Table 22. Evidence table of case reports - Death

Event type			
Report date Age, Sex Constituent Source	Product Dose* Timing; Duration	Investigation for Etiology	RAND Classification
Death		Autopsy conducted: Yes	Sentinel event
21 yo Male Ephedra FDA Case	10.0 mg <6 hours; < 48 hours Ripped Fuel Unknown Not described; not described		
	Slacker II Unknown Not described; 14-60 days (acute)	Autopsy conducted: Yes	Sentinel event
	MiniTabs 250.0 mg Not described; >60 days (chronic)	Autopsy conducted: Yes	Sentinel event
33 yo Male	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
Ephedra FDA Case (9508)	Unknown Not described; >60 days (chronic)		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)	1 . ,	Possible sentinel event

^{*} dose reported in total daily alkaloids

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

Source (ID) Death 07/25/1997 38 yo Male Ephedra FDA Case (12485)	Product Dose* Timing; Duration Ripped Fuel 43.2 mg <6 hours; >60 days (chronic)	Investigation for Etiology Autopsy conducted: Yes	RAND Classification Possible sentinel event
21 yo Male Ephedra FDA Case (12722)	Thermogenics Plus 23.1 mg Not described; Not described	Autopsy conducted: Yes	Possible sentinel event
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
08/03/1999	Ripped Fuel Unknown Not described; 2-13 days (acute)	Autopsy conducted: Yes	Possible sentinel event
02/16/2000	Diet Fuel 26.6 mg Not described; >60 days (chronic)	Autopsy conducted: Yes	Possible sentinel event
01/09/2001	Hydroxycut 20.0 mg 6-24 hours; 2-13 days	Autopsy conducted: Yes	Possible sentinel event
Death 23 yo Male	Ripped Fuel 50.0 mg Not described; >60 days (chronic)	Autopsy conducted: Yes	Possible sentinel event

^{*} dose reported in total daily alkaloids

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

Event type			
Event type			
Report date Age, Sex			
Age, Sex Constituent	Dreduct		
Source	Product		
	Dose*	Investigation for Etipleau	BAND Classification
(ID)	Timing; Duration	Investigation for Etiology	RAND Classification
Death	Street drug ("speed")	Autopsy conducted: Yes	Possible sentinel
42 yo Male	306.0 mg		event
Ephedrine	Not described; >60 days (chronic)		
Literature Case			
(44)			
Death	Unknown	Autopsy conducted: Yes	Possible sentinel
84 yo Female	Unknown		event
Ephedrine	Not described; Not described		
Literature Case			
(44)	In a sefficient information	Automore and set of Men	Describle southward
Death	Insufficient information	Autopsy conducted: Yes	Possible sentinel
Literature Case			event
Ephedrine	<24 hours; 14-60 days (acute)		
44 yo Male			
(224) Death		Autonov conducted: No	latra an aratic (a
31 yo Female	Ephedrine Unknown	Autopsy conducted: No	Intraoperative ephedrine
Ephedrine	<6 hours: <48 hours		epnedine
FDA Case	~0 110urs, ~40 110urs		
(313104)			
Death	Insufficient information	Autopsy conducted: Yes	Suicide
30 yo Female	Unknown	Autopsy conducted. Tes	Salcide
	Not described; Not described		
(17)	Trot decembed, fret decembed		
Death	Insufficient information	Autopsy conducted: Yes	Suicide
19 yo Female	Unknown	latopo, comunican rec	0.101.0.0
	<6 hours; Not described		
(96)			
Death	Insufficient information	Autopsy conducted: Yes	Suicide
21 yo Male	Unknown		
	<6 hours; Not described		
(96)	·		
Death	Ripped Fuel	Autopsy conducted: Yes	Probably not related
06/11/1999	Unknown		-
24 yo Male	<6 hours; < 48 hours		
Ephedra			
FDA Case			
(13672)			
Death	Max Alert	Autopsy conducted: No	Probably not related
40 yo Male	Not described		
Ephedrine	Not described		
FDA Case			
(1859087)			

^{*} dose reported in total daily alkaloids

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

Event type Report date Age, Sex Constituent Source (ID) Death	Product Dose* Timing; Duration Unknown	Investigation for Etiology Autopsy conducted: Yes	RAND Classification Probably not related
Not described yo Male Ephedrine FDA Case (1902493)	Not described Not described		·
Death 30 yo Male Ephedrine FDA Case (3491515)	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)	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

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

Event type			
Report date Age, Sex			
Constituent	Product		
Source	Dose*		
(ID)	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

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

Event type Report date Age, Sex Constituent Source (ID) Death		0	RAND Classification Insufficient information
Death 03/14/1996 20 yo Male Ephedra FDA Case (10862)	Unknown <6 hours; < 48 hours	Autopsy conducted: No	insunicient 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'I) Unknown Not described; 14-60 days (acute)	Autopsy conducted: No	Insufficient information
	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)	60.0 mg Not described; >60 days (chronic)		Insufficient information
37 yo Male	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

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

Event type Report date			
Age, Sex			
Constituent	Product		
Source	Dose*		
(ID)	Timing; Duration	Investigation for Etiology	RAND Classification
Death	Herbalife Original Green	Autopsy conducted: No	Insufficient information
07/11/1996	26.4 mg		
59 yo Male Ephedra	Not described; 14-60 days (acute)		
FDA Case			
(11307)			
Death	Herbalife Original Green	Autopsy conducted: No	Insufficient information
06/25/1996	Unknown	' '	
34 yo Female	Not described; Not described		
Ephedra			
FDA Case			
(11417)	5: 15 1		
Death 07/23/1996	Ripped Fuel	Autopsy conducted: No	Insufficient information
27 yo Male	51.4 mg Not described; >60 days (chronic)		
Ephedra	Not described, >00 days (critoriic)		
FDA Case			
(11441)			
Death	Cybergenic super anti-fatigue	Autopsy conducted: No	Insufficient information
07/12/1996	3.3 mg		
24 yo Male	Not described; 14-60 days (acute)		
Ephedra			
FDA Case (11444)			
Death	Easy Trim	Autopsy conducted: No	Insufficient information
10/07/1996	Unknown	ratopsy contacted. No	
56 yo Female	Not described; Not described		
Ephedra	·		
FDA Case			
(11721)			
Death	Escalation	Autopsy conducted: Yes	Insufficient information
08/25/1997	Unknown		
32 yo Female Ephedra	Not described; Not described		
FDA Case			
(12506)			
Death	Ripped Fuel	Autopsy conducted: No	Insufficient information
10/06/1997	20.0 mg		
0 yo Female	Not described; >60 days (chronic)		
Ephedra			
FDA Case			
(12594)			

^{*} dose reported in total daily alkaloids

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

F., a no. 4 a			
Event type			
Report date			
Age, Sex			
Constituent	Product		
Source	Dose*		
(ID)	Timing; Duration	Investigation for Etiology	RAND Classification
Death	Ripped Fuel	Autopsy conducted: Yes	Did not meet temporal
12/19/1997	Unknown		relationship criterion
22 yo Male	>24 hours; Not described		rolation on pontonon
Ephedra	2 i floure, frot described		
FDA Case			
(12720)			
Death	Horbolifo Original Croop	Autopay conducted: No	Insufficient information
	Herbalife Original Green	Autopsy conducted: No	insufficient information
04/23/1998	42.0 mg		
34 yo Male	Not described; 14-60 days (acute)		
Ephedra			
FDA Case			
(12859)			
Death	Diet Fuel	Autopsy conducted: No	Insufficient information
04/24/1998	20.1 mg		
46 yo Male	Not described; Not described		
Ephedra			
FDA Case			
(12871)			
Death	Ripped Fuel	Autopsy conducted: No	Insufficient information
07/11/1998	63.6 mg		
43 yo Male	Not described; >60 days (chronic)		
Ephedra			
FDA Case			
(13021)			
Death	Metabolife 356	Autopsy conducted: Yes	Insufficient information
09/16/1998	Unknown	ratopsy conducted. Tes	modificate information
37 yo Female	Not described; 2-13 days		
Ephedra	l described, 2-15 days		
FDA Case			
(13096)	Thin Tabs	Autopsy conducted: Vos	Insufficient information
Death		Autopsy conducted: Yes	mounicient information
10/08/1998	Unknown		
	Not described; Not described		
Ephedra			
FDA Case			
(13127)			
Death	Ultimate Orange	Autopsy conducted: No	Insufficient information
02/27/1999	Unknown		
18 yo Male	<6 hours; Not described		
Ephedra			
FDA Case			
(13380)			

