days (chronic)	Angiography: Yes	Possible sentinel event
MI 03/01/1995 35 yo Male Ephedra FDA Case (10009)	Metabolift 50.0 mg <6 hours; 14-60 days (acute)	Angiography: Yes	Possible sentinel event

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – MI (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation of Etiology	RAND Classification
MI 06/15/1998 38 yo Female Ephedra FDA Case (13009)	Herbalife Original Green 25.6 mg <6 hours; < 48 hours	Angiography: Yes	Possible sentinel event
MI 04/18/2000 37 yo Female Ephedra FDA Case (14114)	Metabolife 356 Unknown <6 hours; 14-60 days (acute)	Angiography: Yes	Possible sentinel event
MI 11/08/2000 43 yo Female Ephedra FDA Case (14530)	Metab-O-Lite 72.0 mg <6 hours; >60 days (chronic)	Angiography: Yes	Possible sentinel event
MI 25 yo Male Literature Case (64)	Ephedrine Unknown <6 hours; Not described	Angiography: No	Intravenous injection of ephedrine
MI 04/22/1994 34 yo Female Ephedra FDA Case (9373)	E'ola Amp II Pro Drops Unknown Not described; 2-13 days	Angiography: Yes	Insufficient information
MI 06/17/1994 Not described yo Male Ephedra FDA Case (9381)	The Edge Unknown Not described; Not described	Angiography: No	Insufficient information
MI 05/24/1994 56 yo Female Ephedra FDA Case (9512)	Nature's Nutrition-Formula One Unknown >24 hours; >60 days (chronic)	Angiography: No	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – MI (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation of Etiology	RAND Classification
MI 08/26/1994 49 yo Female Ephedra FDA Case (9572)	Nature's Nutrition-Formula One Unknown Not described; 14-60 days (acute)	Angiography: Yes	Insufficient information
MI 03/16/1995 67 yo Female Ephedra FDA Case (10065)	Nature's Nutrition-Formula One Unknown Not described; 2-13 days	Angiography: Yes	Insufficient information
MI 07/03/1997 59 yo Female Ephedra FDA Case (12452)	Omnitrition Herbal Tea 60.0 mg Not described; 14-60 days (acute)	Angiography: Yes	Insufficient information
MI 04/21/1999 39 yo Female Ephedra FDA Case (13532)	Metabolife 356 24.0 mg Not described; >60 days (chronic)	Angiography: Yes	Insufficient information
MI 08/05/1999 51 yo Male Ephedra FDA Case (13815)	Metabolife 356 Unknown Not described; Not described	Angiography: No	Insufficient information
MI 04/06/2000 30 yo Female Ephedra FDA Case (14123)	Metabolife 356 Unknown Not described; Not described	Angiography: No	Insufficient information
MI 04/15/2000 53 yo Male Ephedra FDA Case (14222)	Natural Herbal Energizer Unknown Not described; Not described	Angiography: Yes	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – MI (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation of Etiology	RAND Classification
MI 07/05/2000 39 yo Male Ephedra FDA Case (14259)	Diet Fuel 60.0 mg Not described; 14-60 days (acute)	Angiography: Yes	Insufficient information
MI 11/15/2000 45 yo Male Ephedra FDA Case (14521)	Xenadrine Unknown Not described; >60 days (chronic) Thermocut Unknown Not described; >60 days (chronic)	Angiography: Yes	Insufficient information
MI 12/02/2000 Not described yo Not described Ephedra FDA Case (14555)	Metabolife 356 Unknown Not described; 2-13 days	Angiography: No	Insufficient information
MI 01/07/2001 50 yo Female Ephedra FDA Case (14645)	Metabolife 356 Unknown Not described; 14-60 days (acute)	Angiography: Yes	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Cerebrovascular Accident/ Stroke

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation of Etiology	RAND Classification
CVA 01/03/1996 26 yo Female Ephedra FDA Case (10874)	Thermo Slim Unknown <6 hours; 2-13 days	Implicit review	Sentinel event
CVA 04/12/1996 42 yo Female Ephedra FDA Case (11062)	Power Trim Unknown Not described; >60 days (chronic)	Implicit review	Sentinel event
CVA 04/17/1996 31 yo Female Ephedra FDA Case (11105)	Trim Easy 72.0 mg 6-24 hours; >60 days (chronic)	Implicit review	Sentinel event
CVA 09/04/1996 28 yo Male Ephedra FDA Case (11675)	Ripped Fuel 63.6 mg Not described; >60 days (chronic)	Implicit review	Sentinel event
CVA 06/16/1998 39 yo Male Ephedra FDA Case (12980)	Ultimate Orange Unknown <6 hours; Not described	Implicit review	Sentinel event
CVA 12/31/1998 29 yo Male Ephedra FDA Case (13418)	Ultimate Orange 62.1 mg <6 hours; 14-60 days (acute)	Implicit review	Sentinel event
CVA 09/12/2000 53 yo Female Ephedra FDA Case (14372)	Slim Caps 24.0 mg 6-24 hours; 14-60 days (acute)	Implicit review	Sentinel event

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Cerebrovascular Accident/ Stroke (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation of Etiology	RAND Classification
CVA 10/20/2000 46 yo Female Ephedra FDA Case (14473)	Xenadrine Unknown <6 hours; 2-13 days	Implicit review	Sentinel event
CVA 33 yo Male Ephedra Literature Case (552)	Thermadrene Unknown 6-24 hours; Not described	Implicit review	Sentinel event
CVA 19 yo Female Ephedrine Literature Case (184)	Ephedrine Unknown <6 hours; Not described	Implicit review	Sentinel event
CVA 20 yo Female Ephedrine Literature Case (514)	"Purported amphetamine look-alike" Unknown <6 hours; < 48 Hours	Implicit review	Sentinel event
CVA 04/17/1992 30 yo Female Ephedra FDA Case (9296)	E'ola Amp II Pro Drops 75.0 mg <6 hours; 2-13 days	Implicit review	Possible sentinel event Note that this product was removed from the market- it contained illegal doses of ephedrine.
CVA 04/22/1994 56 yo Female Ephedra FDA Case (9335)	E'ola Amp II Pro Drops Unknown 6-24 hours; >60 days (chronic)	Implicit review	Possible sentinel event Note that this product was removed from the market- it contained illegal doses of ephedrine.
CVA 03/15/1995 24 yo Female Ephedra FDA Case (10094)	Super Fat Burners Unknown 6-24 hours; <48 hours	Implicit review	Possible sentinel event

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Cerebrovascular Accident/ Stroke (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation of Etiology	RAND Classification
CVA 01/09/1998 64 yo Female Ephedra FDA Case (12713)	FitAmerica Natural Weight ControlAid 100.0 mg <6 hours; >60 days (chronic)	Implicit review	Possible sentinel event
CVA 12/23/1997 47 yo Male Ephedra FDA Case (12733)	Purple Blast Unknown <6 hours; 14-60 days (acute)	Implicit review	Possible sentinel event
CVA 04/27/1998 41 yo Female Ephedra FDA Case (12888)	Diet Phen 13.5 mg 6-24 hours; 14-60 days (acute)	Implicit review	Possible sentinel event
CVA 09/13/2000 25 yo Female Ephedra FDA Case (14378)	Natural Trim 44.0 mg 6-24 hours; 14-60 days (acute)	Implicit review	Possible sentinel event
CVA 10/12/2000 42 yo Male Ephedra FDA Case (14434)	Slim 'N Up Unknown 6-24 hours; >60 days (chronic)	Implicit review	Possible sentinel event
CVA/ Subarachnoid hemorrhage 11/16/2000 55 yo Female Ephedra FDA Case (14553)	Metabolife 356 Unknown 6-24 hours; 14-60 days (acute)	Implicit review	Possible sentinel event
CVA 33 yo Male Ephedra Literature Case (270)	Ma huang 40 mg 6-24 hours; 14-60 days	Implicit review	Possible sentinel event

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Cerebrovascular Accident/ Stroke (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation of Etiology	RAND Classification
CVA 37 yo Male Ephedrine Literature Case (44)	"Street drug" 153.0 mg Not described; 14-60 days (acute)	Implicit review	Possible sentinel event
CVA 20 yo Male Ephedrine Literature Case (438)	"Speed" Unknown <6 hours; Not described	Implicit review	Possible sentinel event
CVA 29 yo Female Ephedrine FDA Case (3720184)	Ephedrine Unknown <6 hours; < 48 hours	Not relevant	Intraoperative ephedrine
CVA 45 yo Female Literature Case (485)	Ephedrine Unknown <6 hours; < 48 hours	Not relevant	Intraoperative ephedrine
CVA 05/12/1994 36 yo Female Ephedra FDA Case (9521)	Nature's Nutrition-Formula One Unknown <6 hours; >60 days (chronic)	Implicit review	Insufficient information
CVA 06/22/1994 52 yo Male Ephedra FDA Case (9545)	Nature's Nutrition-Formula One Unknown Not described; >60 days (chronic)	Not reviewed	Insufficient information
CVA 10/26/1994 40 yo Female Ephedra FDA Case (9749)	Equillizer Fast Start Unknown >24 hours; 2-13 days	Not reviewed	Did not meet the temporal relationship criterion
CVA 09/14/1994 49 yo Male Ephedra FDA Case (9865)	Nature's Nutrition-Formula One Unknown Not described; 14-60 days (acute)	Not reviewed	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Cerebrovascular Accident/ Stroke (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation of Etiology	RAND Classification
CVA 05/12/1995 53 yo Female Ephedra FDA Case (10187)	Nature's Nutrition-Formula One Unknown Not described; >60 days (chronic)	Not reviewed	Insufficient information
CVA 10/19/1995 31 yo Female Ephedra FDA Case (10477)	TriChromolean Unknown Not described; 14-60 days (acute)	Not reviewed	Insufficient information
CVA 10/12/1995 19 yo Female Ephedra FDA Case (10508)	Thermoburn Unknown Not described; >60 days (chronic)	Not reviewed	Insufficient information
CVA 02/07/1996 30 yo Female Ephedra FDA Case (10893)	Metabolift 60.0 mg Not described; 14-60 days (acute)	Not reviewed	Insufficient information
CVA 04/13/1996 34 yo Female Ephedra FDA Case (10957)	E'ola Amp II Pro Drops Unknown Not described; >60 days (chronic)	Not reviewed	Insufficient information
CVA 07/11/1996 55 yo Female Ephedra FDA Case (11306)	Natural Trim Unknown Not described; >60 days (chronic)	Not reviewed	Insufficient information
CVA 07/18/1996 39 yo Female Ephedra FDA Case (11442)	Herbalife Original Green Unknown Not described; >60 days (chronic)	Not reviewed	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Cerebrovascular Accident/ Stroke (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation of Etiology	RAND Classification
CVA 06/18/1996 35 yo Female Ephedra FDA Case (11619)	E'ola Amp II Pro Drops 21.5 mg >24 hours; Not described	Not reviewed	Did not meet the temporal relationship criterion
CVA 08/21/1996 33 yo Female Ephedra FDA Case (11706)	Herbalife Original Green Unknown Not described; >60 days (chronic) AP300 Unknown Not described; >60 days (chronic)	Not reviewed	Insufficient information
CVA 10/21/1996 69 yo Female Ephedra FDA Case (12340)	E'ola Amp II Pro Drops 36.8 mg Not described; 14-60 days (acute)	Not reviewed	Insufficient information
CVA 06/05/1997 64 yo Female Ephedra FDA Case (12460)	Shape Fast 30.0 mg Not described; Not described	Not reviewed	Insufficient information
CVA 08/01/1997 34 yo Female Ephedra FDA Case (12483)	Shape Fast 36.0 mg Not described; 2-13 days	Not reviewed	Insufficient information
CVA 04/22/1998 43 yo Female Ephedra FDA Case (12861)	Metabolife 356 Unknown Not described; >60 days (chronic)	Not reviewed	Insufficient information
CVA 02/11/1999 47 yo Female Ephedra FDA Case (13336)	Total Control 66.0 mg >24 hours; >60 days (chronic)	Not reviewed	Did not meet the temporal relationship criterion

