

Enforcement and Administrative Actions taken against firms for failure to notify FDA of a new dietary ingredient

Firm type	Firm name	Enforcement or Administrative Action	Issue date	NDI	Product name	Notes
Domestic	H&L Jerch Inc. (d.b.a.) Bell Lifestyle Products	Regulatory Meeting	4/11/2012	spermine and spermidine	Spermelene	
Domestic	Fahrenheit Nutrition	Warning Letter	4/24/2012	DMAA or methylhexanamine	Lean Efx	
Domestic	Formulife, Inc.	Warning Letter	4/24/2012	DMAA or methylhexanamine	Fat Smackm XR Thermolipolytic, Muscle Marinade® Fresh Fruit, and Muscle Marinade® Cherry Limeade	
Domestic	USP Labs, LLC	Warning Letter	4/24/2012	DMAA or methylhexanamine	Oxy Elite Pro and Jack3D	
Domestic	SNI LLC	Warning Letter	4/24/2012	DMAA or methylhexanamine	Nitric Blast	
Domestic	SEI Pharmaceuticals	Warning Letter	4/24/2012	DMAA or methylhexanamine	MethylHex 4,2	
Domestic	Gaspari Nutrition, Inc.	Warning Letter	4/24/2012	DMAA or methylhexanamine	Spirodex	
Domestic	Muscle Warfare Inc.	Warning Letter	4/24/2012	DMAA or methylhexanamine	Napalm	
Domestic	Exclusive Supplements, Inc.	Warning Letter	4/24/2012	DMAA or methylhexanamine	Biorhythm SSIN Juice	
Domestic	Muscle Meds Performance Technologie	Warning Letter	4/24/2012	DMAA or methylhexanamine	Code Red	
Domestic	Nutrex Research, Inc.	Warning Letter	4/24/2012	DMAA or methylhexanamine	Hemo Rage Black, Lipo-6 Black Ultra Concentrate, Lipo-6 Black, Lipo-6 Black Hers Ultra Concentrate and Lipo-6 Black Hers	
Domestic	iSatori Global Technologies, LLC	Warning Letter	4/24/2012	DMAA or methylhexanamine	PWR	
Foreign	Teguh Ap	Detention	4/24/2012	Mitragyna Speciosa (kratom)	Mitragyna Speciosa (kratom)	
Domestic	Regeneca	Warning Letter	8/28/2012	DMAA or methylhexanamine	RegeneSlim	(b) (7)(A), (b) (5)
Foreign	Cv Mandiri Bersama	Detention	9/21/2012	Mitragyna Speciosa Powder (Kratom)	Mitragyna Speciosa Powder (Kratom)	
Domestic	VPX Redline Nutrex Research, Inc. BPI Sports USPlabs lovate Health Sciences USA Inc.	Detention	9/24/2012	DMAA or methylhexanamine	Rx6 Ultra Concentrated Fat Loss, Redline Ultra Hardcore, OxyElite Pro Super Thermogenic, Lipo 6 Hers black, Lipo 6 black, Jack3d (tropical fruit punch), Jack3d (lemon-lime) and Hemo Rage black and Hemo Rage black ultra concentrate	

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Foreign	Shanghai Y ongyi Biotechnology Co Ltd	Detention	10/15/2012	DMAA or methylhexanamine	1,3 Dimethylamine	
Foreign	Sinochem Jiangsu	Detention	10/15/2012	Beta-Methylphenylethylamine	Beta-Methylphenylethylamine	
Domestic	Quincy Bioscience Manufacturing Inc.	Warning Letter	10/16/2012	Apoaequorin	Prevagen	(b) (7)(A), (b) (5)
Foreign	Faisal Putra Perdana	Detention	11/14/2012	Mitragyna Speciosa (kratom)	Mitragyna Speciosa (kratom)	
Foreign	Malaspina Gifts	Detention	1/7/2013	Kratom	Spiritual Herb Intense Euphoric, Spiritual Herb Green Goddess and Spiritual Herb All Natural Blend	
Foreign	BC Ltd.	Detention	1/29/2013	Mitragyna Speciosa (kratom)	Research Herbs	
Foreign	Bintang Data	Detention	4/3/2013	Mitragyna javnica	Mitragyna javnica	
Foreign	PTA Trading	Detention	5/7/2013	Mitragyna	Mitragyna	
Foreign	Three Ocean Export	Detention	5/21/2013	Mitragyna speciosa Dried leaf	Mitragyna speciosa Dried leaf	
Domestic	USP Labs, LLC	Administrative Detention Order (ADO)	6/24/2013	DMAA or methylhexanamine	Oxy Elite Pro and Jack3D	
Domestic	Pure Energy Products, Inc.	Warning Letter	9/6/2013	DMAA or methylhexanamine	Obestrim	
Domestic	USP Labs, LLC	Warning Letter	10/11/2013	Aegeline, also referred to as N-[2-hydroxy-2(4-methoxyphenyl) ethyl]-3-phenyl-2-propenamide	Oxy Elite Pro and VERSA-1	
Domestic	Young You International, Inc.	Recall	1/30/2014	DMAA or methylhexanamine	Megaslim Herbal Appetite Management	
Domestic	Exclusive Supplements Inc.	Warning Letter	1/31/2014	4-etioallocholen-3,6,17-trione	BioRhythm Androbolix	