^{*} dose reported in total daily alkaloids

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

Event type			<u> </u>
Report date			
Age, Sex	Duadeed		
Constituent	Product		
Source	Dose*		
(ID)	Timing; Duration	Investigation for Etiology	RAND Classification
Death	Metabolife 356	Autopsy conducted: No	Insufficient information
05/19/1999	60.0 mg		
49 yo Male	Not described; < 48 hours		
Ephedra			
FDA Case			
(13634)			
Death	Metabolife 356	Autopsy conducted: Yes	Did not meet temporal
06/04/1999	72.0 mg	, ,	relationship criterion
40 yo Female	>24 hours; 14-60 days (acute)		· ·
Ephedra			
FDA Case			
(13706)			
Death	Thermadrene	Autopsy conducted: No	Insufficient information
06/30/1999	Unknown	ratopoy conductou. No	meanioren mornation
37 yo Female	Not described; Not described		
Ephedra	Tvot described, rvot described		
FDA Case			
(13762)			
(13702) Death	Metabolife 356	Autopsy conducted: No	Insufficient information
08/06/1999	Unknown	Autopsy conducted. No	insuncient information
	Not described; Not described		
59 yo Female	Not described, Not described		
Ephedra FDA Case			
(13802)	Matabalifa 250	Automore and cated Was	la sufficient information
Death	Metabolife 356	Autopsy conducted: Yes	Insufficient information
08/03/1999	Unknown		
37 yo Male	<6 hours; 2-13 days		
Ephedra			
FDA Case			
(13806)			
Death	Herbalife Original Green	Autopsy conducted: Yes	Insufficient information
10/06/1999	Unknown		
	Not described; 14-60 days (acute)		
Ephedra			
FDA Case			
(13901)			
Death	Metabolife 356	Autopsy conducted: No	Insufficient information
10/13/1999	Unknown		
62 yo Female	Not described; Not described		
Ephedra			
FDA Case			
(13993)			
u. /	·	<u> </u>	<u>. </u>

^{*} dose reported in total daily alkaloids

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

Event type Report date Age, Sex			
Constituent	Product		
Source	Dose*		
(ID)	Timing; Duration	Investigation for Etiology	RAND Classification
Death	Metabolife 356	Autopsy conducted: Yes	Did not meet temporal
04/04/2000	Unknown >24 hours; >60 days (chronic)		relationship criterion
29 yo Female Ephedra	Omnitrition Herbal Tea		
FDA Case	Unknown		
(14113)	Not described; 14-60 days (acute)		
- /	Not described		
	Unknown		
	Not described; Not described		
Death	Metabolift	Autopsy conducted: Yes	Insufficient information
08/10/2000	60.0 mg		
32 yo Female	Not described; 2-13 days		
Ephedra FDA Case			
(14323)			
Death	Metabomax	Autopsy conducted: No	Insufficient information
08/31/2000	72.0 mg		
46 yo Female	Not described; 2-13 days		
Ephedra			
FDA Case			
(14347)	NA () 15 050		
Death 09/14/2000	Metabolife 356	Autopsy conducted: No	Insufficient information
40 yo Female	Unknown Not described; 14-60 days (acute)		
Ephedra	Not described, 14-00 days (acute)		
FDA Case			
(14370)			
Death	Thermogen Plus Liquid	Autopsy conducted: Yes	Insufficient information
03/28/2000	72.0 mg		
56 yo Male	Not described; 2-13 days		
Ephedra			
FDA Case			
(14465) Death	Up Your Gas	Autopsy conducted: Not	Insufficient information
10/16/2000	34.2 mg	described	mounicient iniornation
46 yo Female	Not described; Not described		
Ephedra			
FDA Case			
(14470)			

^{*} dose reported in total daily alkaloids

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

Event type			
Report date			
Age, Sex			
Constituent	Product		
Source	Dose*		
(ID)	Timing; Duration	Investigation for Etiology	RAND Classification
Death	Xenadrine	Autopsy conducted: Yes	Insufficient information
11/14/2000	40.0 mg	Adiopsy conducted. Tes	insuncient information
39 yo Male	Not described; >60 days (chronic)		
Ephedra	liver described, 7 or days (ornorne)		
FDA Case			
(14498)			
Death	Metabolife 356	Autopsy conducted: No	Insufficient information
11/18/2000	24.0 mg		
45 yo Female	>24 hours; 2-13 days		
Ephedra			
FDA Case			
(14509)			
Death	Diet 2X	Autopsy conducted: No	Insufficient information
12/06/2000	Unknown		
49 yo Female	Not described; 14-60 days (acute)		
Ephedra			
FDA Case			
(14561)			
Death	Metabolife 356	Autopsy conducted: Yes	Insufficient information
12/24/2000	72.0 mg		
40 yo Male	Not described; >60 days (chronic)		
Ephedra			
FDA Case			
(14585)	AA: · TI ·		
Death	Mini Thin	Autopsy conducted: Yes	Insufficient information
03/18/2001	75.0 mg		
28 yo Female	Not described; >60 days (chronic) Yellow Jacket		
Ephedra FDA Case	Unknown		
(14747)			
(14747) Death	Not described; >60 days (chronic) Metabolife 356	Autopsy conducted: Yes	Insufficient information
03/29/2001	Unknown	Autopsy conducted. Tes	mounicient inionnation
31 yo Female	Not described; >60 days (chronic)		
Ephedra	Tot described, > 00 days (critofile)		
FDA Case			
(14808)			
Death	Ephedrine	Autopsy conducted: No	Insufficient information
3 yo Male	Unknown		camolon information
Ephedrine	<6 hours; < 48 hours		
FDA Case	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
(1772115)			
<u></u>	<u> </u>	1	

^{*} dose reported in total daily alkaloids

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

Event type			
Report date			
Age, Sex			
	Product		
	Dose*		
	Timing; Duration	Investigation for Etiology	RAND Classification
` '	Unknown	Autopsy conducted: Yes	Insufficient information
	Not described	Latopsy conducted. Tes	
	Not described		
FDA Case	140t described		
(1874879)			
	MiniTabs	Autopsy conducted: Yes	Insufficient information
	Unknown	Transpoy contaction. Tes	
	Not described; Not described		
FDA Case	,		
(3135225)			
Death	Mini 2 Way Action	Autopsy conducted: Yes	Insufficient information
46 yo Male	Unknown		
	Not described; >60 days (chronic)		
FDA Case			
(3173538)			
	Metabolift	Autopsy conducted: N/A	Insufficient information
,	Unknown		
	<6 hours; Not described		
	D: + 0\/		
		Autopsy conducted: No	Insufficient information
	Not described; 14-60 days (acute)		
` /	Linknown	Autonsy conducted: No	Insufficient information
		Hatopsy conducted. NO	misamoleni imomialion
,			
	itot decembed, - ee daye (ememo)		
` /	Ultimate Xphoria	Autopsy conducted: Not	Insufficient information
	Unknown	described	
	<6 hours; < 48 Hours		
(462)	,		
FDA Case (3551127) Death 99 yo Female Ephedrine FDA Case (3623625) Death 44 yo Female Ephedrine FDA Case (3768335) Death 20 yo Male Literature Case	Diet 2X Unknown Not described; 14-60 days (acute) Unknown Not described Not described; >60 days (chronic) Ultimate Xphoria Unknown	Autopsy conducted: No Autopsy conducted: No Autopsy conducted: Not described	Insufficient information

^{*} dose reported in total daily alkaloids

Table 22. Evidence table of case reports – MI

Event type			
Report date			
Age, Sex			
	Product		
Source	Dose*		
(ID)	Timing; Duration	Investigation of Etiology	RAND Classification
MI	Nature's Nutrition-Formula One	Angiography: Yes	Sentinel event
03/20/1995	Unknown		
45 yo Male	<6 hours; 2-13 days		
Ephedra			
FDA Case			
(10024)			
	Midnight Ecstacy	Angiography: Yes	Sentinel event
,	Unknown		
Ephedrine	<6 hours; < 48 hours		
FDA Case			
(3446357)			
	Ma huang	Angiography: Yes	Sentinel event
30 yo Male	Unknown		
Ephedra	<24 hours; Not described		
Literature Case			
(244)	D (1:)//	A : 1 X	0 " 1 1
	Dymetradine Xtreme	Angiography: Yes	Sentinel event
,	48.0 .		
Ephedra	<6 hours; Not described		
Literature Case (516)			
	Product unknown	Angiography: Yes	Sentinel event
	Unknown	Angiography. Tes	Serilinei everil
J	<24 hours; 14-60 days (acute)		
Literature Case	14-00 days (acute)		
(224)			
	E'ola Amp II Pro Drops	Angiography: Yes	Possible sentinel event
	Unknown	, inglograpiny. 100	Note that this product
37 yo Male	<6 hours; 2-13 days		was removed from the
Ephedra	,		market- it contained
FDA Case			illegal doses of
(9372)			ephedrine.
	Nature's Nutrition-Formula One	Angiography: Yes	Possible sentinel event
	Unknown		
	6-24 hours; >60 days (chronic)		
Ephedra			
FDA Case			
(9504)			
MI	Metabolift	Angiography: Yes	Possible sentinel event
	50.0 mg		
35 yo Male	<6 hours; 14-60 days (acute)		
Ephedra			
FDA Case			
(10009)			

^{*} dose reported in total daily alkaloids

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

Source (ID)	Product Dose* Timing; Duration	Investigation of Etiology	
06/15/1998	Herbalife Original Green 25.6 mg <6 hours; < 48 hours	Angiography: Yes	Possible sentinel event
04/18/2000	Metabolife 356 Unknown <6 hours; 14-60 days (acute)	Angiography: Yes	Possible sentinel event
11/08/2000	Metab-O-Lite 72.0 mg <6 hours; >60 days (chronic)	Angiography: Yes	Possible sentinel event
25 yo Male	Ephedrine Unknown <6 hours; Not described	Angiography: No	Intravenous injection of ephedrine
MI 04/22/1994	E'ola Amp II Pro Drops Unknown Not described; 2-13 days	Angiography: Yes	Insufficient information
	The Edge Unknown Not described; Not described	Angiography: No	Insufficient information
05/24/1994	Nature's Nutrition-Formula One Unknown >24 hours; >60 days (chronic)	Angiography: No	Insufficient information