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Cerebrovascular Accident/ Stroke (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation of Etiology	RAND Classification
CVA 02/01/1999 48 yo Female Ephedra FDA Case (13341)	Metacut 12.3 mg Not described; 2-13 days	Not reviewed	Insufficient information
CVA 06/01/1999 16 yo Male Ephedra FDA Case (13661)	Hydroxycut (Muscle Tech R&D) 160.0 mg >24 hours; 14-60 days (acute)	Not reviewed	Did not meet the temporal relationship criterion
CVA 06/23/1999 18 yo Female Ephedra FDA Case (13779)	Metabolife 356 Unknown Not described; 14-60 days (acute)	Not reviewed	Insufficient information
CVA 08/03/1999 24 yo Female Ephedra FDA Case (13797)	Metabolife 356 Unknown Not described; >60 days (chronic)	Not reviewed	Insufficient information
CVA 08/04/1999 30 yo Female Ephedra FDA Case (13829)	Metabolife 356 48.0 mg <6 hours; 2-13 days	Implicit review	Insufficient information
CVA 07/01/1999 26 yo Female Ephedra FDA Case (13837)	Metabolife 356 Unknown Not described; 14-60 days (acute)	Not reviewed	Insufficient information
CVA 10/27/1999 36 yo Female Ephedra FDA Case (13905)	Metabolife 356 Unknown <6 hours; >60 days(chronic)	Implicit review	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Cerebrovascular Accident/ Stroke (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation of Etiology	RAND Classification
CVA 10/08/1998 Not described yo Female Ephedra FDA Case (14056)	Ripped Fuel Unknown Not described; Not described	Not reviewed	Insufficient information
CVA 06/13/2000 46 yo Female Ephedra FDA Case (14231)	Metabolife 356 Unknown Not described; 14-60 days (acute) Xenadrine Unknown Not described; 14-60 days (acute)	Not reviewed	Insufficient information
CVA 10/03/2000 21 yo Female Ephedra FDA Case (14431)	Slacker II Unknown Not described; 2-13 days	Not reviewed	Insufficient information
CVA 01/16/2001 48 yo Female Ephedra FDA Case (14632)	LiquiFit Exercise Drops 75.0 mg Not described; 14-60 days (acute)	Not reviewed	Insufficient information
CVA 32 yo Female Ephedrine FDA Case (1823550)	Ephedrine (“Maxi Thins”) Unknown Not described; >60 days (chronic)	Implicit review	Insufficient information
CVA 68 yo Male Literature Case (515)	“Over-the-counter anti-asthma pill” 60.0 mg <6 hours; >60 days (chronic)	Implicit review	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Other Cardiovascular

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Invesigation of Etiology	RAND Classification
Cardiac/ Near sudden death 04/08/1998 22 yo Male Ephedra FDA Case (12851)	Ripped Force 20.4 mg 6-24 hours; >60 days (chronic)	Angiography: No	Possible sentinel event
Cardiac/ Cardiomyopathy 28 yo Female Literature Case (110)	Ephedrine 2000.0 mg Not described; >60 days (chronic)	Angiography: Yes	Possible sentinel event
Cardiac/ Cardiomyopathy 39 yo Male Literature Case (297)	Herbalife Original Green Unknown Not described; 14-60 days (acute)	Angiography: Yes	Possible sentinel event
Cardiac 59 yo Female Ephedrine FDA Case (3359234)	Ephedrine Unknown <6 hours; < 48 hours	Not relevant	Intraoperative ephedrine
Cardiac 99 yo Male Ephedrine FDA Case (3537599)	Ephedrine Unknown <6 hours; < 48 hours	Not relevant	Intraoperative ephedrine
Cardiac 42 yo Male Literature Case (174)	Ephedrine Unknown <6 hours; < 48 hours	Not relevant	Intraoperative ephedrine
Cardiac 14 yo Female Literature Case (281)	RJB 450.0 mg <6 hours; < 48 hours	Not relevant	Suicide attempt
Cardiac 07/19/1994 43 yo Male Ephedra FDA Case (9818)	Power Trim Unknown Not described; 14-60 days (acute)	Not reviewed	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Other Cardiovascular (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Invesigation of Etiology	RAND Classification
Cardiac 06/02/1995 63 yo Female Ephedra FDA Case (10275)	Nature's Nutrition-Formula One Unknown Not described; 14-60 days (acute)	Not reviewed	Insufficient information
Cardiac 05/07/1996 47 yo Female Ephedra FDA Case (11133)	Natural Trim Unknown Not described; 14-60 days (acute)	Not reviewed	Insufficient information
Cardiac 05/15/1996 66 yo Female Ephedra FDA Case (11282)	E'ola Amp II Pro Drops Unknown Not described; >60 days (chronic)	Not reviewed	Insufficient information
Cardiac 06/24/1996 35 yo Female Ephedra FDA Case (11464)	Shape Fast 80.0 mg Not described; 2-13 days	Not reviewed	Insufficient information
Cardiac 01/21/1996 48 yo Male Ephedra FDA Case (11782)	Pro ripped Unknown Not described; >60 days (chronic)	Not reviewed	Insufficient information
Cardiac 01/22/1998 31 yo Female Ephedra FDA Case (12740)	Ripped Fuel Unknown Not described; 2-13 days	Not reviewed	Insufficient information
Cardiac/ Near sudden death 07/29/1998 28 yo Female Ephedra FDA Case (13031)	Herbalife Original Green 43.2 mg <6 hours; < 48 Hours	Angiography: Unknown	Insufficient Information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Other Cardiovascular (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Invesigation of Etiology	RAND Classification
Cardiac 04/19/1999 57 yo Female Ephedra FDA Case (13516)	Metabolife 356 Unknown Not described; >60 days (chronic)	Not reviewed	Insufficient information
Cardiac/ Near sudden death 05/19/1999 32 yo Female Ephedra FDA Case (13643)	Natural Trim 88.0 mg <6 hours; 14-60 days (acute)	Angiography: Unknown	Insufficient Information
Cardiac/ Cardiomyopathy 07/23/1999 65 yo Female Ephedra FDA Case (13793)	Thermolean Unknown <6 hours; >60 days (chronic) Power Trim 84.0 mg <6 hours; >60 Days (chronic)	Not reviewed	Insufficient Information
Cardiac 07/23/1999 39 yo Male Ephedra FDA Case (13796)	Natural Trim Unknown Not described; >60 days (chronic)	Not reviewed	Insufficient information
Cardiac/ Ventricular Tachycardia 11/15/1999 48 yo Female Ephedra FDA Case (13945)	Metabolife 356 Unknown <6 hours; 14-60 days (acute)	Not reviewed	Insufficient Information
Cardiac 12/24/1999 48 yo Female Ephedra FDA Case (13992)	Unknown 45.0 mg Not described; >60 days (chronic)	Not reviewed	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Other Cardiovascular (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Invesigation of Etiology	RAND Classification
Cardiac 11/08/1999 46 yo Male Ephedra FDA Case (14017)	Metabolife 356 Unknown Not described; 14-60 days (acute)	Not reviewed	Insufficient information
Cardiac 03/08/2000 26 yo Male Ephedra FDA Case (14080)	Ripped Fuel Unknown Not described; >60 days (chronic) Hydroxycut (Muscle Tech R&D) Unknown Not described; >60 Days (chronic)	Not reviewed	Insufficient information
Cardiac 03/23/2000 47 yo Female Ephedra FDA Case (14108)	Herbalife Original Green Unknown >24 hours; >60 days (chronic)	Not reviewed	Insufficient information
Cardiac 04/19/2000 41 yo Female Ephedra FDA Case (14143)	Metabolife 356 24.0 mg Not described; >60 days (chronic)	Not reviewed	Insufficient information
Cardiac 04/11/2000 43 yo Female Ephedra FDA Case (14242)	Metabolize Unknown Not described; >60 days (chronic) Unknown Unknown Not described; Not described	Not reviewed	Insufficient information
Cardiac 07/19/2000 26 yo Female Ephedra FDA Case (14284)	FitAmerica Int'l Weight ControlAid Unknown >24 hours; 2-13 days	Not reviewed	Insufficient information
Cardiac 09/14/2000 39 yo Female Ephedra FDA Case (14383)	Biolean Unknown Not described; >60 days (chronic)	I Not reviewed	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Other Cardiovascular (continued)

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Invesigation of Etiology	RAND Classification
Cardiac/ Cardiomyopathy 32 yo Female Literature Case (260)	Ephedrine 450.0 mg Not described; >60 days (chronic)	Angiography: No	Insufficient information
Cardiac/ Cardiomyopathy 35 yo Male Literature Case (271)	Insufficient information Unknown <24 hours; >60 days (chronic)	Angiography: No	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Other Neurological