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Foreign	Borneo Khatulistiwa	Detention	2/3/2014	Mitragyna Speciosa	Mitragyna Speciosa	
Foreign	Nutraland Limited	Detention	3/24/2014	Pyrrroloquinoline Quinone Disodium Salt (PQQ)	Pyrrroloquinoline Quinone Disodium Salt (PQQ)	
Domestic	Driven Sports Inc.	Warning Letter	4/4/2014	Dendrobex	CRAZE	
Foreign	Alpak Shoservices Bv.	Detention	6/10/2014	Palmitoylethanolamide	PeaPure	
Foreign	Shanghai Waseta International Trading Co. Ltd	Detention	10/10/2014	DMBA or 1,3-Dimethylbutylamine	1,3-dimethlybutylamine HCL 1,3-dimethlybutylamine Citrate	
Foreign	Aviva Pharmaceuticals Ltd	Detention	3/30/2015	Synephrine HCL	Synephrine HCL	
Domestic	Vital Pharmaceuticals	Warning Letter	4/24/2015	DMBA or 1,3-Dimethylbutylamine	VPX Redline White Heat (strawberry, fruit punch, and watermelon) and MD2 Meltdown	
Domestic	Nutrex Research, Inc.	Warning Letter	4/24/2015	DMBA or 1,3-Dimethylbutylamine	Adipodex	
Domestic	Powder City LLC	Warning Letter	4/24/2015	DMBA or 1,3-Dimethylbutylamine	AMP Citrate	
Domestic	Prime Nutrition	Warning Letter	4/24/2015	DMBA or 1,3-Dimethylbutylamine	PWO/STIM	
Domestic	Beta Labs	Warning Letter	4/24/2015	DMBA or 1,3-Dimethylbutylamine	Oxyphen XR Amp'd™	
Domestic	Genomyx LLC	Warning Letter	4/24/2015	DMBA or 1,3-Dimethylbutylamine	EVOL	
Domestic	Iron Forged Nutrition d/b/a TGB Supplements	Warning Letter	4/24/2015	DMBA or 1,3-Dimethylbutylamine	Contraband	
Domestic	Blackstone Labs LLC	Warning Letter	4/24/2015	DMBA or 1,3-Dimethylbutylamine	Angel Dust	
Domestic	1ViZN LLC	Warning Letter	4/24/2015	DMBA or 1,3-Dimethylbutylamine	Velocity	
Domestic	Core Nutritionals LLC	Warning Letter	4/24/2015	DMBA or 1,3-Dimethylbutylamine	AMP Citrate	
Domestic	RPM Nutrition, LLC	Warning Letter	4/24/2015	DMBA or 1,3-Dimethylbutylamine	Red Rum SS	
Domestic	Brand New Energy LLC	Warning Letter	4/24/2015	DMBA or 1,3-Dimethylbutylamine	Yellow Bullet AMP	
Domestic	DSEO LLC	Warning Letter	4/24/2015	DMBA or 1,3-Dimethylbutylamine	HybriLean and PREAMP	
Domestic	Lecheek Nutrition	Warning Letter	4/24/2015	DMBA or 1,3-Dimethylbutylamine	AMPilean and AMPitropin	
Domestic	Cody Pederson	Import Alert	6/2/2015	Mitragyna Speciosa (Kratom)	Mitragyna Speciosa (Kratom)	
Domestic	Nathan John Watters	Import Alert	6/2/2015	Mitragyna Speciosa (Kratom)	Mitragyna Speciosa (Kratom)	
Foreign	Cv Anugrah	Detention	Open case	Mitragyna Speciosa (kratom)	Mitragyna Speciosa (Kratom)	
	(b) (7)(A), (b) (5)					
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