^{*} dose reported in total daily alkaloids

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

Event type Report date Age, Sex Constituent Source (ID) MI 08/26/1994 49 yo Female Ephedra FDA Case (9572) MI	Product Dose* Timing; Duration Nature's Nutrition-Formula One Unknown Not described; 14-60 days (acute) Nature's Nutrition-Formula One	Investigation of Etiology Angiography: Yes	RAND Classification Insufficient information Insufficient information
03/16/1995 67 yo Female Ephedra FDA Case (10065)	Unknown Not described; 2-13 days	Angiography: Yes	msunicient mornation
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

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

Event type Report date Age, Sex Constituent Source	Product Dose*		
(ID)	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)	Unknown Not described; 2-13 days		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

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

Event type			
Report date			
Age, Sex			
	Product		
Source	Dose*		DANID OL 15 11
(ID)	Timing; Duration	Investigation of Etiology	
CVA	Thermo Slim	Implicit review	Sentinel event
01/03/1996	Unknown		
26 yo Female	<6 hours; 2-13 days		
Ephedra			
FDA Case			
(10874)			
CVA	Power Trim	Implicit review	Sentinel event
04/12/1996	Unknown		
42 yo Female	Not described; >60 days (chronic)		
Ephedra			
FDA Case			
(11062)			
CVA	Trim Easy	Implicit review	Sentinel event
04/17/1996	72.0 mg	Implicit review	Sentiner event
31 yo Female	6-24 hours; >60 days (chronic)		
	0-24 flours, >60 days (chiloffic)		
Ephedra FDA Case			
(11105)	b		
CVA	Ripped Fuel	Implicit review	Sentinel event
09/04/1996	63.6 mg		
28 yo Male	Not described; >60 days (chronic)		
Ephedra			
FDA Case			
(11675)			
CVA	Ultimate Orange	Implicit review	Sentinel event
06/16/1998	Unknown		
39 yo Male	<6 hours; Not described		
Ephedra			
FDA Case			
(12980)			
CVA	Ultimate Orange	Implicit review	Sentinel event
12/31/1998	62.1 mg	· ·	
29 yo Male	<6 hours; 14-60 days (acute)		
Ephedra			
FDA Case			
(13418)			
CVA	Slim Caps	Implicit review	Sentinel event
09/12/2000	24.0 mg	In phote review	CONTRIBUTE CACHE
53 yo Female	6-24 hours; 14-60 days (acute)		
Ephedra	2 - Hours, 14-00 days (acute)		
FDA Case			
(14372)			
(14312)			

^{*} dose reported in total daily alkaloids

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

Event type			
Report date			
Age, Sex			
Constituent	Product		
Source	Dose*		
(ID)	Timing; Duration	Investigation of Etiology	RAND Classification
CVA	Xenadrine	Implicit review	Sentinel event
10/20/2000	Unknown		
46 yo Female	<6 hours; 2-13 days		
Ephedra			
FDA Case			
(14473)			
CVA	Thermadrene	Implicit review	Sentinel event
33 yo Male	Unknown		
	6-24 hours; Not described		
Literature Case			
(552)			
CVA	Ephedrine	Implicit review	Sentinel event
19 yo Female	Unknown		
Ephedrine	<6 hours; Not described		
Literature Case			
(184)	(C) () () () () () () () () ()	1 1 1 1	0 (')
CVA	"Purported amphetamine look-alike" Unknown	Implicit review	Sentinel event
20 yo Female			
Ephedrine Literature Case	<6 hours; < 48 Hours		
(514)			
CVA	E'ola Amp II Pro Drops	Implicit review	Possible sentinel event
04/17/1992	75.0 mg	Implicit review	Note that this product
30 yo Female	<6 hours; 2-13 days		was removed from the
Ephedra	To flours, 2 To days		market- it contained
FDA Case			illegal doses of
(9296)			ephedrine.
CVA	E'ola Amp II Pro Drops	Implicit review	Possible sentinel event
04/22/1994	Unknown		Note that this product
	6-24 hours; >60 days (chronic)		was removed from the
Epĥedra			market- it contained
FDA Case			illegal doses of
(9335)			ephedrine.
CVA	Super Fat Burners	Implicit review	Possible sentinel event
03/15/1995	Unknown		
	6-24 hours; <48 hours		
Ephedra			
FDA Case			
(10094)			

^{*} dose reported in total daily alkaloids

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

Event type			
Report date Age, Sex			
	Product		
	Dose*		
(ID)		Investigation of Etiology	RAND Classification
		Implicit review	Possible sentinel event
01/09/1998	100.0 mg	Implicit review	i ossible serilirler everit
64 yo Female	<6 hours; >60 days (chronic)		
Ephedra	Tours, 200 days (critoriic)		
FDA Case			
(12713)			
` '	Purple Blast	Implicit review	Possible sentinel event
	Unknown		
47 yo Male	<6 hours; 14-60 days (acute)		
Ephedra			
FDA Case			
(12733)			
	Diet Phen	Implicit review	Possible sentinel event
04/27/1998	13.5 mg		
41 yo Female	6-24 hours; 14-60 days (acute)		
Ephedra			
FDA Case			
(12888)			
	Natural Trim	Implicit review	Possible sentinel event
	44.0 mg		
	6-24 hours; 14-60 days (acute)		
Ephedra			
FDA Case			
(14378)	Oliver INT I I I	Lange Balk and days	Describle as attack as a second
	Slim 'N Up	Implicit review	Possible sentinel event
	Unknown		
42 yo Male Ephedra	6-24 hours; >60 days (chronic)		
FDA Case			
(14434)			
	Metabolife 356	Implicit review	Possible sentinel event
	Unknown	Implicit review	i ossible seritirer everit
	6-24 hours; 14-60 days (acute)		
11/16/2000			
55 yo Female			
Ephedra			
FDA Case			
(14553)			
	Ma huang	Implicit review	Possible sentinel event
	40 mg		
Ephedra	6-24 hours; 14-60 days		
Literature Case			
(270)			

^{*} dose reported in total daily alkaloids

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

Event tune		1	
Event type			
Report date			
Age, Sex			
Constituent	Product		
Source	Dose*		
(ID)	Timing; Duration	Investigation of Etiology	RAND Classification
CVA	"Street drug"	Implicit review	Possible sentinel event
37 yo Male	153.0 mg	·	
Ephedrine	Not described; 14-60 days (acute)		
Literature Case			
(44)			
CVA	"Speed"	Implicit review	Possible sentinel event
20 yo Male	Unknown	implient review	
Ephedrine	<6 hours; Not described		
Literature Case	10 Hours, Not described		
(438)			
	Ephedrine	Not relevant	Intraoperative
	Ephedine Unknown	INOLIGIEVALIL	
,			ephedrine
Ephedrine	<6 hours; < 48 hours		
FDA Case			
(3720184)			
	Ephedrine	Not relevant	Intraoperative
	Unknown		ephedrine
	<6 hours; < 48 hours		
(485)			
CVA	Nature's Nutrition-Formula One	Implicit review	Insufficient information
05/12/1994	Unknown		
36 yo Female	<6 hours; >60 days (chronic)		
Ephedra			
FDA Case			
(9521)			
CVA	Nature's Nutrition-Formula One	Not reviewed	Insufficient information
06/22/1994	Unknown		
52 yo Male	Not described; >60 days (chronic)		
Ephedra	, , , , , , , , , , , , , , , , , , , ,		
FDA Case			
(9545)			
CVA	Equillizer Fast Start	Not reviewed	Did not meet the
	Unknown		temporal relationship
	>24 hours; 2-13 days		criterion
Ephedra	24 Hours, 2 To days		
FDA Case			
(9749)			
(9749) CVA	Nature's Nutrition-Formula One	Not reviewed	Insufficient information
09/14/1994	Unknown	INOL TEVIEWEG	
	Not described; 14-60 days (acute)		
Ephedra			
FDA Case			
(9865)			

^{*} dose reported in total daily alkaloids

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

Event type Report date Age, Sex Constituent Source (ID) CVA 05/12/1995 53 yo Female Ephedra FDA Case (10187)	Product Dose* Timing; Duration Nature's Nutrition-Formula One Unknown Not described; >60 days (chronic)	Investigation of Etiology 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