Event type Report date Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation of Etiology	RAND classification
Neurological/ TIA 06/29/1998 57 yo Female Ephedra FDA Case (13062)	Metabolife 356 48.0 mg 6-24 hours; < 48 hours	Implicit review	Possible sentinel event
Neurological 11/27/1995 54 yo Female Ephedra FDA Case (10573)	Thermogenic Fat Burner (Joe Weider) 48.0 mg Not described; 14-60 days (acute)	Not reviewed	Insufficient information
Neurological 08/12/1996 39 yo Male Ephedra FDA Case (11900)	Excel Energy 24.0 mg Not described; >60 days (chronic)	Not reviewed	Insufficient information
Neurological 02/10/2000 59 yo Female Ephedra FDA Case (14018)	Metabolife 356 24.0 mg >24 hours; >60 days (chronic)	Implicit review	Did not meet temporal relationship criterion
Neurological 08/31/2000 31 yo Female Ephedra FDA Case (14352)	Ripped Fuel Unknown Not described; 14-60 days (acute)	Not reviewed	Insufficient information
Neurological 11/07/2000 35 yo Female Ephedra FDA Case (14495)	Metab-O-Lite 24.0 mg Not described; >60 days (chronic)	Not reviewed	Insufficient information
Neurological 29 yo Male Ephedrine FDA Case (1535075)	Ephedrine Unknown Not described; Not described	Implicit review	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Other Neurological (continued)

Event type **Report date** **Age, Sex** **Constituent** **Source** **(ID)**	**Product** **Dose*** **Timing; Duration**	**Investigation of Etiology**	**RAND classification**
Neurological/ TIA 12 yo Female Literature Case (218)	E'ola Unknown <6 hours; < 48 hours	Implicit review	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Seizure

Event type Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Seizure 19 YO Female Ephedra FDA Case (10974)	Shape Fast/Rite Not described Not described; 14-60 days (acute)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: Yes Magnesium: No Temperature: Yes EEG: Yes	Sentinel event
Seizure 38 YO Female Ephedrine Literature Case (224)	Ephedrine Not described 6-24 hours; Duration Not described	CT/MRI of Head: No Serum Electrolytes: No Glucose: No Calcium: No Magnesium: No Temperature: No EEG: No	Sentinel event
Seizure 47 YO Female Ephedra FDA Case (9534)	Nature's Nutrition-Formula One Not described 6-24 hours; 14-60 days (acute)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: No Magnesium: No Temperature: Yes EEG: Yes	Possible sentinel event
Seizure 37 YO Female Ephedra FDA Case (10221)	Nature's Nutrition-Formula One Not described Not described; >60 days (chronic)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: Yes Magnesium: Yes Temperature: Yes EEG: Yes	Possible sentinel event
Seizure 62 YO Male Ephedra FDA Case (10432)	Thermo Slim Not described Not described; >60 days (chronic)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: Yes Magnesium: Yes Temperature: Yes EEG: Yes	Possible sentinel event
Seizure 23 YO Female Ephedra FDA Case (11649)	Metabolife 356 Not described Not described; >60 days (chronic)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: Yes Magnesium: No Temperature: Yes EEG: Yes	Possible sentinel event

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Seizure (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Seizure 26 YO Male Ephedra FDA Case (13408)	Ripped Fuel Not described <6 hours; >60 days (chronic)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: Yes Magnesium: Yes Temperature: Yes EEG: Yes	Possible sentinel event
Seizure 30 YO Female Ephedra FDA Case (14275)	Metab-O-Lite Not described 6-24 hours; >60 days (chronic)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: Yes Magnesium: No Temperature: Yes EEG: Yes	Possible sentinel event
Seizure 31 YO Female Ephedra FDA Case (14571)	Thin Tabs Not described 6-24 hours; 14-60 days (acute)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: Yes Magnesium: No Temperature: Yes EEG: Yes	Possible sentinel event
Seizure 38 YO Female Ephedra FDA Case (9528)	Nature's Nutrition-Formula One Not described Not described; 14-60 days (acute)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: Yes Magnesium: No Temperature: Yes EEG: Yes	Insufficient Information
Seizure 47 YO Female Ephedra FDA Case (9547)	Nature's Nutrition-Formula One Not described Not described; 2-13 days	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: No Calcium: Yes Magnesium: Yes Temperature: Yes EEG: Yes	Insufficient information
Seizure 40 YO Female Ephedra FDA Case (9747)	Ripped Fuel 25 mg Not described; 2-13 days	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: No Magnesium: No Temperature: No EEG: No	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Seizure (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Seizure Age Not described, Male Ephedra FDA Case (9799)	E'ola Amp II Pro Drops Not described Not described; 14-60 days (acute)	CT/MRI of Head: No Serum Electrolytes: No Glucose: No Calcium: No Magnesium: No Temperature: No EEG: Yes	Insufficient information
Seizure 34 YO Female Ephedra FDA Case (10301)	Thermogenics Plus Not described Not described; 14-60 days (acute)	CT/MRI of Head: Yes Serum Electrolytes: No Glucose: No Calcium: No Magnesium: No Temperature: No EEG: Yes	Insufficient information
Seizure 32 YO Male Ephedra FDA Case (10416)	Slim Now Not described <6 hours; >60 days (chronic)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: Yes Magnesium: No Temperature: Yes EEG: Yes	Insufficient information
Seizure 55 YO Female Ephedra FDA Case (10437)	Herbalife Original Green Not described <6 hours; 2-13 days	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: Yes Magnesium: No Temperature: No EEG: No	Insufficient information
Seizure 38 YO Female Ephedra FDA Case (10570)	Thermochrome 5000 21 mg 6-24 hours; <48 hours	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: Yes Magnesium: Yes Temperature: Yes EEG: Yes	Insufficient information
Seizure 29 YO Female Ephedra FDA Case (10964)	Diet Max/Super Diet Max Not described Not described; >60 days (chronic)	CT/MRI of Head: No Serum Electrolytes: No Glucose: No Calcium: No Magnesium: No Temperature: No EEG: No	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Seizure (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Seizure 41 YO Female Ephedra FDA Case (11001)	Guarana Plus Not described Not described; >60 days (chronic)	CT/MRI of Head: No Serum Electrolytes: No Glucose: No Calcium: No Magnesium: No Temperature: No EEG: No	Insufficient information
Seizure 36 YO Female Ephedra FDA Case (11078)	Quick Start Not described Not described; Not described Nature's Nutrition-Formula One Not described 6-24 hours; >60 days (chronic)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: No Magnesium: Yes Temperature: Yes EEG: Yes	Insufficient information
Seizure 19 YO Male Ephedra FDA Case (11181)	Ripped Fuel Not described 6-24 hours; 2-13 days	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: No Magnesium: No Temperature: Yes EEG: Yes	Insufficient information
Seizure 24 YO Male Ephedra FDA Case (11215)	Ripped Fuel Not described Not described; Not described Ripped Force Not described >24 hours; >60 days (chronic)	CT/MRI of Head: No Serum Electrolytes: No Glucose: No Calcium: No Magnesium: No Temperature: No EEG: No	Insufficient information
Seizure 20 YO Male Ephedra FDA Case (11249)	Victory Turbo Pump Not described Not described; >60 days (chronic)	CT/MRI of Head: Yes Serum Electrolytes: No Glucose: Yes Calcium: No Magnesium: No Temperature: No EEG: Yes	Insufficient information
Seizure 38 YO Female Ephedra FDA Case (11304)	E'ola Amp Pro Drops Not described <6 hours; <48 hours	CT/MRI of Head: No Serum Electrolytes: No Glucose: No Calcium: No Magnesium: No Temperature: No EEG: No	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Seizure (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Seizure 37 YO Male Ephedra FDA Case (11316)	Nature's Nutrition-Formula One Not described 6-24 hours; 14-60 days (acute)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: Yes Magnesium: Yes Temperature: Yes EEG: Yes	Insufficient information
Seizure 34 YO Female Ephedra FDA Case (11594)	Fit America Intnl Weight Control Aid Not described Not described; 2-13 days	CT/MRI of Head: No Serum Electrolytes: Yes Glucose: Yes Calcium: Yes Magnesium: Yes Temperature: Yes EEG: Yes	Insufficient information
Seizure 15 YO Male Ephedra FDA Case (12477)	Up Your Gas Not described <6 hours; <48 hours	CT/MRI of Head: No Serum Electrolytes: No Glucose: No Calcium: No Magnesium: No Temperature: No EEG: No	Insufficient information
Seizure Age Not described, Female Ephedra FDA Case (12948)	Escalation Not described Not described; 2-13 days	CT/MRI of Head: No Serum Electrolytes: No Glucose: No Calcium: No Magnesium: No Temperature: No EEG: No	Insufficient information
Seizure 42 YO Female Ephedra FDA Case (13110)	E-Z Trim Tablets 24 mg Not described; 2-13 days	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: Yes Magnesium: Yes Temperature: Yes EEG: Yes	Insufficient information
Seizure 53 YO Female Ephedra FDA Case (13514)	Metabolift Not described <6 hours; 14-60 days (acute)	CT/MRI of Head: No Serum Electrolytes: No Glucose: No Calcium: No Magnesium: No Temperature: No EEG: No	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Seizure (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Seizure Age Not described, Female Ephedra FDA Case (13519)	Metabolife 356 Not described Not described; Not described	CT/MRI of Head: No Serum Electrolytes: Yes Glucose: No Calcium: No Magnesium: No Temperature: No EEG: No	Insufficient information
Seizure 46 YO Female Ephedra FDA Case (13625)	Metabolife 356 Not described Not described; 14-60 days (acute)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: No Magnesium: No Temperature: No EEG: Yes	Insufficient information
Seizure 25 YO Female Ephedra FDA Case (13715)	Diet Fuel Not described Not described; Not described Ripped Fuel Not described Not described; Not described Hydroxycut Not described <6 hours; >60 days (chronic)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: No Magnesium: No Temperature: No EEG: Yes	Insufficient information
Seizure 51 YO Male Ephedra FDA Case (13895)	Metabolife 356 Not described Not described; 14-60 days (acute)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: No Magnesium: No Temperature: No EEG: Yes	Insufficient information
Seizure 17 YO Male Ephedra FDA Case (13946)	Ripped Fuel Not described Not described; Not described Thermo-Tek Not described <6 hours; >60 days (chronic)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: No Magnesium: No Temperature: Yes EEG: Yes	Insufficient information
Seizure 58 YO Male Ephedra FDA Case (13972)	Metabolife 356 Not described Not described; >60 days (chronic)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: No Magnesium: No Temperature: No EEG: Yes	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Seizure (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Seizure 39 YO Female Ephedra FDA Case (14116)	Thermo-Gen Not described 6-24 hours; >60 days (chronic)	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: Yes Magnesium: Yes Temperature: Yes EEG: Yes	Insufficient information
Seizure 23 YO Male Ephedra FDA Case (14258)	Ripped Fuel Not described <6 hours; <48 hours	CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: Yes Magnesium: Yes Temperature: Yes EEG: Yes	Insufficient information
Seizure 42 YO Female Ephedra FDA Case (14297)	Natural Trim Not described 6-24 hours; <48 hours	CT/MRI of Head: Yes Serum Electrolytes: No Glucose: No Calcium: No Magnesium: No Temperature: No EEG: Yes	Insufficient information
Seizure Age Not described, Female Ephedrine FDA Case (3549038)	Ephedrine Plus Not described <6 hours; 14-60 days (acute)	CT/MRI of Head: No Serum Electrolytes: No Glucose: No Calcium: No Magnesium: No Temperature: No EEG: No	Insufficient information

