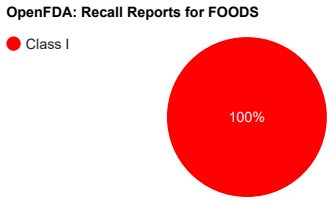
Regulatory Action Search Report - RAW DEAL; Raw Deal, Inc

1. RAW DEAL



	State	Classification	Recalling Firm	Reason	Report Date	Product Type	Product Description	Voluntary or Mandated
1	NJ	Class I	RAW DEAL	Raw Deal is recalling dietary blends which may contain salmonella.	20140521	Food	Cilantro Powder Item #13151 22.5 KGS PO #P41049 Raw Deal Inc. PO Box 412 Allamuchy, NJ 07820 Phone: 973-347-6400 Fax: 973-347-5999 www.raw-deal.net	Voluntary: Firm Initiated
2	NJ	Class I	RAW DEAL	Raw Deal is recalling dietary blends which may contain salmonella.	20140521	Food	Parsley Powder Organic 25 KGS PO# GV93-6 & PO#RV19-4 Raw Deal Inc. PO Box 412 Allamuchy, NJ 07820 Phone: 973-347-6400 Fax: 973-347-5999 www.raw-deal.net	Voluntary: Firm Initiated
3	NJ	Class I	RAW DEAL	Raw Deal is recalling dietary blends which may contain salmonella.	20140521	Food	Adult Herbal Blend 992 Item #H039 30 KGS PO#33590 Raw Deal Inc. PO Box 412 Allamuchy, NJ 07820 Phone: 973-347-6400 Fax: 973-347-5999 www.raw-deal.net	Voluntary: Firm Initiated

Found recalls at OpenFDA [1]

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2. Raw Deal, Inc

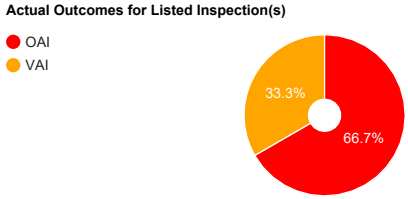
Recall Type	Classification	Number of Reports
FOOD	Class I	3

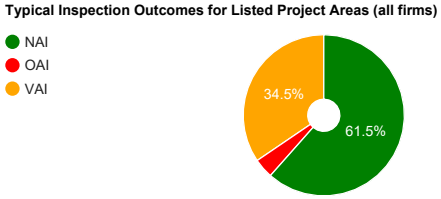
This may be a duplicate from the first list. Click button to check.

Found 1 **FDA Warning Letter(s)**[2]

Firm Name	Issue Date	Office	Subject	Closeout Date?
Raw Deal, Inc	2013-11-21	New Jersey District Office	Dietary Supplement/Adulterated	

Found 3 **FDA inspections with classifications**[3]





District	Firm Name	City	State	Zip	Country	Inspection End Date	Center	Project Area	District Decision†
NWJ	Raw Deal, Inc	Flanders	NJ	07836-9642	US	2014-03-21	CFSAN	Food Composition, Standards, Labeling and Econ	VAI
NWJ	Raw Deal, Inc	Flanders	NJ	07836-9642	US	2013-05-06	CFSAN	Foodborne Biological Hazards	OAI
NWJ	Raw Deal, Inc	Flanders	NJ	07836-9642	US	2012-03-08	CFSAN	Food Composition, Standards, Labeling and Econ	OAI

† FDA Classification (District Decision) NAI = No Action Indicated (no 483); VAI = Voluntary Action Indicated (483 issued); OAI = Official Action Indicated (483 Issued and may indicate risk of a Warning Letter)

Found 13 **'Form 483' observation(s)**[4],[5]