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

Event type			
Report date			
Age, Sex			
Constituent	Product		
Source	Dose*		
(ID)	Timing; Duration	Investigation of Etiology	RAND Classification
CVA	E'ola Amp II Pro Drops	Not reviewed	Did not meet the
06/18/1996	21.5 mg		temporal relationship
35 yo Female	>24 hours; Not described		criterion
Ephedra	, , , , , , , , , , , , , , , , , , , ,		
FDA Case			
(11619)			
CVA	Herbalife Original Green	Not reviewed	Insufficient information
08/21/1996	Unknown		
33 yo Female	Not described; >60 days (chronic)		
Epĥedra	AP300		
FDA Case	Unknown		
(11706)	Not described; >60 days (chronic)		
CVA	E'ola Amp II Pro Drops	Not reviewed	Insufficient information
10/21/1996	36.8 mg		
69 yo Female	Not described; 14-60 days (acute)		
Ephedra			
FDA Case			
(12340)			
CVA	Shape Fast	Not reviewed	Insufficient information
06/05/1997	30.0 mg		
64 yo Female	Not described; Not described		
Ephedra			
FDA Case			
(12460)			
CVA	Shape Fast	Not reviewed	Insufficient information
08/01/1997	36.0 mg		
34 yo Female	Not described; 2-13 days		
Ephedra			
FDA Case			
(12483)	Matabalifa 256	Not reviewed	Inc. officions information
CVA	Metabolife 356	Not reviewed	Insufficient information
04/22/1998	Unknown		
43 yo Female Ephedra	Not described; >60 days (chronic)		
Ephedra FDA Case			
(12861)			
(12661) CVA	Total Control	Not reviewed	Did not meet the
02/11/1999	66.0 mg	INOLIEVIEWEU	temporal relationship
47 yo Female	>24 hours; >60 days (chronic)		criterion
Ephedra	- 27 Hours, -00 days (Cilionic)		GITIGITOTT
FDA Case			
(13336)			
(10000)			

^{*} dose reported in total daily alkaloids

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

^{*} dose reported in total daily alkaloids

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

Source (ID) CVA 10/08/1998 Not described yo Female Ephedra FDA Case (14056)	Product Dose* Timing; Duration Ripped Fuel Unknown Not described; Not described	Investigation of Etiology Not reviewed	Insufficient information
06/13/2000 46 yo Female Ephedra FDA Case	Metabolife 356 Unknown Not described; 14-60 days (acute) Xenadrine Unknown Not described; 14-60 days (acute)	Not reviewed	Insufficient information
10/03/2000	Slacker II Unknown Not described; 2-13 days	Not reviewed	Insufficient information
01/16/2001	LiquiFit Exercise Drops 75.0 mg Not described; 14-60 days (acute)	Not reviewed	Insufficient information
32 yo Female	Ephedrine ("Maxi Thins") Unknown Not described; >60 days (chronic)	Implicit review	Insufficient information
ČVA 68 yo Male	"Over-the-counter anti-asthma pill" 60.0 mg <6 hours; >60 days (chronic)	Implicit review	Insufficient information

^{*} dose reported in total daily alkaloids

Table 22. Evidence table of case reports – Other Cardiovascular

	T		
Event type			
Report date			
Age, Sex			
Constituent	Product		
Source	Dose*		
(ID)	Timing; Duration	Invesigation of Etiology	RAND Classification
Cardiac/ Near	Ripped Force	Angiography: No	Possible sentinel event
sudden death	20.4 mg	rangiography. No	i ossibie sentinei event
04/08/1998	6-24 hours; >60 days (chronic)		
	0-24 flours, >00 days (chilofile)		
22 yo Male			
Ephedra			
FDA Case			
(12851)			
Cardiac/	Ephedrine	Angiography: Yes	Possible sentinel event
Cardiomyopathy			
28 yo Female	Not described; >60 days		
	(chronic)		
(110)			
Cardiac/	Herbalife Original Green	Angiography: Yes	Possible sentinel event
Cardiomyopathy	Unknown		
39 yo Male	Not described; 14-60 days		
Literature Case	(acute)		
(297)			
Cardiac	Ephedrine	Not relevant	Intraoperative
59 yo Female	Unknown		ephedrine
Ephedrine	<6 hours; < 48 hours		'
FDA Case	, , , , , , , , , , , , , , , , , , , ,		
(3359234)			
Cardiac	Ephedrine	Not relevant	Intraoperative
99 yo Male	Unknown	rtot rolo raint	ephedrine
Ephedrine	<6 hours; < 48 hours		opiliodi il lo
FDA Case	To find to,		
(3537599)			
Cardiac	Ephedrine Ephedrine	Not relevant	Intraoperative
42 yo Male	Unknown	TOUTO VALIE	ephedrine
Literature Case	<6 hours; < 48 hours		opricumic
(174)	To Hours, 1 To Hours		
Cardiac	RJB	Not relevant	Suicide attempt
	450.0 mg	Not relevant	Suiciue attempt
Literature Case	<6 hours; < 48 hours		
(281)	Danier Trins	NI-4	Language and the second
Cardiac	Power Trim	Not reviewed	Insufficient information
07/19/1994	Unknown		
43 yo Male	Not described; 14-60 days (acute)		
Ephedra			
FDA Case			
(9818)			

^{*} dose reported in total daily alkaloids

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

Event type Report date Age, Sex Constituent Source (ID) Cardiac 06/02/1995 63 yo Female Ephedra FDA Case	Product Dose* Timing; Duration Nature's Nutrition-Formula One Unknown Not described; 14-60 days (acute)	Invesigation of Etiology Not reviewed	RAND Classification Insufficient information
(10275) 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

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

Source	Product Dose*		
<u> </u>	Timing; Duration	0 0,	RAND Classification
04/19/1999	Metabolife 356 Unknown Not described; >60 days (chronic)	Not reviewed	Insufficient information
Cardiac/ Near sudden death	Natural Trim 88.0 mg <6 hours; 14-60 days (acute)	Angiography: Unknown	Insufficient Information
65 yo Female	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	Natural Trim Unknown Not described; >60 days (chronic)	Not reviewed	Insufficient information
Cardiac/ Ventricular	Metabolife 356 Unknown <6 hours; 14-60 days (acute)	Not reviewed	Insufficient Information
	Unknown 45.0 mg Not described; >60 days (chronic)	Not reviewed	Insufficient information

^{*} dose reported in total daily alkaloids

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

F 4 4:	1		
Event type			
Report date			
Age, Sex			
Constituent	Product		
Source	Dose*		
(ID)	Timing; Duration	Invesigation of Etiology	RAND Classification
Cardiac	Metabolife 356	Not reviewed	Insufficient information
11/08/1999	Unknown		
46 yo Male	Not described; 14-60 days (acute)		
Ephedra			
FDA Case			
(14017)			
Cardiac	Ripped Fuel	Not reviewed	Insufficient information
03/08/2000	Unknown	Not reviewed	modification information
26 yo Male	Not described; >60 days (chronic)		
Ephedra	Hydroxycut (Muscle Tech R&D)		
FDA Case	Unknown		
(14080)	Not described; >60 Days (chronic)		
Cardiac		Not reviewed	Insufficient information
03/23/2000	Herbalife Original Green Unknown	INOT I EVIEWED	
	>24 hours; >60 days (chronic)		
47 yo Female	24 flours, >60 days (chronic)		
Ephedra			
FDA Case			
(14108)	NA	N. (
Cardiac	Metabolife 356	Not reviewed	Insufficient information
04/19/2000	24.0 mg		
41 yo Female	Not described; >60 days (chronic)		
Ephedra			
FDA Case			
(14143)			
Cardiac	Metabolize	Not reviewed	Insufficient information
04/11/2000	Unknown		
43 yo Female	Not described; >60 days (chronic)		
Ephedra	Unknown		
FDA Case	Unknown		
(14242)	Not described; Not described		
Cardiac	FitAmerica Int'l Weight ControlAid	Not reviewed	Insufficient information
07/19/2000	Unknown		
26 yo Female	>24 hours; 2-13 days		
Ephedra			
FDA Case			
(14284)			
Cardiac	Biolean	l Not reviewed	Insufficient information
09/14/2000	Unknown		
39 yo Female	Not described; >60 days (chronic)		
Ephedra	1111111111111111111111111111111111111		
FDA Case			
(14383)			
(1 +000 <i>)</i>		1	

^{*} dose reported in total daily alkaloids

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

Source	Product Dose* Timing; Duration	Invesigation of Etiology	RAND Classification
Cardiomyopathy	Ephedrine 450.0 mg Not described; >60 days (chronic)	Angiography: No	Insufficient information
Cardiac/ Cardiomyopathy	Insufficient information Unknown <24 hours; >60 days (chronic)	Angiography: No	Insufficient information

^{*} dose reported in total daily alkaloids

Table 22. Evidence table of case reports – Other Neurological

F 4 4	I	I	
Event type			
Report date			
Age, Sex			
Constituent	Product		
Source	Dose*		
(ID)	Timing; Duration	Investigation of Etiology	RAND classification
Neurological/	Metabolife 356	Implicit review	Possible sentinel event
TIA	48.0 mg	·	
06/29/1998	6-24 hours; < 48 hours		
57 yo Female	,		
Ephedra			
FDA Case			
(13062)			
Neurological	Thermogenic Fat Burner (Joe Weider)	Not reviewed	Insufficient information
11/27/1995	48.0 mg		
54 yo Female	Not described; 14-60 days (acute)		
Ephedra			
FDA Case			
(10573)			
Neurological	Excel Energy	Not reviewed	Insufficient information
08/12/1996	24.0 mg		
39 yo Male	Not described; >60 days (chronic)		
Ephedra	l vot accombed, > oc days (cilionic)		
FDA Case			
(11900)			
Neurological	Metabolife 356	Implicit review	Did not meet temporal
02/10/2000	24.0 mg	implient review	relationship criterion
59 yo Female	>24 hours; >60 days (chronic)		
Ephedra	24 flours, 200 days (officials)		
FDA Case			
(14018)			
Neurological	Ripped Fuel	Not reviewed	Insufficient information
08/31/2000	Unknown	T TO	
31 yo Female	Not described; 14-60 days (acute)		
Ephedra	liter decembed, 11 ee daye (deate)		
FDA Case			
(14352)			
Neurological	Metab-O-Lite	Not reviewed	Insufficient information
11/07/2000	24.0 mg		
35 yo Female	Not described; >60 days (chronic)		
Ephedra	list associated, see days (ornormo)		
FDA Case			
(14495)			
Neurological	Ephedrine Ephedrine	Implicit review	Insufficient information
29 yo Male	Unknown	The state of the s	
Ephedrine	Not described; Not described		
FDA Case	, tot dooribod, rtot dooribod		
(1535075)			
(1000010)		<u> </u>	1