* dose reported in total daily alkaloids yo = year old

Table 22. Evidence table of case reports – Psychiatric

Event type Age, Sex Constituent Source (ID)	Product Dose* Duration Addiction Data**	Investigation for Etiology***	RAND Classification
Psychosis, Sleep disturbance, Palpitations, Dizzy 21 YO Male Ephedra FDA Case (9509)	Nature's Nutrition-Formula One Not described <48 hours Addiction: No	Psychiatric History: No Other Substances/Meds: No	Sentinel Event
Psychosis, Hallucinations, Sleep disturbance 39 YO Female Ephedra FDA Case (11678)	Diet Now 12 mg Over 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: No	Sentinel Event
Mania or severe agitation, Suicidal ideation, Violent, Personality changes, Headache 19 YO Female Ephedra FDA Case (13809)	Hydroxycut Not described 2-13 days Addiction: No	Psychiatric History: No Other Substances/Meds: No	Sentinel Event
Psychosis, Mania or severe agitation, Severe depression, Suicidal ideation, Sleep disturbance, Homicidal ideation 29 YO Male Ephedra FDA Case (14529)	Xenadrine Not described 60 days to 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: No	Sentinel Event
Mania or severe agitation, Ventricular tachycardia / fibrillation, Insomnia, Violent 16 YO Male Ephedrine FDA Case (1855921)	Max Alert Mini Thin Not described 60 days to 1 year Addiction: Yes	Psychiatric History: No Other Substances/Meds: No	Sentinel Event
Mania or severe agitation, Sleep disturbance 45 YO Male Ephedra Literature Case (48)	Ma huang/Ephedra Not described 14-60 days (acute) Addiction: No	Psychiatric History: No Other Substances/Meds: No	Sentinel Event

* dose reported in total daily alkaloids yo = year old

** Addiction: Yes = diagnosis or self-reported addiction to the product

*** Psychiatric history: Yes = recorded psychiatric history

Other substances/meds: Yes = patient taking other substances or medications known to cause psychiatric symptoms

Table 22. Evidence table of case reports – Psychiatric (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Duration Addiction Data**	Investigation for Etiology***	RAND Classification
Psychosis, Paranoia 30 YO Female Ephedrine Literature Case (238)	Tedral 144 mg Over 1 year Addiction: Yes	Psychiatric History: No Other Substances/Meds: No	Sentinel Event
Psychosis, Hallucinations, Confusion/Delusional 59 YO Male Ephedrine Literature Case (285)	Bronchi Pax 360 mg Over 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: No	Sentinel Event
Severe depression, Suicide attempt 28 YO Female Ephedra FDA Case (9751)	Slim NRG+ Not described 60 days to 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: No	Possible Sentinel Event
Psychosis, Suicidal ideation, Palpitations, Increased hypertension, 19 YO Male Ephedra FDA Case (11157)	Ripped Fuel Not described 60 days to 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: No	Possible Sentinel Event
Psychosis, Hallucinations, Memory Loss 13 YO Female Ephedra FDA Case (12372)	Nature's Nutrition-Formula One Not described 14-60 days (acute) Addiction: No	Psychiatric History: No Other Substances/Meds: No	Possible Sentinel Event
Mania or severe agitation, Sleep disturbance 21 YO Male Ephedra FDA Case (13005)	Ripped Fuel Not described 14-60 days (acute) Addiction: No	Psychiatric History: No Other Substances/Meds: No	Possible Sentinel Event
Psychosis, Hallucinations 52 YO Female Ephedra FDA Case (14436)	Metab-O-Lite Not described 60 days to 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: No	Possible Sentinel Event

* dose reported in total daily alkaloids yo = year old
** Addiction: Yes = diagnosis or self-reported addiction to the product
*** Psychiatric history: Yes = recorded psychiatric history
Other substances/meds: Yes = patient taking other substances or medications known to cause psychiatric symptoms

Table 22. Evidence table of case reports – Psychiatric (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Duration Addiction Data**	Investigation for Etiology***	RAND Classification
Psychosis, Suicide attempt, Insomnia, Ventricular tachycardia / fibrillation, Dizzy 28 YO Female Ephedra FDA Case (14528)	Metab-O-Lite Not described 60 days to 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: No	Possible Sentinel Event
Psychosis, Addiction/Substance Abuse, Paranoia 31 YO Male Ephedrine FDA Case (1661966)	Max Alert up to 1250 mg / day Over 1 year Addiction: Yes	Psychiatric History: No Other Substances/Meds: No	Possible Sentinel Event
Psychosis, Mania or severe agitation, Hallucinations, Paranoia 34 YO Male Ephedra Literature Case (79)	Unknown Not described 2-13 days Addiction: No	Psychiatric History: No Other Substances/Meds: No	Possible Sentinel Event
Psychosis, Sleep disturbance, Headache 40 YO Female Ephedra FDA Case (9060)	Do-Do Tablet or Herbal Balance 100 mg 14-60 days (acute) Addiction: No	Psychiatric History: Yes Other Substances/Meds: No	Inconclusive – Prior psychiatric history
Severe depression, Suicidal ideation 47 YO Male Ephedra FDA Case (9727)	Nature's Nutrition-Formula One Not described 14-60 days (acute) Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Severe depression, Suicidal ideation 38 YO Female Ephedra FDA Case (9727)	Nature's Nutrition-Formula One Not described >60 days (chronic) Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Severe depression, Suicidal ideation 30 YO Female Ephedra FDA Case (9727)	Nature's Nutrition-Formula One Not described >60 days (chronic) Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history

* dose reported in total daily alkaloids yo = year old
** Addiction: Yes = diagnosis or self-reported addiction to the product
*** Psychiatric history: Yes = recorded psychiatric history
Other substances/meds: Yes = patient taking other substances or medications known to cause psychiatric symptoms

Table 22. Evidence table of case reports – Psychiatric (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Duration Addiction Data**	Investigation for Etiology***	RAND Classification
Psychosis, Insomnia 43 YO Female Ephedra FDA Case (9403)	Therachrome Not described 60 days to 1 year Addiction: No	Psychiatric History: Yes Other Substances/Meds: No	Inconclusive – Prior psychiatric history
Psychosis, Violent 39 YO Male Ephedra FDA Case (10042)	Diet Gel Not described Not described Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Psychosis, Mania or severe agitation, Sleep disturbance 17 YO Male Ephedra FDA Case (10078)	Ripped Force Not described 60 days to 1 year Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Psychosis, Severe depression, Suicide attempt, Addiction/Substance Abuse 38 YO Female Ephedra/Ephedrine FDA Case (11052)	Mini Thin 285 mg 60 days to 1 year Addiction: Yes	Psychiatric History: Yes Other Substances/Meds: No	Inconclusive – Prior psychiatric history
Psychosis, Mania or severe agitation, Violent, Addiction/Substance Abuse 17 YO Male Ephedra FDA Case (11096)	Up Your Gas Not described Not described Addiction: Yes	Psychiatric History: Yes Other Substances/Meds: No	Inconclusive – Prior psychiatric history
Severe depression, Anxiety, Headache 31 YO Male Ephedra FDA Case (11145)	Nature's Nutrition-Formula One Not described >60 days (chronic) Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Violent 35 YO Male Ephedra FDA Case (11289)	Up Your Gas Not described 14-60 days (acute) Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history

* dose reported in total daily alkaloids yo = year old

** Addiction: Yes = diagnosis or self-reported addiction to the product

*** Psychiatric history: Yes = recorded psychiatric history

Other substances/meds: Yes = patient taking other substances or medications known to cause psychiatric symptoms

Table 22. Evidence table of case reports – Psychiatric (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Duration Addiction Data**	Investigation for Etiology***	RAND Classification
Severe depression, Addiction/Substance Abuse, Sleep disturbance 38 YO Female Ephedra FDA Case (11651)	Nature's Nutrition-Formula One Not described 60 days to 1 year Addiction: Yes	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Psychosis 34 YO Female Ephedra FDA Case (11717)	M-80 pills Not described 60 days to 1 year Addiction: No	Psychiatric History: Yes Other Substances/Meds: No	Inconclusive – Prior psychiatric history
Severe depression, Suicidal ideation 57 YO Female Ephedra FDA Case (11828)	Herbalife Original Green Not described 14-60 days (acute) Addiction: No	Psychiatric History: Yes Other Substances/Meds: No	Inconclusive – Prior psychiatric history
Mania or severe agitation, Suicidal ideation, Cyclothymia 15 YO Female Ephedra FDA Case (13072)	Caloslim Not described >60 days (chronic) Addiction: No	Psychiatric History: Yes Other Substances/Meds: No	Inconclusive – Prior psychiatric history
Psychosis, Mania or severe agitation, Hallucinations, Sleep disturbance, Migraine 20 YO Male Ephedra/Ephedrine FDA Case (13099)	Mini Thin 75 mg Not described Hydroxycut Not described 60 days to 1 year Addiction: No	Psychiatric History: Yes Other Substances/Meds: No	Inconclusive – Prior psychiatric history
Severe depression 28 YO Female Ephedra FDA Case (14089)	Xenadrine Not described 60 days to 1 year Addiction: No	Psychiatric History: Yes Other Substances/Meds: No	Inconclusive – Prior psychiatric history
Mania or severe agitation, Severe depression, Addiction/Substance Abuse 29 YO Female Ephedra FDA Case (14276)	Up Your Gas Not described Over 1 year Addiction: Yes	Psychiatric History: Yes Other Substances/Meds: No	Inconclusive – Prior psychiatric history

* dose reported in total daily alkaloids yo = year old
** Addiction: Yes = diagnosis or self-reported addiction to the product
*** Psychiatric history: Yes = recorded psychiatric history
Other substances/meds: Yes = patient taking other substances or medications known to cause psychiatric symptoms

