

Supplement Company Name	Reason for Enforcement Action (*this could have resulted from an establishment inspection, website review or import entry review)	Date of Initial contact	Description of First Enforcement Action	Company Response, Including Date	Descriptions of Subsequent Actions, Including Dates, Company Response and Outcome	Was this matter referred to another Agency: if yes, please provide the name of the agency and a description of the outcome.	Is this matter closed? If yes, provide the closing date.
Novacare	Failure to conform with 403(r)(6)	Issued 12/28/10	Warning letter	Firm response not in case	No subsequent actions	(b) (7)(A), (b) (5)	
Unlimited Nutrition	Failure to conform with 403(r)(6)	Issued 8/30/10	Warning letter	No response from firm in case	No subsequent actions		
Prolatis	Failure to conform with 403(r)(6)	Issued 12/2/10	Warning letter	Firm responded 12/8/10 (voluntary recall)	No subsequent actions		
For Earth Inc.	Unauthorized health claims 403(r)(1)(B)	issued 9/14/11	Warning letter	No response from firm in case	No subsequent actions		
Intelli Health Products, LLC	Failure to conform with 403(r)(6)	Issued 4/27/11	Warning letter	Firm responded 5/13/11 (ceased operations)	No subsequent actions		
VivaCeuticals, Inc. dba Regeneca Worldwide	Failure to conform with 403(r)(6)	Issued 5/25/11	Warning letter	Firm responded (initial) 6/15/11	Warning letter issued 8/28/12 Injunction ongoing (these subsequent actions did not include the unsubstantiated structure/function claims, but were for other reasons)		
Green Planet Inc.	Failure to conform with 403(r)(6)	Issued 12/5/13	Warning Letter	Firm responded 12/20/13, 1/15/14, 7/28/14, 11/5/14	No subsequent actions	No	Yes, 11/12/14

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USA Far Ocean Group Llc and Health & Beauty Group Inc.	Failure to conform with 403(r)(6)	Issued 10/24/12	Warning Letter	No firm response in case	No subsequent actions	(b) (7)(A), (b) (5)	
Vitamins Direct (USA), Inc. and Golden Pride, Inc. (416825/416826) Joint case	Unauthorized health claims 403(r)(1)(B)	Issued 10/20/14	Warning Letter	Firm responded on 11/7/14	No subsequent actions		
Prime Nutri	Failure to conform with 403(r)(6) – label fails to bear FDA disclaimer	Detention request sent 4/3/15, CFSAN decision 5/7/15	Import refused entry	No firm response in case	No subsequent actions	No	N/A
Enerex Botanicals Ltd.	Failure to conform with 403(r)(6)	Detention request sent 7/14/11, CFSAN decision 7/25/11	Import refused entry	No firm response in case	Firm added to Import Alert 66-41 “Detention Without Physical Examination of Unapproved New Drugs Promoted In The U.S.”	No	N/A
	Labels appear to contain claims described under section 403(r)(6) of the Act but fails to bear the statement: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”						

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Accurex Healthcare Mfg Inc	Failure to conform with 403(r)(6) – label fails to bear FDA disclaimer	Detention request sent 1/5/15, CFSA decision 1/16/15	Import refused entry	No firm response in case	Firm added to Import Alert 66-41 “Detention Without Physical Examination of Unapproved New Drugs Promoted In The U.S.”	No	N/A
	Labels appear to contain claims described under section 403(r)(6) of the Act but fails to bear the statement: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”						
Rico Lunch	Unauthorized health claims 403(r)(1)(B)	Detention request sent 4/7/15, CFSA decision 5/14/15	Import refused entry	No firm response in case	No subsequent actions	No	N/A
Erdic International	Failure to conform with 403(r)(6) – label fails to bear FDA disclaimer	Import Alert Notification sent on 7/18/13	Firm added to Import Alert #99-20, “Detention Without Physical Examination of Imported Food Products Due to NLEA Violations.”	No firm response in case	No subsequent actions	No	N/A
	labels appear to contain claims described under section 403(r)(6) of the Act but fails to bear the statement: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”						

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Webber Naturals	Failure to conform with 403(r)(6) – label fails to bear FDA disclaimer	Import Alert Notification sent on 2/25/15	Firm added to Import Alert 66-41 “Detention Without Physical Examination of Unapproved New Drugs Promoted In The U.S.”	No firm response in case	Firm was also added to Import Alert #99-20, “Detention Without Physical Examination of Imported Food Products	No	N/A
	Labels appear to contain claims described under section 403(r)(6) of the Act but fails to bear the statement: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”						
Nestle Canada, Inc.	Unauthorized health claims 403(r)(1)(B)	Import Alert Notification sent on 3/27/15	Firm added to Import Alert 66-41 “Detention Without Physical Examination of Unapproved New Drugs Promoted In The U.S.”	No firm response in case	Firm was also added to Import Alert #99-20, “Detention Without Physical Examination of Imported Food Products	No	N/A