^{*} dose reported in total daily alkaloids

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

Source	Product Dose* Timing; Duration	Investigation of Etiology	RAND classification
TIA	Unknown <6 hours; < 48 hours	Implicit review	Insufficient information

^{*} dose reported in total daily alkaloids

Table 22. Evidence table of case reports – Seizure

Event type			
Age, Sex			
Constituent	Product		
Source	Dose*		
(ID)	Timing; Duration	Investigation for Etiology	RAND Classification
Seizure	Shape Fast/Rite	CT/MRI of Head: Yes	Sentinel event
19 YO Female	Not described	Serum Electrolytes: Yes	
Ephedra	Not described; 14-60 days (acute)	Glucose: Yes	
FDA Case		Calcium: Yes	
(10974)		Magnesium: No	
		Temperature: Yes	
		EEG: Yes	
Seizure	Ephedrine	CT/MRI of Head: No	Sentinel event
38 YO Female	Not described	Serum Electrolytes: No	
Ephedrine	6-24 hours; Duration Not described	Glucose: No	
Literature Case		Calcium: No	
(224)		Magnesium: No	
		Temperature: No EEG: No	
Seizure	Nature's Nutrition-Formula One	CT/MRI of Head: Yes	Possible sentinel event
47 YO Female	Not described	Serum Electrolytes: Yes	Possible sentinel event
Ephedra	6-24 hours; 14-60 days (acute)	Glucose: Yes	
FDA Case	0-24 flours, 14-00 days (acute)	Calcium: No	
(9534)		Magnesium: No	
(333.)		Temperature: Yes	
		EEG: Yes	
Seizure	Nature's Nutrition-Formula One	CT/MRI of Head: Yes	Possible sentinel event
37 YO Female	Not described	Serum Electrolytes: Yes	
Ephedra	Not described; >60 days (chronic)	Glucose: Yes	
FDA Case		Calcium: Yes	
(10221)		Magnesium: Yes	
		Temperature: Yes	
Seizure	Thermo Slim	EEG: Yes CT/MRI of Head: Yes	Possible sentinel event
Seizure 62 YO Male	Not described	Serum Electrolytes: Yes	L negativite settititiei evetti
Ephedra	Not described; >60 days (chronic)	Glucose: Yes	
FDA Case	Two described, 700 days (critorile)	Calcium: Yes	
(10432)		Magnesium: Yes	
(10102)		Temperature: Yes	
		EEG: Yes	
Seizure	Metabolife 356	CT/MRI of Head: Yes	Possible sentinel event
23 YO Female	Not described	Serum Electrolytes: Yes	
Ephedra	Not described; >60 days (chronic)	Glucose: Yes	
FDA Case		Calcium: Yes	
(11649)		Magnesium: No	
		Temperature: Yes	
		EEG: Yes	

^{*} dose reported in total daily alkaloids

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

Event type			
Age, Sex			
Constituent	Product		
Source	Dose*		
(ID)	Timing; Duration	Investigation for Etiology	RAND Classification
Seizure	Ripped Fuel	CT/MRI of Head: Yes	Possible sentinel event
26 YO Male	Not described	Serum Electrolytes: Yes	
Ephedra	<6 hours; >60 days (chronic)	Glucose: Yes	
FDA Case		Calcium: Yes	
(13408)		Magnesium: Yes	
		Temperature: Yes	
0:	Matak O Lita	EEG: Yes	Descible continue avent
Seizure 30 YO Female	Metab-O-Lite	CT/MRI of Head: Yes	Possible sentinel event
Ephedra	Not described 6-24 hours; >60 days (chronic)	Serum Electrolytes: Yes Glucose: Yes	
FDA Case	0-24 flours, > 00 days (critoffic)	Calcium: Yes	
(14275)		Magnesium: No	
()		Temperature: Yes	
		EEG: Yes	
Seizure	Thin Tabs	CT/MRI of Head: Yes	Possible sentinel event
31 YO Female	Not described	Serum Electrolytes: Yes	
Ephedra	6-24 hours; 14-60 days (acute)	Glucose: Yes	
FDA Case		Calcium: Yes	
(14571)		Magnesium: No	
		Temperature: Yes	
0 - !	National Alatelia Farmada One	EEG: Yes	
Seizure 38 YO Female	Nature's Nutrition-Formula One	CT/MRI of Head: Yes	Insufficient Information
Ephedra	Not described; 14-60 days (acute)	Serum Electrolytes: Yes Glucose: Yes	
FDA Case	Not described, 14-00 days (acute)	Calcium: Yes	
(9528)		Magnesium: No	
(5525)		Temperature: Yes	
		EEG: Yes	
Seizure	Nature's Nutrition-Formula One	CT/MRI of Head: Yes	Insufficient information
47 YO Female	Not described	Serum Electrolytes: Yes	
Ephedra	Not described; 2-13 days	Glucose: No	
FDA Case		Calcium: Yes	
(9547)			
Coizuro	Dinned Fuel		Inquifficient information
	• •		insufficient information
	livot described, 2-10 days		
()			
		EEG: No	
FDA Case (9547) Seizure 40 YO Female Ephedra FDA Case (9747)	Ripped Fuel 25 mg Not described; 2-13 days	Magnesium: Yes Temperature: Yes EEG: Yes CT/MRI of Head: Yes Serum Electrolytes: Yes Glucose: Yes Calcium: No Magnesium: No Temperature: No	Insufficient information

^{*} dose reported in total daily alkaloids

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

Event type			
Age, Sex			
Constituent	Product		
Source	Dose*		
(ID)	Timing; Duration	Investigation for Etiology	
Seizure	E'ola Amp II Pro Drops	CT/MRI of Head: No	Insufficient information
Age Not	Not described	Serum Electrolytes: No	
	Not described; 14-60 days (acute)	Glucose: No	
Ephedra		Calcium: No	
FDA Case		Magnesium: No	
(9799)		Temperature: No	
0 :	. DI	EEG: Yes	
Seizure	Thermogenics Plus	CT/MRI of Head: Yes	Insufficient information
34 YO Female	Not described: 14 60 days (acuta)	Serum Electrolytes: No Glucose: No	
Ephedra FDA Case	Not described; 14-60 days (acute)	Calcium: No	
(10301)		Magnesium: No	
(10001)		Temperature: No	
		EEG: Yes	
Seizure	Slim Now	CT/MRI of Head: Yes	Insufficient information
32 YO Male	Not described	Serum Electrolytes: Yes	
Ephedra	<6 hours; >60 days (chronic)	Glucose: Yes	
FDA Case		Calcium: Yes	
(10416)		Magnesium: No	
		Temperature: Yes	
		EEG: Yes	
Seizure	Herbalife Original Green	CT/MRI of Head: Yes	Insufficient information
55 YO Female	Not described	Serum Electrolytes: Yes	
Ephedra	<6 hours; 2-13 days	Glucose: Yes	
FDA Case (10437)		Calcium: Yes	
(10437)		Magnesium: No Temperature: No	
		EEG: No	
Seizure	Thermochrome 5000	CT/MRI of Head: Yes	Insufficient information
38 YO Female	21 mg	Serum Electrolytes: Yes	
Ephedra	6-24 hours; <48 hours	Glucose: Yes	
FDA Case		Calcium: Yes	
(10570)		Magnesium: Yes	
		Temperature: Yes	
		EEG: Yes	
Seizure	Diet Max/Super Diet Max	CT/MRI of Head: No	Insufficient information
29 YO Female	Not described	Serum Electrolytes: No	
Ephedra	Not described; >60 days (chronic)	Glucose: No	
FDA Case		Calcium: No	
(10964)		Magnesium: No Temperature: No	
		EEG: No	
		ILLG. NU	