Table 22. Evidence table of case reports – Psychiatric (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Duration Addiction Data**	Investigation for Etiology***	RAND Classification
Psychosis, Severe depression, Insomnia 17 YO Male Ephedra FDA Case (14294)	Hydroxycut Not described 2-13 days Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Psychosis, Severe depression, Motor vehicle accident, Paranoia, Confusion/Delusional 42 YO Female Ephedra FDA Case (14394)	Fen-Chi Not described 14-60 days (acute) Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Psychosis, Suicide/Suicide attempt, Hallucinations, Anxiety, Paranoia 36 YO Female Ephedra FDA Case (14493)	Herbalife Original Green Not described >60 days (chronic) Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Mania or severe agitation, Hallucinations 32 YO, Sex Not described Ephedra FDA Case (14541)	Metabolife 356 Not described 60 days to 1 year Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Psychosis, Severe depression, Suicidal ideation, Hallucinations, Insomnia 22 YO Female Ephedra FDA Case (14543)	Metabolift Not described 14-60 days (acute) Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Psychosis, Mania or severe agitation 20 YO Male Ephedra Literature Case (136)	Metabolife 356 Not described >60 days (chronic) Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history

* dose reported in total daily alkaloids yo = year old
** Addiction: Yes = diagnosis or self-reported addiction to the product
*** Psychiatric history: Yes = recorded psychiatric history
Other substances/meds: Yes = patient taking other substances or medications known to cause psychiatric symptoms

Table 22. Evidence table of case reports – Psychiatric (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Duration Addiction Data**	Investigation for Etiology***	RAND Classification
Severe depression, Suicidal ideation, Violent 27 YO Male Ephedra Literature Case (136)	Metabolife 356 Not described Over 1 year Addiction: No	Psychiatric History: Yes Other Substances/Meds: No	Inconclusive – Prior psychiatric history
Mania or severe agitation, Severe depression 40 YO Female Ephedra Literature Case (519)	Product Not described Not described Over 1 year Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Psychosis, Suicidal ideation, Anxiety, Dizzy, Increased hypertension 33 YO Female Ephedra FDA Case (9516)	Nature's Nutrition-Formula One Not described 60 days to 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: Yes	Inconclusive – Other meds / substances
Mania or severe agitation, Suicidal ideation, Sleep disturbance 45 YO Male Ephedra FDA Case (10233)	Nature's Nutrition-Formula One Not described 14-60 days (acute) Addiction: No	Psychiatric History: No Other Substances/Meds: Yes	Inconclusive – Other meds / substances
Psychosis, Catatonia 36 YO Male Ephedra FDA Case (12488)	Nature's Super Cap 99mg Thermadrene Just Be Natural Gorilla Nitro Plus Mega Creatine Fuel Bolt Not described Over 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: Yes	Inconclusive – Other meds / substances

* dose reported in total daily alkaloids yo = year old
** Addiction: Yes = diagnosis or self-reported addiction to the product
*** Psychiatric history: Yes = recorded psychiatric history
Other substances/meds: Yes = patient taking other substances or medications known to cause psychiatric symptoms

Table 22. Evidence table of case reports – Psychiatric (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Duration Addiction Data**	Investigation for Etiology***	RAND Classification
Mania or severe agitation, Hallucinations, Headache, Sleep disturbance, Irregular heart rate 19 YO Male Ephedra/Ephedrine FDA Case (13370)	Metacuts Not described >60 days (chronic) Addiction: No	Psychiatric History: No Other Substances/Meds: Yes	Inconclusive – Other meds / substances
Psychosis, Mania or severe agitation, Hallucinations, Motor vehicle accident, Sleep disturbance 27 YO Female Ephedra FDA Case (13526)	Xenadrine 40 mg 2-13 days Addiction: No	Psychiatric History: No Other Substances/Meds: Yes	Inconclusive – Other meds / substances
Severe depression, Suicidal ideation, Sleep disturbance 15 YO Male Ephedra FDA Case (14082)	Ripped Force Not described 60 days to 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: Yes	Inconclusive – Other meds / substances
Psychosis, Suicide attempt Age Not described, Female Ephedra FDA Case (14213)	Thermogenics Plus Not described Over 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: Yes	Inconclusive – Other meds / substances
Mania or severe agitation, Severe depression, Aneurysm, ruptured cerebra, Encephalopathy Age Not described, Male Ephedra FDA Case (14287)	Diet Fuel Not described 60 days to 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: Yes	Inconclusive – Other meds / substances
Psychosis, Hyperkalemia 37 YO Female Ephedra FDA Case (14300)	Metabolife 356 Not described 14-60 days (acute) Addiction: No	Psychiatric History: No Other Substances/Meds: Yes	Inconclusive – Other meds / substances

* dose reported in total daily alkaloids yo = year old

** Addiction: Yes = diagnosis or self-reported addiction to the product

*** Psychiatric history: Yes = recorded psychiatric history

Other substances/meds: Yes = patient taking other substances or medications known to cause psychiatric symptoms

Table 22. Evidence table of case reports – Psychiatric (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Duration Addiction Data**	Investigation for Etiology***	RAND Classification
Psychosis, Sleep disturbance, Confusion/Delusional 36 YO Female Ephedra FDA Case (14546)	Metabolife 356 Not described >60 days (chronic) Addiction: No	Psychiatric History: No Other Substances/Meds: Yes	Inconclusive – Other meds / substances
Psychosis 39 YO Female Ephedra FDA Case (14575)	Up Your Gas Not described Over 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: Yes	Inconclusive – Other meds / substances
Psychosis, Mania or severe agitation, Confusion/Delusional, Headache 54 YO Female Ephedra FDA Case (14582)	Metabolife 356 Not described 14-60 days (acute) Addiction: No	Psychiatric History: No Other Substances/Meds: Yes	Inconclusive – Other meds / substances
Psychosis, Hallucinations Age Not described, Female Ephedra FDA Case (10019)	Ripped Fuel Not described 60 days to 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: No	Insufficient Information
Psychosis, Irregular heart rate, Insomnia, Dizzy, Gastrointestinal problems 24 YO Female Ephedra FDA Case (10614)	Diet Max Not described 14-60 days (acute) Addiction: No	Psychiatric History: No Other Substances/Meds: No	Insufficient Information
Hallucinations, Nausea, Dizzy, Headache 20 YO Male Ephedra FDA Case (11131)	Herbal Ecstasy Not described <48 hours Addiction: No	Psychiatric History: No Other Substances/Meds: Yes	Insufficient Information
Anxiety, Palpitations 25 YO Male Ephedra FDA Case (11354)	Ripped Fuel Not described 14-60 days (acute) Addiction: No	Psychiatric History: No Other Substances/Meds: No	Insufficient Information

* dose reported in total daily alkaloids yo = year old
** Addiction: Yes = diagnosis or self-reported addiction to the product
*** Psychiatric history: Yes = recorded psychiatric history
Other substances/meds: Yes = patient taking other substances or medications known to cause psychiatric symptoms

Table 22. Evidence table of case reports – Psychiatric (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Duration Addiction Data**	Investigation for Etiology***	RAND Classification
Hallucinations Age Not described, Sex Not described Ephedra FDA Case (12368)	Power Trim Not described Not described Addiction: No	Psychiatric History: No Other Substances/Meds: No	Insufficient Information
Psychosis, Severe depression, Seizure 32 YO Female Ephedra FDA Case (14105)	Metab-O-Lite Not described 60 days to 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: No	Insufficient Information
Psychosis, Seizure, Transient ischemic attack 37 YO Female Ephedra FDA Case (14615)	Metab-O-Lite Not described 60 days to 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: No	Insufficient Information
Suicide attempt 15 YO Female Ephedra FDA Case (10378)	Thermogenic Fat Burner Not described <48 hours Addiction: No	Psychiatric History: No Other Substances/Meds: No	Product taken solely as suicide attempt
Suicide attempt, Headache 16 YO Male Ephedra FDA Case (13331)	Metabolife 356 Not described <48 hours Addiction: No	Psychiatric History: No Other Substances/Meds: No	Product taken solely as suicide attempt
Severe depression, Suicide attempt, Addiction/Substance Abuse 25 YO Male Ephedrine FDA Case (11103)	Ephedrine 2500 mg Over 1 year Addiction: Yes	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Mania or severe agitation 50 YO Female Ephedra FDA Case (11780)	Ma Huang/Ephedra + Caffeine 5.6 mg 14-60 days (acute) Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history

* dose reported in total daily alkaloids yo = year old

** Addiction: Yes = diagnosis or self-reported addiction to the product

*** Psychiatric history: Yes = recorded psychiatric history

Other substances/meds: Yes = patient taking other substances or medications known to cause psychiatric symptoms

Table 22. Evidence table of case reports – Psychiatric (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Duration Addiction Data**	Investigation for Etiology***	RAND Classification
Mania or severe agitation, Violent, Addiction/Substance Abuse 30 YO Male Ephedrine FDA Case (185564)	Mini Thin Not described Over 1 year Addiction: Yes	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Mania or severe agitation, Encephalopathy, Rhabdomyolysis, Hyperthermia 28 YO Female Ephedrine Literature Case (69)	Do-Do Tablet or Herbal Balance 18.31 mg <48 hours Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Psychosis, Severe depression, Hallucinations 54 YO Female Ephedrine Literature Case (120)	Ephedrine Not described Over 1 year Addiction: Yes	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Mania or severe agitation, Confusion/Delusional, Insomnia, Palpitations 21 YO Male Ephedrine Literature Case (157)	Black Beauty Not described <48 hours Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Psychosis, Hallucinations, Confusion/Delusional, Violent 26 YO Male Ephedrine Literature Case (238)	Ephedrine Not described 2-13 days Addiction: No	Psychiatric History: Yes Other Substances/Meds: No	Inconclusive – Prior psychiatric history
Psychosis, Mania or severe agitation, Hallucinations, Confusion/Delusional, Violent 26 YO Male Ephedrine Literature Case (238)	Ephedrine 300 mg 14-60 days (acute) Addiction: No	Psychiatric History: Yes Other Substances/Meds: No	Inconclusive – Prior psychiatric history

* dose reported in total daily alkaloids yo = year old

** Addiction: Yes = diagnosis or self-reported addiction to the product

*** Psychiatric history: Yes = recorded psychiatric history

Other substances/meds: Yes = patient taking other substances or medications known to cause psychiatric symptoms

