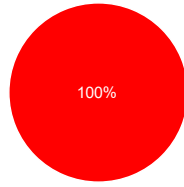


# Regulatory Action Search Report - RAW DEAL; Raw Deal, Inc

## 1. RAW DEAL

OpenFDA: Recall Reports for FOODS

● Class I



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]

**Disclaimer:** Do not rely on openFDA to make decisions regarding medical care. While we make every effort to ensure that data is accurate, you should assume all results are unvalidated. We may limit or otherwise restrict your access to the API in line with our Terms of Service.

License: <https://open.fda.gov/license/>

## 2. Raw Deal, Inc

Recall Type	Classification	Number of Reports
FOOD	Class I	3

This may be a duplicate from the first list.

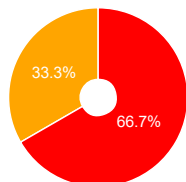
Found 2 FDA Warning Letter(s)<sup>[2]</sup>

Firm Name	Issue Date	Office	Subject	Closeout Date?
<a href="#">Raw Deal, Inc</a>	2013-11-21	New Jersey District Office	Dietary Supplement/Adulterated	
<a href="#">Raw Deal, Inc</a>	2012-10-04	New Jersey District Office	CGMP/Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements/Adulterated	

Found 3 FDA inspections with classifications<sup>[3]</sup>

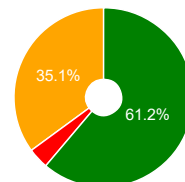
Actual Outcomes for Listed Inspection(s)

● OAI  
● VAI



Typical Inspection Outcomes for Listed Project Areas (all firms)

● NAI  
● OAI  
● VAI



District	Firm Name	City	State	Zip	Country	Inspection End Date	Center	Project Area	District Decision
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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
<a href="#">1 Food and Drug Recalls</a>	0000-00-00	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: <a href="https://open.fda.gov/">https://open.fda.gov/</a>
<a href="#">2 Warning Letters</a>	2017-06-08	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: <a href="http://www.accessdata.fda.gov/scripts/warningletters/wlSearchExcel.cfm">http://www.accessdata.fda.gov/scripts/warningletters/wlSearchExcel.cfm</a>

**Link to FDA or other data source Last Updated****Notes**

3 <a href="#">Inspection Classifications</a>	2016-09-30	Inspection classifications listed in this report reflect the compliance status when the report was generated and may not represent the final Agency determination. FDA is disclosing the final inspection classification for inspections related to currently marketed FDA-regulated products. 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. See: <a href="http://www.fda.gov/ICECI/Inspections/ucm222557.htm">http://www.fda.gov/ICECI/Inspections/ucm222557.htm</a>
4 <a href="#">Inspections Citations (Form 483 Observations)</a>	2016-03-31	Citations data contained in these spreadsheets reflect data pulled from FDA's Turbo Establishment Inspection Report (EIR) system. Turbo EIR is FDA's automated Form 483 reporting system. Turbo EIR is utilized to generate the FDA Form 483 when applicable cite modules exist. Not all FDA Form 483s are generated in Turbo EIR as some 483s are manually prepared and not available in this format. In addition, in the event that changes were made to the FDA Form 483 subsequent to uploading into Turbo, the results may not fully reflect the actual final Form 483 copy provided to the firm. See: <a href="http://www.fda.gov/ICECI/Inspections/ucm346077.htm">http://www.fda.gov/ICECI/Inspections/ucm346077.htm</a>
5 <a href="#">Tainted Products</a>	2017-05-23	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 and identify all products marketed as dietary supplements on the market that have potentially harmful hidden ingredients. See: <a href="http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted_supplements_cder">http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted_supplements_cder</a>

---- END SEARCH ----

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