^{*} dose reported in total daily alkaloids

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

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

Event type			
Age, Sex Constituent	Draduct		
Source	Product Dose*		
(ID)	Timing; Duration	Investigation for Etiology	RAND Classification
Seizure	Nature's Nutrition-Formula One	CT/MRI of Head: Yes	Insufficient information
37 YO Male	Not described	Serum Electrolytes: Yes	
Ephedra	6-24 hours; 14-60 days (acute)	Glucose: Yes	
FDA Case		Calcium: Yes	
(11316)		Magnesium: Yes	
		Temperature: Yes	
		EEG: Yes	
Seizure	Fit America Intnl Weight Control Aid	CT/MRI of Head: No	Insufficient information
34 YO Female	Not described	Serum Electrolytes: Yes	
Ephedra FDA Case	Not described; 2-13 days	Glucose: Yes Calcium: Yes	
(11594)		Magnesium: Yes	
(11394)		Temperature: Yes	
		EEG: Yes	
Seizure	Up Your Gas	CT/MRI of Head: No	Insufficient information
15 YO Male	Not described	Serum Electrolytes: No	
Ephedra	<6 hours; <48 hours	Glucose: No	
FDA Case		Calcium: No	
(12477)		Magnesium: No	
		Temperature: No	
Seizure	Escalation	EEG: No CT/MRI of Head: No	Insufficient information
Age Not	Not described	Serum Electrolytes: No	
described,	Not described; 2-13 days	Glucose: No	
Female	Tet decembed, 2 Te days	Calcium: No	
Ephedra		Magnesium: No	
FDA Case		Temperature: No	
(12948)		EEG: No	
Seizure	E-Z Trim Tablets	CT/MRI of Head: Yes	Insufficient information
42 YO Female	24 mg	Serum Electrolytes: Yes	
Ephedra FDA Case	Not described; 2-13 days	Glucose: Yes Calcium: Yes	
(13110)		Magnesium: Yes	
(13110)		Temperature: Yes	
		EEG: Yes	
Seizure	Metabolift	CT/MRI of Head: No	Insufficient information
53 YO Female	Not described	Serum Electrolytes: No	
Ephedra	<6 hours; 14-60 days (acute)	Glucose: No	
FDA Case		Calcium: No	
(13514)		Magnesium: No	
		Temperature: No	
		EEG: No	

^{*} dose reported in total daily alkaloids

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

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^{*} dose reported in total daily alkaloids

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

Event type Age, Sex Constituent	Product		
Source	Dose*		
(ID)	Timing; Duration	Investigation for Etiology	RAND Classification
Seizure	Thermo-Gen Not described 6-24 hours; >60 days (chronic)		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
42 YO Female Ephedra FDA Case (14297)	Natural Trim Not described 6-24 hours; <48 hours	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

Table 22. Evidence table of case reports – Psychiatric

Event type			
Age, Sex	Product		
Constituent	Dose*		
Source	Duration	Investigation for	
(ID)	Addiction Data**	Etiology***	RAND Classification
Psychosis, Sleep	1	Psychiatric History: No	Sentinel Event
disturbance,	Not described	Other Substances/Meds:	
Palpitations, Dizzy	<48 hours	No	
21 YO Male	Addiction: No		
Ephedra			
FDA Case (9509)			
Psychosis,	Diet Now	Psychiatric History: No	Sentinel Event
Hallucinations, Sleep	12 mg	Other Substances/Meds:	
disturbance	Over 1 year	No	
39 YO Female	Addiction: No		
Ephedra			
FDA Case (11678)			
Mania or severe	Hydroxycut	Psychiatric History: No	Sentinel Event
agitation, Suicidal	Not described	Other Substances/Meds:	
ideation, Violent,	2-13 days	No	
Personality changes,	Addiction: No		
Headache			
19 YO Female			
Ephedra			
FDA Case (13809)			
Psychosis, Mania or	Xenadrine	Psychiatric History: No	Sentinel Event
severe agitation,	Not described	Other Substances/Meds:	
Severe depression,	60 days to 1 year	No	
Suicidal ideation,	Addiction: No		
Sleep disturbance,			
Homicidal ideation			
29 YO Male			
Ephedra			
FDA Case (14529)			
Mania or severe	Max Alert	Psychiatric History: No	Sentinel Event
agitation, Ventricular	Mini Thin	Other Substances/Meds:	
tachycardia /	Not described	No	
fibrillation, Insomnia,	60 days to 1 year		
Violent	Addiction: Yes		
16 YO Male			
Ephedrine (10.55004)			
FDA Case (1855921)		D 1: 1: 1: 1: 1	0 (: 15 (
Mania or severe	Ma huang/Ephedra	Psychiatric History: No	Sentinel Event
agitation, Sleep	Not described	Other Substances/Meds:	
disturbance	14-60 days (acute)	No	
45 YO Male	Addiction: No		
Ephedra			
Literature Case (48)		<u> </u>	

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

Event type			
Age, Sex	Product		
Constituent	Dose*		
Source		Investigation for	
		Investigation for	BAND Classification
(ID)	Addiction Data**	Etiology***	RAND Classification
Psychosis, Paranoia		Psychiatric History: No	Sentinel Event
30 YO Female	144 mg	Other Substances/Meds:	
Ephedrine	J	No	
Literature Case (238)	Addiction: Yes		
Psychosis,		Psychiatric History: No	Sentinel Event
Hallucinations,	360 mg	Other Substances/Meds:	
Confusion/Delusional		No	
59 YO Male	Addiction: No		
Ephedrine			
Literature Case (285)			
Severe depression,	Slim NRG+	Psychiatric History: No	Possible Sentinel
Suicide attempt	Not described	Other Substances/Meds:	Event
28 YO Female	60 days to 1 year	No	
Ephedra	Addiction: No		
FDA Case (9751)			
Psychosis, Suicidal	Ripped Fuel	Psychiatric History: No	Possible Sentinel
ideation, Palpitations,	Not described	Other Substances/Meds:	Event
Increased		No	
hypertension,	Addiction: No		
19 YO Male			
Ephedra			
FDA Case (11157)			
Psychosis,	Nature's Nutrition-Formula One	Psychiatric History: No	Possible Sentinel
Hallucinations,	Not described	Other Substances/Meds:	Event
Memory Loss		No	Lvent
13 YO Female	Addiction: No		
Ephedra	Addiction: No		
FDA Case (12372)			
Mania or severe	Ripped Fuel	Psychiatric History: No	Possible Sentinel
agitation, Sleep	Not described	Other Substances/Meds:	Event
disturbance			LVCIIL
	14-60 days (acute) Addiction: No	No	
21 YO Male	Addiction. No		
Ephedra			
FDA Case (13005)	Matala O Lita	Davida del a 1 P. 4	Describbe Oscillator
Psychosis,		Psychiatric History: No	Possible Sentinel
Hallucinations	Not described	Other Substances/Meds:	Event
52 YO Female		No	
Ephedra (44400)	Addiction: No		
FDA Case (14436)	1		

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

Event type Age, Sex Constituent Source (ID) Psychosis, Suicide attempt, Insomnia, Ventricular tachycardia / fibrillation, Dizzy 28 YO Female Ephedra FDA Case (14528)	Addiction Data** Metab-O-Lite Not described 60 days to 1 year Addiction: No	Psychiatric History: No Other Substances/Meds: No	RAND Classification Possible Sentinel Event
Psychosis, Addiction/Substance Abuse, Paranoia 31 YO Male Ephedrine FDA Case (1661966)	up to 1250 mg / day	, ,	Possible Sentinel Event
Psychosis, Mania or severe agitation, Hallucinations, Paranoia 34 YO Male Ephedra Literature Case (79)	Not described 2-13 days Addiction: No	No	Possible Sentinel Event
Psychosis, Sleep disturbance, Headache 40 YO Female Ephedra FDA Case (9060)			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	Other Substances/Meds: Yes	Inconclusive – Prior psychiatric history
Severe depression, Suicidal ideation 38 YO Female Ephedra FDA Case (9727)	>60 days (chronic) Addiction: No	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		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			
	Draduct		
Age, Sex Constituent	Product		
	Dose*		
Source	Duration	Investigation for	DAND OLIVISION
(ID)	Addiction Data**	Etiology***	RAND Classification
Psychosis, Insomnia	Therachrome	Psychiatric History: Yes	Inconclusive – Prior
43 YO Female	Not described	Other Substances/Meds:	psychiatric history
Ephedra	60 days to 1 year	No	
FDA Case (9403)	Addiction: No		
Psychosis, Violent	Diet Gel	Psychiatric History: Yes	Inconclusive – Prior
39 YO Male	Not described	Other Substances/Meds:	psychiatric history
Ephedra	Not described	Yes	
FDA Case (10042)	Addiction: No		
Psychosis, Mania or	Ripped Force	Psychiatric History: Yes	Inconclusive – Prior
severe agitation, Sleep	Not described	Other Substances/Meds:	psychiatric history
disturbance	60 days to 1 year	Yes	, ,
17 YO Male	Addiction: No		
Ephedra			
FDA Case (10078)			
Psychosis, Severe	Mini Thin	Psychiatric History: Yes	Inconclusive – Prior
depression,	285 mg	Other Substances/Meds:	psychiatric history
Suicide attempt,	60 days to 1 year	No	
Addiction/Substance	Addiction: Yes		
Abuse			
38 YO Female			
Ephedra/Ephedrine			
FDA Case (11052)			
Psychosis, Mania or	Up Your Gas	Psychiatric History: Yes	Inconclusive – Prior
severe agitation,	Not described	Other Substances/Meds:	psychiatric history
Violent,	Not described	No	poyernaulo metery
Addiction/Substance	Addiction: Yes		
Abuse			
17 YO Male			
Ephedra			
FDA Case (11096)			
Severe depression,	Nature's Nutrition-Formula One	Psychiatric History: Yes	Inconclusive – Prior
Anxiety, Headache	Not described	Other Substances/Meds:	psychiatric history
31 YO Male	>60 days (chronic)	Yes	, - ,
Ephedra	Addiction: No		
FDA Case (11145)			
Violent	Up Your Gas	Psychiatric History: Yes	Inconclusive – Prior
35 YO Male	Not described	Other Substances/Meds:	psychiatric history
Ephedra	14-60 days (acute)	Yes	poyoniati io riistory
FDA Case (11289)	Addiction: No	163	
DA Case (11203)	Addiction: NO		1