Table 22. Evidence table of case reports – Psychiatric (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Duration Addiction Data**	Investigation for Etiology***	RAND Classification
Suicide attempt, Ventricular tachycardia / fibrillation 20 YO Female Ephedrine Literature Case (250)	Product Not described 22500 gm <48 hours Addiction: No	Psychiatric History: Yes Other Substances/Meds: No	Inconclusive – Prior psychiatric history
Psychosis, Hallucinations, Sleep disturbance, Confusion/Delusional 61 YO Male Ephedrine Literature Case (488)	Vicks inhaler Not described Over 1 year Addiction: No	Psychiatric History: Yes Other Substances/Meds: No	Inconclusive – Prior psychiatric history
Addiction/Substance Abuse, Palpitations 29 YO Female Ephedrine Literature Case (493)	Ephedrine 2500 mg Over 1 year Addiction: Yes	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Addiction/Substance Abuse 23 YO Male Ephedrine Literature Case (493)	Ephedrine 2500 mg 60 days to 1 year Addiction: Yes	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Addiction/Substance Abuse, Sleep disturbance, Palpitations 22 YO Male Ephedrine Literature Case (493)	Ephedrine 1500 mg 60 days to 1 year Addiction: Yes	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Job Loss, Motor vehicle accident 33 YO Male Ephedrine Literature Case (493)	Ephedrine 1000 mg Over 1 year Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Psychosis, Addiction/Substance Abuse 35 YO Male Ephedrine FDA Case (130741)	Ephedrine Not described Not described Addiction: Yes	Psychiatric History: No Other Substances/Meds: Yes	Inconclusive – Other substances involved

* dose reported in total daily alkaloids yo = year old
** Addiction: Yes = diagnosis or self-reported addiction to the product
*** Psychiatric history: Yes = recorded psychiatric history
Other substances/meds: Yes = patient taking other substances or medications known to cause psychiatric symptoms

Table 22. Evidence table of case reports – Psychiatric (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Duration Addiction Data**	Investigation for Etiology***	RAND Classification
Psychosis, Mania or severe agitation 19 YO Male Ephedrine Literature Case (490)	Marax 125 mg 14-60 days (acute) Addiction: No	Psychiatric History: No Other Substances/Meds: Yes	Inconclusive – Other meds / substances
Addiction/Substance Abuse 33 YO Female Ephedrine Literature Case (493)	Ephedrine 1500 mg Over 1 year Addiction: Yes	Psychiatric History: No Other Substances/Meds: Yes	Inconclusive – Other meds / substances
Psychosis, Paranoia, Violent, Impotence 65 YO Male Ephedrine Literature Case (120)	Ephedrine Not described Over 1 year Addiction: Yes	Psychiatric History: No Other Substances/Meds: Yes	Inconclusive – Other substances involved
Psychosis, Mania or severe agitation, Severe depression, Hallucinations 27 YO Female Ephedrine FDA Case (14542)	Thermolift Not described 14-60 days (acute) Addiction: No	Psychiatric History: No Other Substances/Meds: No	Not related – exacerbation of previously undiagnosed bipolar disorder
Psychosis, Suicide attempt, Paranoia, Confusion/Delusional 46 YO Male Ephedrine FDA Case (94799)	Mini Thin Not described 14-60 days (acute) Addiction: Yes	Psychiatric History: No Other Substances/Meds: No	Product taken solely as suicide attempt
Suicide attempt 19 YO Male Ephedrine FDA Case (1454817)	Max Alert Not described Not described Addiction: No	Psychiatric History: No Other Substances/Meds: No	Product taken solely as suicide attempt
Suicide attempt, Arrhythmia (NOS) 14 YO Female Ephedrine Literature Case (281)	RJ8 Not described <48 hours Addiction: No	Psychiatric History: No Other Substances/Meds: No	Product taken solely as suicide attempt

* dose reported in total daily alkaloids yo = year old
** Addiction: Yes = diagnosis or self-reported addiction to the product
*** Psychiatric history: Yes = recorded psychiatric history
Other substances/meds: Yes = patient taking other substances or medications known to cause psychiatric symptoms

Table 22. Evidence table of case reports – Psychiatric (continued)

Event type Age, Sex Constituent Source (ID)	Product Dose* Duration Addiction Data**	Investigation for Etiology***	RAND Classification
Psychosis, Severe depression, Palpitations 40 YO Male Ephedrine FDA Case (1761109)	Max Alert Not described 60 days to 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: No	Insufficient Information
Psychosis, Severe depression, Hallucinations, Addiction/Substance Abuse 38 YO Female Ephedrine FDA Case (1834206)	Mini Thin Not described Not described Excel Energy Not described Not described Addiction: Yes	Psychiatric History: No Other Substances/Meds: No	Insufficient Information
Severe depression, Suicide/Suicide attempt 43 YO Female Ephedra/Ephedrine FDA Case (9568)	E'ola Amp Pro Drops 38 mg 14-60 days (acute) Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Product removed from market- Contained illegal doses of ephedrine
Mania or severe agitation, Confusion/Delusional, Jumped out of car, Cardiac Enlargement 47 YO Female Ephedra FDA Case (12486)	LiquiThin Not described Not described E'ola Amp Pro Drops 97.2 mg 2-13 days Addiction: No	Psychiatric History: Yes Other Substances/Meds: Yes	Product removed from market- Contained illegal doses of ephedrine
Psychosis, Hallucinations, Rhabdomyolysis 54 YO Male Ephedra/Ephedrine FDA Case (10894)	E'ola Amp Pro Drops Not described 14-60 days (acute) Addiction: No	Psychiatric History: No Other Substances/Meds: Yes	Product removed from market- Contained illegal doses of ephedrine
Psychosis, Hallucinations, Paranoia, Confusion/Delusional 54 YO Female Ephedra/Ephedrine Literature Case (275)	E'ola Amp Pro Drops 28000 mg Over 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: Yes	Product removed from market- Contained illegal doses of ephedrine

* dose reported in total daily alkaloids yo = year old
** Addiction: Yes = diagnosis or self-reported addiction to the product
*** Psychiatric history: Yes = recorded psychiatric history
Other substances/meds: Yes = patient taking other substances or medications known to cause psychiatric symptoms

Table 23. Summary of adverse events with ephedra consumption*

Demographics / Type of Event	Death	MI	Other Cardiac	CVA / Stroke	Other Neurological	Seizure	Psychiatric Symptoms
Total Events							
Sentinel Events	2	3	0	9	0	3	5
Possible Sentinel Events	9	7	2	10	1	7	7
Events by Sex							
Female							
Sentinel Events	1	0	0	5	0	3	2
Possible Sentinel Events	3	4	0	7	1	5	4
Male							
Sentinel Events	1	3	0	4	0	0	3
Possible Sentinel Events	6	3	2	3	0	2	3
Events by Age							
13–30							
Sentinel Events	2	2	0	3	0	2	3
Possible Sentinel Events	5	0	1	2	0	3	5
31–50							
Sentinel Events	0	1	0	5	0	1	2
Possible Sentinel Events	4	6	1	5	0	3	1
51–70							
Sentinel Events	0	0	0	1	0	0	0
Possible Sentinel Events	0	1	0	3	1	1	1

* includes three events from Metabolife analysis.

Table 24. Summary of adverse events with ephedrine consumption

Demographics / Type of Event	Death	MI	Other Cardiac	CVA / Stroke	Other Neurological	Seizure	Psychiatric Symptoms
Total Events							
Sentinel Events	3	2	0	2	0	1	3
Possible Sentinel Events	3	0	1	2	0	0	1
Events by Sex							
Female							
Sentinel Events	1	2	0	2	0	1	1
Possible Sentinel Events	1	0	1	0	0	0	0
Male							
Sentinel Events	2	0	0	0	0	0	2
Possible Sentinel Events	1	0	1	2	0	0	1
Events by Age							
13–30							
Sentinel Events	2	1	0	2	0	0	2
Possible Sentinel Events	0	0	1	1	0	0	0
31–50							
Sentinel Events	1	1	0	0	0	1	0
Possible Sentinel Events	1	0	1	1	0	0	1
51–70							
Sentinel Events	0	0	0	0	0	0	1
Possible Sentinel Events	1	0	0	0	0	0	0

Table 25. Summary of adverse events not reviewed in detail

Adverse Event	Number of Events Reported
Fainting/ loss of consciousness	39
Heart rate >120 or <50	45
Hypertension, systolic >180 or diastolic >120	51
Paralysis	7
Liver failure,ALT/AST >200	7
Rhabdomyolysis, CPK >400	3
Coma	1
Miscarriage	1

Table 26. Summary data of key variables from Metabolife file analysis

Age	N	%
≤ 10	5	< 1
11–20	340	2
21–30	2163	12
31–40	2369	13
41–50	1598	9
51–60	912	5
>60	343	2
No Data	10627	57

Average Age	38

Gender	N	%
Male	707	4
Female	6792	36*
No Data	11032	30

*91 percent of files with reported gender are female.

Adverse Event	N	%
No adverse event reported	2019	11
Death	3	< 1
Cardiovascular: Heart rate, >120 or <50	23	< 1
Cardiovascular: Heart rate, 50-120, or not otherwise unspecified	584	3
Cardiovascular: Hypertension, Systolic>180 or Diastolic>105	45	< 1
Cardiovascular: Hypertension, Systolic<180 or Diastolic<105, not otherwise specified	405	2
Cardiovascular: Myocardial Infarction/ Heart Attack	22	< 1
Cardiovascular: Cardiac Dysrythmia, Other/ Palpitations	630	3
Cardiovascular: Cardiac arrest	3	< 1
Cardiovascular: Ventricular Tachycardia/ Fibrillation	0	0
Cardiovascular: Chest Pain, not specified as MI	582	3
Pulmonary: Respiratory arrest	2	< 1
Neurological: Transient Ischemic Attack	5	< 1
Neurological: CVA/ Stroke, not known to be hemorrhage	29	< 1
Neurological: Brain Hemorrhage	2	< 1
Neurological: Fainting / Loss of consciousness	41	< 1
Neurological: Coma	0	0
Neurological: Seizure	46	< 1
Psychiatric: Depression	57	< 1
Psychiatric: Hallucinations	2	< 1
Psychiatric: Mania or severe agitation	1	< 1
Psychiatric: Psychosis	3	< 1
Psychiatric: Suicide attempt	0	0
Autonomic Hyperactivity (Includes: Tremor, twitching, jitteriness, insomnia, increased sweating, agitation, nervousness, and irritability)	2536	14
Changes in glucose <40 *or* >400	56	< 1
Liver failure ALT/AST >200	5	< 1
Liver abnormality, not otherwise specified	46	< 1
Rhabdomyolysis CPK >400	1	< 1
Rhabdomyolysis, not otherwise specified	0	0
Miscarriage	6	< 1

Table 26. Summary data of key variables from Metabolife file analysis (continued)

Adverse Event	N	%
Allergic Reaction	614	3
Anesthesia complication	2	< 1
Fatigue/Fever/ Chills	724	4
Abnormal lab values, not otherwise specified	216	1
Ear, Eye, Nose, or Throat	795	4
Respiratory System	374	2
Cardiovascular System	255	1
Gastrointestinal System	4680	26
Hepatobiliary System	25	< 1
Musculoskeletal System	1136	6
Genitourinary System	395	2
Gynecologic (includes breast and menstrual symptoms)	1009	5
Sexual Dysfunction	115	1
Neurological System (includes headache)	2475	13
Mental Health	462	3
Skin (Includes Pruritis)	1385	7
Hematologic System	126	1
Oncologic System	4	< 1
Other symptoms not specified above	396	2