	Firm Name	Inspection End Date	CFR #	Long Description	Fiscal Year
1	Raw Deal, Inc	2012-03-08	21 CFR 110.10(b)(1)	Suitable outer garments are not worn that protect against contamination of food, food contact surfaces, and food packaging materials.	2012
2	Raw Deal, Inc	2012-03-08	21 CFR 110.10(b)(9)	Failure to take necessary precautions to protect against contamination of food, food contact surfaces, and food packaging systems with microorganisms and foreign substances.	2012
3	Raw Deal, Inc	2012-03-08	21 CFR 110.20(b)(4)	The plant is not constructed in such a manner as to allow floors, walls, and ceilings to be adequately cleaned and kept clean.	2012
4	Raw Deal, Inc	2012-03-08	21 CFR 110.40(e)	Lack of an accurate indicating thermometer, temperature measuring device, or temperature recording device in each freezer and cold storage compartment used to store food capable of supporting the growth of microorganisms.	2012
5	Raw Deal, Inc	2012-03-08	21 CFR 110.80(a)(5)	Failure to hold raw materials and ingredients at proper temperature and humidity to prevent the food from becoming adulterated.	2012
6	Raw Deal, Inc	2012-03-08	21 CFR 110.80(b)(1)	Failure to maintain equipment and utensils in an acceptable condition through appropriate cleaning and sanitizing.	2012
7	Raw Deal, Inc	2012-03-08	21 CFR 111.12(a)	Your personnel are not qualified to manufacture, package, label, and hold dietary supplements.	2012
8	Raw Deal, Inc	2012-03-08	21 CFR 111.255(a)	You did not prepare a batch production record every time you manufactured a batch of dietary supplement.	2012
9	Raw Deal, Inc	2012-03-08	21 CFR 111.27(b)	You did not calibrate instruments or controls used in manufacturing or testing a component or dietary supplement to ensure the accuracy and precision of the instruments or controls.	2012
10	Raw Deal, Inc	2012-03-08	21 CFR 111.35(b)(2)	You did not make and keep documentation of the date of the use, maintenance, cleaning, and sanitizing of the equipment.	2012
11	Raw Deal, Inc	2012-03-08	21 CFR 111.455(a)	You did not hold dietary supplements under appropriate conditions of temperature, humidity, or light so that their identity, purity, strength, and composition are not affected.	2012
12	Raw Deal, Inc	2012-03-08	21 CFR 111.75(a)(1)(i)	You did not conduct at least one appropriate test or examination to verify the identity of a dietary ingredient, prior to its use.	2012
13	Raw Deal, Inc	2012-03-08	21 CFR 111.75(c)	You did not verify that your finished batch of dietary supplement meets product specifications for identity, purity, strength, composition, and limits on contamination that may adulterate or that may lead to adulteration of the dietary supplement.	2012

Found 0 **tainted product(s)**[6]

Data Sources and References

	Link to FDA or other data source	Last Updated	Notes
1	Inspection Observations	2017-09-30	These spreadsheets are not a comprehensive listing of all inspectional observations but represent the area of regulation and the number of times it was cited as an observation on an FDA Form 483 during inspections conducted by FDA and its representatives. Inspectional observations reflect data pulled from FDA's electronic inspection tools. These tools are used to generate the FDA Form 483 when necessary. Not all FDA Form 483s are generated by these tools as some 483s are manually prepared. See: https://www.fda.gov/ICECI/Inspections/ucm250720.htm
2	Food and Drug Recalls	0000-00-00	This is the openFDA API endpoint for all food product recalls monitored by the FDA. When an FDA-regulated product is either defective or potentially harmful, recalling that product - removing it from the market or correcting the problem - is the most effective means for protecting the public. Queries are real-time to openFDA, an FDA beta research project and not for clinical use. FDA may limit or otherwise restrict access to the API in line with their Terms of Service. See: https://open.fda.gov/food/
3	Warning Letters	2018-02-12	Matters described in FDA warning letters may have been subject to subsequent interaction between FDA and the letter recipient that may have changed the regulatory status of issues discussed in the letter. See: http://www.accessdata.fda.gov/scripts/warningletters/wlSearchExcel.cfm
4	Inspection Classifications	2018-02-09	Inspections are classified to reflect the compliance status of a firm. Classifications are based upon findings identified during an inspection and Agency review for compliance. During the Agency assessment, classifications may be subject to change after a review of all relevant information. To maintain current knowledge of a firm's compliance status, it may be important to recheck the Inspections Database for updates. The disclosure of this information is not intended to interfere with planned enforcement actions, therefore some information may be withheld from posting until such action is taken. Therefore, this database does not represent a comprehensive listing of all conducted inspections and should not be used a source to compile official counts. Contains 173,734 records. See: http://www.fda.gov/ICECI/Inspections/ucm222557.htm
5	Inspections Citations (Form 483 Observations)	2018-02-15	Citations data contained in the FDA spreadsheets used to generate this database reflect data pulled from FDA's electronic inspection tools. These tools are used to generate the FDA Form 483 when necessary. Not all FDA Form 483s are generated by these tools as some 483s are manually prepared. In addition, if changes were made to the FDA Form 483 and not synchronized with the electronic inspection tools, the results will not fully reflect the actual final Form 483 that was provided to the firm. See: http://www.fda.gov/ICECI/Inspections/ucm346077.htm
6	Tainted Products	2017-12-13	Disclaimer: This list only includes a small fraction of the potentially hazardous products with hidden ingredients marketed to consumers on the internet and in retail establishments. FDA is unable to test

Link to FDA or other data source	Last Updated	Notes
		and identify all products marketed as dietary supplements on the market that have potentially harmful hidden ingredients. See: http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted_supplements_cder

---- END SEARCH ----