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

E 4 4			1
Event type			
Age, Sex	Product		
Constituent	Dose*		
Source	Duration	Investigation for	
(ID)	Addiction Data**	Etiology***	RAND Classification
Severe depression,		Psychiatric History: Yes	Inconclusive – Prior
Addiction/Substance	Not described	Other Substances/Meds:	psychiatric history
Abuse, Sleep	60 days to 1 year	Yes	
disturbance	Addiction: Yes		
38 YO Female			
Ephedra			
FDA Case (11651)			
Psychosis	M-80 pills	Psychiatric History: Yes	Inconclusive – Prior
34 YO Female	Not described	Other Substances/Meds:	psychiatric history
Ephedra	60 days to 1 year	No	
FDA Case (11717)	Addiction: No		
Severe depression,	Herbalife Original Green	Psychiatric History: Yes	Inconclusive – Prior
Suicidal ideation	Not described	Other Substances/Meds:	psychiatric history
57 YO Female	14-60 days (acute)	No	
Ephedra	Addiction: No		
FDA Case (11828)			
Mania or severe	Caloslim	Psychiatric History: Yes	Inconclusive – Prior
agitation, Suicidal	Not described	Other Substances/Meds:	psychiatric history
ideation, Cyclothymia	>60 days (chronic)	No	
15 YO Female	Addiction: No		
Ephedra			
FDA Case (13072)			
Psychosis, Mania or	Mini Thin	Psychiatric History: Yes	Inconclusive – Prior
severe agitation,	75 mg	Other Substances/Meds:	psychiatric history
Hallucinations, Sleep	Not described	No	
disturbance, Migraine	Hydroxycut		
20 YO Male	Not described		
Ephedra/Ephedrine	60 days to 1 year		
FDA Case (13099)	Addiction: No		
Severe depression	Xenadrine	Psychiatric History: Yes	Inconclusive – Prior
28 YO Female	Not described	Other Substances/Meds:	psychiatric history
Ephedra	60 days to 1 year	No	
FDA Case (14089)	Addiction: No		
Mania or severe	Up Your Gas	Psychiatric History: Yes	Inconclusive – Prior
agitation, Severe	Not described	Other Substances/Meds:	psychiatric history
depression,	Over 1 year	No	
Addiction/Substance	Addiction: Yes		
Abuse			
29 YO Female			
Ephedra			
FDA Case (14276)			

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

F	<u> </u>		1
Event type Age, Sex	Product		
Constituent	Dose*		
Source	Duration	Investigation for	
(ID)	Addiction Data**	Etiology***	RAND Classification
Psychosis, Severe	Hydroxycut	Psychiatric History: Yes	Inconclusive – Prior
depression, Insomnia	Not described	Other Substances/Meds:	psychiatric history
17 YO Male	2-13 days	Yes	psychiatric mistory
Ephedra	Addiction: No	163	
FDA Case (14294)	Addiction: No		
Psychosis, Severe	Fen-Chi	Psychiatric History: Yes	Inconclusive – Prior
depression, Motor	Not described	Other Substances/Meds:	
vehicle accident,	14-60 days (acute)	Yes	psychiatric history
Paranoia,	Addiction: No	res	
Confusion/Delusional	Addiction. No		
42 YO Female			
Ephedra			
II •			
FDA Case (14394)	Harbalifa Original Croop	Dovebietrie Hietery: Voe	Inconclusive Drier
Psychosis, Suicide/Suicide	Herbalife Original Green Not described	Psychiatric History: Yes Other Substances/Meds:	Inconclusive – Prior
			psychiatric history
attempt,	>60 days (chronic)	Yes	
Hallucinations,	Addiction: No		
Anxiety, Paranoia			
36 YO Female			
Ephedra			
FDA Case (14493)	Markete elife 050	Davida de la Ulataria Va	la a an alvair a Daian
Mania or severe	Metabolife 356	Psychiatric History: Yes	Inconclusive – Prior
agitation,	Not described	Other Substances/Meds:	psychiatric history
Hallucinations	60 days to 1 year	Yes	
32 YO, Sex Not	Addiction: No		
described			
Ephedra (4.45.44)			
FDA Case (14541)			
Psychosis, Severe	Metabolift	Psychiatric History: Yes	Inconclusive – Prior
depression, Suicidal	Not described	Other Substances/Meds:	psychiatric history
ideation,	14-60 days (acute)	Yes	
Hallucinations,	Addiction: No		
Insomnia			
22 YO Female			
Ephedra			
FDA Case (14543)			
Psychosis, Mania or	Metabolife 356	Psychiatric History: Yes	Inconclusive – Prior
severe agitation	Not described	Other Substances/Meds:	psychiatric history
20 YO Male	>60 days (chronic)	Yes	
Ephedra	Addiction: No		
Literature Case (136)			

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

Event type			
Age, Sex	Product		
Constituent	Dose*	larra atimatia a fa a	
Source	Duration	Investigation for	DAND Classification
(ID)	Addiction Data**	Etiology***	RAND Classification
Severe depression,	Metabolife 356	Psychiatric History: Yes	Inconclusive – Prior
Suicidal ideation,	Not described	Other Substances/Meds:	psychiatric history
Violent	Over 1 year	No	
27 YO Male	Addiction: No		
Ephedra			
Literature Case (136)	Dun do at Natida a silla a	Davida dela Lilata de Was	La caracterativa Delan
Mania or severe	Product Not described	Psychiatric History: Yes	Inconclusive – Prior
agitation, Severe	Not described	Other Substances/Meds:	psychiatric history
depression 40 YO Female	Over 1 year Addiction: No	Yes	
	Addiction: No		
Ephedra Literature Case (519)			
	Natura's Nutrition Formula One	Dayahistria History, No.	Inconclusive – Other
Psychosis, Suicidal	Nature's Nutrition-Formula One Not described	Other Substances/Meds:	
ideation, Anxiety, Dizzy, Increased	60 days to 1 year	Yes	meds / substances
hypertension	Addiction: No	165	
33 YO Female	Addiction: No		
Ephedra			
FDA Case (9516)			
Mania or severe	Nature's Nutrition-Formula One	Psychiatric History: No.	Inconclusive – Other
agitation, Suicidal	Not described	Other Substances/Meds:	meds / substances
ideation, Sleep	14-60 days (acute)	Yes	meds / substances
disturbance	Addiction: No	103	
45 YO Male	Addiction: No		
Ephedra			
FDA Case (10233)			
Psychosis, Catatonia	Nature's Super Cap	Psychiatric History: No	Inconclusive – Other
36 YO Male	99mg	Other Substances/Meds:	meds / substances
Ephedra	Thermadrene	Yes	
FDA Case (12488)	Just Be Natural		
	Gorilla Nitro Plus		
	Mega Creatine Fuel		
	Bolt		
	Not described		
	Over 1 year		
	Addiction: No		

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

Event type			
Age, Sex	Product		
Constituent	Dose*		
		Investigation for	
Source	Duration Detait	Investigation for	DAND Classification
(ID)	Addiction Data**	Etiology***	RAND Classification
Mania or severe	Metacuts	Psychiatric History: No	Inconclusive – Other
agitation,	Not described	Other Substances/Meds:	meds / substances
Hallucinations,	>60 days (chronic)	Yes	
Headache, Sleep	Addiction: No		
disturbance, Irregular			
heart rate			
19 YO Male			
Ephedra/Ephedrine			
FDA Case (13370)			
Psychosis, Mania or	Xenadrine	Psychiatric History: No	Inconclusive - Other
severe agitation,	40 mg	Other Substances/Meds:	meds / substances
Hallucinations, Motor	2-13 days	Yes	
vehicle accident, Sleep			
disturbance			
27 YO Female			
Ephedra			
FDA Case (13526)			
Severe depression,	Ripped Force	Psychiatric History: No	Inconclusive – Other
Suicidal ideation,	Not described	Other Substances/Meds:	meds / substances
Sleep disturbance	60 days to 1 year	Yes	inicus / substances
15 YO Male	Addiction: No	163	
Ephedra	radiotion. No		
FDA Case (14082)			
Psychosis,	Thermogenics Plus	Psychiatric History: No	Inconclusive – Other
Suicide attempt	Not described	Other Substances/Meds:	meds / substances
Age Not described,	Over 1 year	Yes	illeus / substances
Female	Addiction: No	165	
	Addiction: No		
Ephedra			
FDA Case (14213)	Diet Fuel	Develorie History No	Incomplyaive Other
Mania or severe		Psychiatric History: No	Inconclusive – Other
agitation, Severe	Not described	Other Substances/Meds:	meds / substances
depression, Aneurysm,	, ,	Yes	
ruptured cerebra,	Addiction: No		
Encephalopathy			
Age Not described,			
Male			
Ephedra (4.4997)			
FDA Case (14287)			
Psychosis,	Metabolife 356	Psychiatric History: No	Inconclusive – Other
Hyperkalemia	Not described	Other Substances/Meds:	meds / substances
37 YO Female	14-60 days (acute)	Yes	
Ephedra	Addiction: No		
FDA Case (14300)			
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Table 22. Evidence table of case reports – Psychiatric (continued)