Table 27. Comparison of serious cases identified by RAND and by Metabolife

RAND #	Metabolife #	Explanation
DEATH		
	No #	Not on our MIPER CD-ROM
	No #	Not on our MIPER CD-ROM
23695		Only notation is "migraine HA, wanted refund (sister's husb died)". Unclear if this death is the consumer or a relative
35062	35062	
MYOCARDIAL INFARCTION/ HEART ATTACK		
16006	16006	
17002	17002	
20416	20416	
20918	20918	
21010		"the man who was taking them [Metabolife 356] has now suffered a heart attack"
22492		"28 yrs old had a heart attack"
22584		"customer had a heart attack thinks it was Met"
	22779	"heart attack, gall bladder surgery, cholecystectomy"
23877		"13 heart att, 3 strokes"
24166	24166	
24236	24236	
24383		"cold sweat ht attack"
24448	24448	
24859	24859	
27941	27941	
28168	28168	
28488	28488	
28835	28835	
	35532	Not on our MIPER CD-ROM
CARDIAC ARREST		
15409	15409	
27600	27600	
35063	35063	
STROKE		
16593	16593	
	17196	"vision disturbance"
18199	18199	
	19474	"short of breath, tachycardia"
20763	20763	
22308		"pain in chest, took NTG, stood up, ?stroke, ?side won't move, CAT scan negative"
22325		"had ministroke…$50 refund…will see neurologist"
22479		"'legal' customer that had 2 strokes – lawyer"
22496		"BP and Premarin 'caffeine' → stroke"
23002	23002	
23663		"stroke that cousin suffered"
23877		"13 heart att, 3 strokes"
24825	24825	
24945	24945	
25011		"stroke" written on note, but remainder of notes are about skin and gastrointestinal symptoms.

Table 27. Comparison of serious cases identified by RAND and by Metabolife (continued)

RAND #	Metabolife #	Explanation
25147		"client had a stroke"
25482	25482	
25495	25495	
25521	25521	
27791		"wife 1997 – had stroke"
	28156	"mild stroke symptoms"
	28157	"facial numbness"
	28201	"muscle weakness"
28281	28281	
28321	28321	
29424	29424	
29469	29469	
30391	30391	
30407	30407	
BRAIN HEMORRHAGE		
27754		"brain bleeding?"
35062		Recorded by Metabolife under death
SEIZURE		
15281	15281	
15345	15345	
16461	16461	
16653	16653	
16703	16703	
16897	16897	
16970	16970	
17369	17369	
17752		"[redacted] and her sister both take Met [redacted] reports [redacted] had a seizure recently"
18335	18335	
18962	18962	
19149	19149	
20812	20812	
20864	20864	
20979	20979	
	22150	Definitely a seizure, but contained in the section of the main file that has refund requests and we inferred these cases were also recorded elsewhere in the MIPER file
	22238	"black out while driving had hot flashes also had 2 screwdrivers"
22364		"seizures like activity"
22539		"friend of a friend had seizure"
22800	22800	
23029	23029	
	23440	"s/e's → dad"
23468		"sister – grand mal seizure"
24172		"seizure"
	24209	Same case as 16897
24344	24344	
24482	24482	
24711	24711	
24839	24839	

Table 27. Comparison of serious cases identified by RAND and by Metabolife (continued)

RAND #	Metabolife #	Explanation
24947		"seizures"
25371	25371	
27487	27487	
27523	27523	
28183	28183	
28329	28329	
28442	28442	
29882		"seizure" checked off on list of symptoms on standardized form
	35568	Not on our MIPER CD-ROM

Table 28. Summary of Metabolife medical records

RAND Case #	Index Case #	Complaint Case #	MIPER#(s)	Notes
1	1	1	20867 20868	This is a 42-year-old male who took two Metabolife pills for the first time and presented with chest pain, chest-tightness and shortness of breath. He ended up in the emergency department where he was found to have a blood pressure of 140/82 with a pulse of 111. The electrocardiogram showed him to be in atrial fibrillation. A discharge summary is not included among the records received. However, the patient's note to Metabolife said that he was discharged after one day and that his doctors were "convinced" that his heart was "back to normal." Of note is that his laboratory values established that he did not have thyroid disease and did not have any evidence of a myocardial infarction.
2	2	2	20871 20872	This is a 28-year-old female who had shortness of breath, dyspnea and wheezing. She was seen in the emergency department and was said to be having an "anaphylactoid reaction." She was treated with epinephrine, steroids and Benadryl with a complete response.
3	3	3	16287 20873-75 21033 24047 24051	This is a 38-year-old female who was admitted to the hospital with acute pancreatitis. The hospital record notes that she is "quite obese." The record also notes that she had a prior total abdominal hysterectomy with bilateral salpingo-oopherectomy and at that time was found to have ovarian cancer with involvement of the bowel. This resulted in partial colectomy with a diverting colostomy, and subsequently she had a renastomosis. She also had a prior cholycystectomy. It is noted that she did not drink alcohol. Her admission records note an elevated white blood cell count with a value of 14,000 but no elevation in amylase or lipase. A subsequent note states that these laboratory tests did become elevated and then returned to normal. She was discharged after recovery. Actual laboratory values are not included with the records. There is no mention of a measurement of serum triglycerides.
4	4	4	20876-78	This case consists of a handwritten note from the patient and a medical care bill for $34. The age and gender of the patient are unknown. The complaint is of headache, dizziness and tingling.

Index Case # taken from *Index of Redacted Consumer Medical Records with Corresponding MIPER Numbers.*
Complaint Case # taken from *Listing of Key Complaint for the Metabolife Medical Records Submitted* .
MIPER #(s) taken from *Index of Redacted Consumer Medical Records with Corresponding MIPER Numbers.*
No MIPER located: this is the text from the *Index of Redacted Consumer Medical Records…* as it pertains to the Index Case #.
n/a: not available, no match found.

Table 28. Summary of Metabolife medical records (continued)

RAND Case #	Index Case #	Complaint Case #	MIPER#(s)	Notes
5	5	5	17895 20879 23365	This file consists of a single physician note of a female of unstated age who came in with the complaints of "pain over the joints, gums would bleed, veins seemed to be thrombosing, some itching, easy bruisability and pain in the back over her kidneys." The physical examination was normal, clotting studies were normal, sedimentation rate was seven, chemistry panel was normal. The patient left in good condition.
6	6	6	20880 20883-85	This is a 28-year-old female who presented with 2 weeks of stomach pain, mostly after eating food, along with explosive diarrhea. Her laboratory work-up was essentially normal with a normal white blood cell count, liver enzymes and amylase. She was diagnosed as having "acute gastritis." She had both upper and lower endoscopy that did not reveal a clear diagnosis. Stool for ova and parasites was negative. Stool was positive for occult blood. Stool culture was negative, abdominal series was negative.
7	7	7	15998 20886	This is a 53-year-old female who presented with emesis and diarrhea after eating a hamburger at a fast food restaurant. Her examination was essentially unremarkable. The diagnostic impression was acute gastroenteritis. She was treated with antibiotics and Kaopectate.
8	8	8	16166 20887 24083-84	This is a 61-year-old female with a history of asthma who presented with headaches. She was found to have a potassium of 3.3 and a sodium of 118. It was noted that she drinks eight glasses of water a day. The diagnosis given was headache, possibly due to low sodium, and a viral upper respiratory tract infection.
9	9	9	20888-89	This is a 53-year-old female who was seen for increased intraoccular pressure. She was under the care of an ophthalmologist for what she called the "iridocorneoendothelial syndrome." It was treated by her ophthalmologist.
10	10	10	20890	This is a female of unstated age who presented with a headache. The records note that she had migraines eight years ago. She had photophobia and emesis. Her blood pressure was 153/73. She was treated with Imitrex with mild relief and she also received Demerol and Phenergan.

Index Case # taken from *Index of Redacted Consumer Medical Records with Corresponding MIPER Numbers.*
Complaint Case # taken from *Listing of Key Complaint for the Metabolife Medical Records Submitted* .
MIPER #(s) taken from *Index of Redacted Consumer Medical Records with Corresponding MIPER Numbers.*
No MIPER located: this is the text from the *Index of Redacted Consumer Medical Records…* as it pertains to the Index Case #.
n/a: not available, no match found.

Table 28. Summary of Metabolife medical records (continued)

RAND Case #	Index Case #	Complaint Case #	MIPER#(s)	Notes
11	11	11	No MIPER located	This is a male of unstated age who presented with abdominal indigestion without vomiting. The records note the patient had a prior vagotomy and pyloroplasty with gastroenterostomy. He received an ultrasound, CT scan and endoscopy. There was no indication of his treatment or response. In addition, there is no mention of taking Metabolife anywhere in the medical records.
12	12	13	16995 20892 25503	This is a 53-year-old female. The complaint that is listed is hyponatremia. However there is no medical record documentation of this. All that is included is a single copy of lab tests showing normal thyroid function and normal complete blood count. Whether these data apply to this patient is unclear, as the patient age on the lab slip is listed as 33. A doctor's note in the MIPER file states she required hospitalization.
13	13	14	15996 20893-95 23828 21035-37	This is a 61-year-old female who presented with supraventricular tachycardia which required cardioversion and subsequent treatment with atenolol. This is documented in a note, possibly from her doctor, however there are no medical records included with this case.
14	n/a	12	n/a	This is a 60-year-old female who presented with palpitations and was found to be in atrial flutter. According to the discharge summary, she was electrically cardioverted and then given Digoxin and Cardizem. Subsequent clinic notes showed her to continue to be in sinus rhythm. There is no indication or records that other diagnostic studies were done.
15	14	15	16642 20897-99 21034 23859	This is a 21-year-old female. The complaint is a rash. The only documentation provided is the bill of an emergency department visit. There are no medical records.
16	15	n/a	17569 20900-01	This is a 49-year-old female, noted to weigh 160 lbs., who presented with chest pain and had an overnight hospitalization to evaluate myocardial infarction. CPK was elevated but the MB fractions were negative. The patient was discharged with the diagnosis of chest wall pain.
n/a	16	n/a	15351 23010	No medical record received

Index Case # taken from *Index of Redacted Consumer Medical Records with Corresponding MIPER Numbers.*
Complaint Case # taken from *Listing of Key Complaint for the Metabolife Medical Records Submitted* .
MIPER #(s) taken from *Index of Redacted Consumer Medical Records with Corresponding MIPER Numbers.*
No MIPER located: this is the text from the *Index of Redacted Consumer Medical Records…* as it pertains to the Index Case #.
n/a: not available, no match found.

Table 28. Summary of Metabolife medical records (continued)

RAND Case #	Index Case #	Complaint Case #	MIPER#(s)	Notes
17	17	16	17605 20904	This is a 36-year-old female who claims to be "only 20 lbs. overweight" who stated that she had elevations in blood pressure, now requiring treatment with Maxzide. However there are no medical records accompanying this complaint, only a copy of bills.
n/a	n/a	17	n/a	(Listing of Key Complaints states chest pain, shortness of breath)
n/a	n/a	18	n/a	(Listing of Key Complaints states elevated blood pressure/ racing pulse)
18	18	19 (?) (Listing of Key Complaints states Fainting)	16199	This is a 73-year-old female who was evaluated for near syncope that occurred while eating in a restaurant. In the emergency department, blood pressure was noted to be 132/37 with a pulse of 64 and glucose was 90. The discharge diagnosis was "syncope related to hypoglycemia vs. Metabolife vs. vasovagal episode." Exercise treadmill test performed later was normal but there was a submaximal heart rate achieved. Carotid ultrasound was normal. Many additional notes cover healthcare judged to be irrelevant to the use of ephedra, including a podiatry consult, breast biopsies, pap smear and an endometrial biopsy.
19	19	20	No MIPER located	This is a 24-year-old female who presented with blood in the urine for one day. The records consist of a urine culture which was negative, a urinalysis which showed 2+ blood and a hemoglobin and hematocrit of 18 and 50, respectively.
20	20	21	20905-06 25529	This is a 47-year-old male who presented in atrial fibrillilation, was shown not to have had a myocardial infarction, and who had an echo and exercise treadmill test that were both normal. There was no evidence of thyroid disease. The patient converted to sinus rhythm with medication and was then treated with Digoxin. A followup doctor's note stated that the patient was in sinus rhythm and implied that he was off Digoxin.
21	21	22	17028 20907-08 24154	This is a 31-year-old female who is noted to weigh 261 lbs. She presented with heart palpitations, shortness of breath and heart "flutter." She had a history of hypertension with pregnancy. A consultant's note reported T-wave inversions in V1 and V3 with an elevated CPK but the MB fraction was normal and the Troponin test was negative. It is unclear exactly what happened, but this apparently resolved.

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Table 28. Summary of Metabolife medical records (continued)

RAND Case #	Index Case #	Complaint Case #	MIPER#(s)	Notes
22	22	23	17277 20914-15	This is a 36-year-old female who presented with nausea, dizziness and vomiting, headache and abdominal pain. Blood pressure was noted to be 134/87 and the pulse was 85. Abdominal ultrasound was normal, pregnancy test was normal. Urinalysis showed moderate ketones. The discharge diagnosis was "abdominal pain of uncertain etiology."
n/a	23	n/a	22408 20916-17	No medical record received
n/a	n/a	24	n/a	(Listing of Key Complaints states difficulty breathing/ anxiety)
23	24	25	20918-21 21032	This is a 38-year-old female who made three visits to the emergency room over four days for epigastric and chest pain, initially being diagnosed as having esophageal reflux, then gastritis and then finally being recognized as having coronary artery disease with an 80% left anterior descending stenosis. This was treated with a coronary stent. Her cardiologist notes that she had a "very positive family history" of coronary artery disease and that her mother had an "early heart attack." There was no indication in the record that a cholesterol test was done.
24	25	26	20950 20953-54 20958-59 20961	This file contains no medical records, only medical bills documenting prescriptions for hydrochlorothiazide and phenazopyridine, along with a urinalysis. The MIPER file indicates the patient said she was diagnosed with hemorrhagic cystitis, and later hypertension.
25	26	27	20962-66 21006-07	There are no medical records in this file, only bills. On one of the bills is written "drug reaction."
26	27	28	18445	This is a 39-year-old female. The complaint is an allergic reaction. There are no medical records in this file, only bills.
n/a	28	n/a	16521 17536	No medical record received
27	29	29	20967-68	This is a 40-year-old female who developed transient elevations of liver enzymes with an ALT of 125. Albumin and bilirubin were normal. Multiple tests for possible etiologies of this were performed, all of which were negative. Metabolife was discontinued and the liver function abnormalities drifted down to normal over time; the last note said that she had recovered totally.

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Table 28. Summary of Metabolife medical records (continued)

RAND Case #	Index Case #	Complaint Case #	MIPER#(s)	Notes
28	30	30	20969 20971-75 20977-78	There are no medical records in this file. The only thing that is listed is a complaint from the patient about a heart rate being 188 and the blood pressure being high, that the patient was treated in the emergency room and that there were "blood tests to assess heart damage." The MIPER includes a long letter from the patient that relates much the same thing.
n/a	32	n/a	No MIPER located	No medical record received
n/a	33	n/a	No MIPER located	No medical record received
n/a	n/a	32	n/a	Listing of Key Complaints states nothing identified- just a bill
n/a	n/a	33	n/a	Listing of Key Complaints states nothing identified- list of medications
29	35	35	16376 21030	This is a 54-year-old male with chest pain and a headache who also complained of high blood pressure and lightheadedness. There are minimal records associated with this report of August 11, 1999, other than that the patient was diagnosed with accelerated hypertension. Of note, however, is that there are numerous clinic visit notes dating back to 1997, documenting that the patient had a history of hypertension, diabetes and hyperlipidemia, with a blood pressure on one occasion 154/92. It is noted that this was taken with a large cuff. In addition, there are clinic visits with chest pain as far back as 1997.
30	34	34	21027 21029	This is a male of unstated age, possibly 40 years old, who wrote a note saying that he had stomach problems, kidney stones, colon problems and anxiety problems. There are no medical records associated with this file, only bills.
31	31	31	21000-01	There are no medical records with this file, only some discharge instructions that say that the diagnosis was "acute nausea." The MIPER file states the patient is a 37-year-old female and that "hypoglycemia was likely."

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Table 28. Summary of Metabolife medical records (continued)

RAND Case #	Index Case #	Complaint Case #	MIPER#(s)	Notes
32	36	36	20979 24840 25498 25501	This is a 50-year-old female who had a witnessed grand mal seizure while driving. Later that day, after undergoing a CT scan in the emergency room, she had a 2nd witnessed seizure and, according to an attorney's letter, she then had a 3rd seizure at some point. An evaluation included a CT of the brain, which was normal, and an electroencephalogram, which was also normal. She had no history of alcoholism. Serum sodium was normal and glucose was normal. Pulse oximetry was 99%. Toxicology screen was positive for amphetamines. There was no prior history of seizure disorder or neurologic disease.
33	37	37	19473 23970	This is a 21-year-old female who is noted to weigh 200 pounds and on whom the MIPER file will say shortness of breath and tachycardia. There are minimal records associated with this, only a discharge diagnosis of hyperventilation, with a notation saying that a friend died two days ago. There is a listing of medications and, by implication, these are being taken by the patient. These are Darvocet (which may have been discontinued), Flexeril, Reglan, Cytotec, Dicyclomine, Viokase, Sudafed, Lopid, Citracel, Pariodel, Benadryl, DDVAP, Zantac, Trilisat, Carafate. Of note, the MIPER may also say the complaint includes aphasia, paralysis, and shortness of breath.
34	n/a	39	n/a	There are no medical records in this file, only a bill.
35	40	n/a	19350	This is a 39-year-old female who had the complaint of abdominal pain. The medical records submitted with this consist of a clinic note which says that the patient has "classic gastrointestinal illness" with mild nausea and no diarrhea, progressing to diarrhea with no vomiting.
36	38	38	20864-66	This is a 29-year-old female who had a witnessed tonic clonic seizure. There is no history of alcoholism. The grandmother had a history of seizures but was also noted to be an alcoholic. Blood pressure was normal at 120/80. Brain MRI was normal. EEG was normal. Toxicology screen by report had "large amount ephedrine and pseudoephedrines."
n/a	39	n/a	24495	No medical record received
n/a	n/a	40	n/a	(Listing of Key Complaints states lower back pain/GI)
37	n/a	41	n/a	This is a patient of unknown age and unknown gender who presented for an allergic reaction. There are no medical records and only bills and medications in this file.

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Table 28. Summary of Metabolife medical records (continued)

RAND Case #	Index Case #	Complaint Case #	MIPER#(s)	Notes
n/a	41	n/a	No MIPER located	No medical record received
38	n/a	42	n/a	There are only bills which have a diagnostic code 780.2 which is "syncope and collapse," along with indications that an echocardiogram and duplex sonography were done. There are no other medical records.
39	42	43	19604	This is a 29-year-old female, who is noted to weigh 230 lbs., who presented for menstrual irregularity, numbness and tingling. Evaluation was unremarkable and no diagnosis was given.
40	n/a	44 (?) (Listing of Key Complaints states intracranial hemo-rrhage, which is mentioned in patient history)	n/a	This is a 36-year-old female who complained of menstrual irregularity. The records document that she recently had a right posterior parietal intracranial hemorrhage with extension into the ventricular system requiring neurosurgery with a drain. This was subsequently shown by angiography to be due to an arteriovenous malformation, which was then subsequently resected. After this neurosurgery she had not had resumption of her menstrual period. In the notes available there was no work up of this symptom.
41	n/a	45	n/a	This is a 26-year-old female, who is noted to weigh 155 lbs., who had chest pains after using Metabolife for two months. She also had asthma and a brother who died of myocardial infarction at age 33. Her discharge diagnoses were asthma and chest pain.
42	n/a	46	n/a	This is a 27-year-old female who presented with sudden abdominal pain which was found to be due to a rupture of a splenic artery aneurysm which required emergency laporatomy and resection. The records note she had a history of congenital multiple ureters which had been surgically repaired at age 7 and she was left with some renal insufficiency as a result. There is no mention of the use of Metabolife in the medical records that are provided.
43	n/a	n/a	n/a	This is a 49-year-old male who had symptoms of chest pressure and pain along with shortness of breath. He had been a cigarette smoker but the record notes he quit. He had an exercise treadmill test that showed a normal electrocardiogram response but he had scintigraphic evidence of ischemia. He underwent coronary angiography that revealed normal coronary arteries. Three months later he was continuing to have unexplained chest pressure and pain.

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Table 28. Summary of Metabolife medical records (continued)

RAND Case #	Index Case #	Complaint Case #	MIPER#(s)	Notes
n/a	43	n/a	No MIPER located	No medical record received
n/a	44	n/a	No MIPER located	No medical record received
n/a	45	n/a	No MIPER located	No medical record received
n/a	46	n/a	No MIPER located	No medical record received.

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