Event type			
Age, Sex	Product		
Constituent	Dose*		
Source	Duration	Investigation for	
(ID)	Addiction Data**		RAND Classification
Psychosis, Sleep	Metabolife 356	Psychiatric History: No	Inconclusive – Other
disturbance,	Not described		meds / substances
Confusion/Delusional	>60 days (chronic)	Yes	
36 YO Female	Addiction: No		
Ephedra (4.4.7.48)			
FDA Case (14546)			
Psychosis	Up Your Gas	Psychiatric History: No	Inconclusive – Other
39 YO Female	Not described		meds / substances
Ephedra	Over 1 year	Yes	
FDA Case (14575)	Addiction: No		
Psychosis, Mania or	Metabolife 356	Psychiatric History: No	Inconclusive – Other
severe agitation,	Not described		meds / substances
Confusion/Delusional,	14-60 days (acute)	Yes	
Headache	Addiction: No		
54 YO Female			
Ephedra			
FDA Case (14582)			
Psychosis,	Ripped Fuel	Psychiatric History: No	Insufficient Information
Hallucinations	Not described	Other Substances/Meds:	
Age Not described,	60 days to 1 year	No	
Female	Addiction: No		
Ephedra			
FDA Case (10019)			
Psychosis, Irregular	Diet Max	Psychiatric History: No	Insufficient Information
heart rate, Insomnia,	Not described	Other Substances/Meds:	
Dizzy, Gastrointestinal		No	
problems	Addiction: No		
24 YO Female			
Ephedra			
FDA Case (10614)			
Hallucinations,	Herbal Ecstasy	Psychiatric History: No	Insufficient Information
Nausea, Dizzy,	Not described	Other Substances/Meds:	
Headache	<48 hours	Yes	
20 YO Male	Addiction: No		
Ephedra			
FDA Case (11131)			
Anxiety, Palpitations	Ripped Fuel	Psychiatric History: No	Insufficient Information
25 YO Male	Not described	Other Substances/Meds:	
Ephedra	14-60 days (acute)	No	
FDA Case (11354)	Addiction: No		

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

Event type Age, Sex Constituent Source (ID) Hallucinations Age Not described, Sex Not described Ephedra FDA Case (12368)	Product Dose* Duration Addiction Data** Power Trim Not described Not described Addiction: No	Investigation for Etiology*** Psychiatric History: No Other Substances/Meds: No	RAND Classification 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)

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		DANID OLGGESS STATE
		RAND Classification
		Inconclusive – Prior
		psychiatric history
	Yes	
Addiction: Yes		
		Inconclusive – Prior
	Other Substances/Meds:	psychiatric history
	Yes	
Addiction: No		
		Inconclusive – Prior
	Other Substances/Meds:	psychiatric history
	Yes	
Addiction: Yes		
		Inconclusive – Prior
		psychiatric history
	Yes	
Addiction: No		
		Inconclusive – Prior
		psychiatric history
	No	
Addiction: No		
l •		Inconclusive – Prior
		psychiatric history
	No	
Addiction: No		
1		1
	Addiction Data** Mini Thin Not described Over 1 year Addiction: Yes Do-Do Tablet or Herbal Balance 18.31 mg <48 hours Addiction: No Ephedrine Not described Over 1 year Addiction: Yes Black Beauty Not described <48 hours Addiction: No Ephedrine Not described 2-13 days Addiction: No Ephedrine Source Sourc	Dose* Duration Addiction Data** Mini Thin Not described Over 1 year Addiction: Yes Do-Do Tablet or Herbal Balance Psychiatric History: Yes Other Substances/Meds: Yes Do-Do Tablet or Herbal Balance Psychiatric History: Yes 18.31 mg <48 hours Addiction: No Ephedrine Not described Over 1 year Addiction: Yes Black Beauty Not described <48 hours Addiction: Yes Black Beauty Not described <48 hours Addiction: No Ephedrine Not described 2-13 days Addiction: No Psychiatric History: Yes Other Substances/Meds: No Other Substances/Meds: No Other Substances/Meds: No Other Substances/Meds: No Other Substances/Meds: No

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

Event type			
Event type	Draduct		
Age, Sex Constituent	Product		
1	Dose*		
Source	Duration	Investigation for	DANID OLDERIGE
(ID)	Addiction Data**	Etiology***	RAND Classification
Suicide attempt,	Product Not described	Psychiatric History: Yes	Inconclusive – Prior
Ventricular tachycardia		Other Substances/Meds:	psychiatric history
/ fibrillation	<48 hours	No	
20 YO Female	Addiction: No		
Ephedrine			
Literature Case (250)			
Psychosis,	Vicks inhaler	Psychiatric History: Yes	Inconclusive – Prior
Hallucinations, Sleep	Not described	Other Substances/Meds:	psychiatric history
disturbance,	Over 1 year	No	
Confusion/Delusional	Addiction: No		
61 YO Male			
Ephedrine			
Literature Case (488)			
Addiction/Substance	Ephedrine	Psychiatric History: Yes	Inconclusive – Prior
Abuse, Palpitations	2500 mg	Other Substances/Meds:	psychiatric history
29 YO Female	Over 1 year	Yes	, , , , , , , , , , , , , , , , , , , ,
Ephedrine	Addiction: Yes		
Literature Case (493)			
Addiction/Substance	Ephedrine	Psychiatric History: Yes	Inconclusive – Prior
Abuse	2500 mg	Other Substances/Meds:	psychiatric history
23 YO Male	60 days to 1 year	Yes	poyermanio
Ephedrine Ephedrine	Addiction: Yes		
Literature Case (493)			
Addiction/Substance	Ephedrine	Psychiatric History: Yes	Inconclusive – Prior
Abuse, Sleep	1500 mg	Other Substances/Meds:	psychiatric history
disturbance,	60 days to 1 year	Yes	Poyernative riletery
Palpitations	Addiction: Yes		
22 YO Male	radiotion: 100		
Ephedrine			
Literature Case (493)			
Job Loss, Motor	Ephedrine	Psychiatric History: Yes	Inconclusive – Prior
vehicle accident	1000 mg	Other Substances/Meds:	psychiatric history
33 YO Male	Over 1 year	Yes	psychiatric history
Ephedrine	Addiction: No		
Literature Case (493)	Addiction. NO		
Psychosis,	Ephedrine	Psychiatric History: No	Inconclusive – Other
	Not described	Other Substances/Meds:	
Addiction/Substance			substances involved
Abuse	Not described	Yes	
35 YO Male	Addiction: Yes		
Ephedrine			
FDA Case (130741)	<u></u>	<u> </u>	J

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

Event type			
Age, Sex	Product		
Constituent	Dose*		
Source		Investigation for	
	Duration		DAND Classification
(ID)	Addiction Data**	Etiology***	RAND Classification
Psychosis, Mania or	Marax	Psychiatric History: No	Inconclusive – Other
severe agitation	125 mg	Other Substances/Meds:	meds / substances
19 YO Male	14-60 days (acute)	Yes	
Ephedrine	Addiction: No		
Literature Case (490)			
Addiction/Substance	Ephedrine	Psychiatric History: No	Inconclusive – Other
Abuse	1500 mg	Other Substances/Meds:	meds / substances
33 YO Female	Over 1 year	Yes	
Ephedrine	Addiction: Yes		
Literature Case (493)			
Psychosis, Paranoia,	Ephedrine	Psychiatric History: No	Inconclusive – Other
Violent, Impotence	Not described	Other Substances/Meds:	substances involved
65 YO Male	Over 1 year	Yes	
Ephedrine	Addiction: Yes		
Literature Case (120)			
Psychosis, Mania or	Thermolift	Psychiatric History: No	Not related –
severe agitation,	Not described	Other Substances/Meds:	exacerbation of
Severe depression,	14-60 days (acute)	No	previously
Hallucinations	Addiction: No		undiagnosed bipolar
27 YO Female			disorder
Ephedrine			
FDA Case (14542)			
Psychosis,	Mini Thin	Psychiatric History: No	Product taken solely
Suicide attempt,	Not described	Other Substances/Meds:	as suicide attempt
Paranoia,	14-60 days (acute)	No	
Confusion/Delusional	Addiction: Yes		
46 YO Male			
Ephedrine			
FDA Case (94799)			
Suicide attempt	Max Alert	Psychiatric History: No	Product taken solely
19 YO Male	Not described	Other Substances/Meds:	as suicide attempt
Ephedrine	Not described	No	Service attempt
FDA Case (1454817)	Addiction: No		
Suicide attempt,	RJ8	Psychiatric History: No	Product taken solely
Arrhythmia (NOS)	Not described	Other Substances/Meds:	as suicide attempt
14 YO Female	<48 hours	No	ao saloido attorript
Ephedrine	Addiction: No		
Literature Case (281)	, tadiotion. 140		
Literature Case (201)		_l	<u>l</u>

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

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