REPORT INFORMATION

Report Profile

Report Version	FPSR.FDA.DSR.V.V1
Report Category	Voluntary Dietary Supplements Report
Submitted	2015-10-20 18:09:01 EST
FDA ICSR ID	1043211
Report Key for Followup	2CE5220D-6D97962A-94A17CE5-9FDD4DEB-1310C7F0-7AEF5B3F-EB9F1DF5-D9DED2CC

Report Identifying Information

Please enter a title to help you identify this report.	IT WORKS fatfighter
What type of report are you submitting?	Adverse event (an adverse health-related event associated with the product)
Regulatory Status	Voluntary

CAERS 10/22/2015

Contact Information- Your Contact Information

Do you wish to remain anonymous to the FDA?	No
First name	(b) (6)
Last name	(b) (6)
Email	(b) (6)
Confirm email	(b) (6)
Phone	(b) (6)
Country	United States
Street adddress line 1	(b) (6)
Street address line 2	<blank>
City/Town	(b) (6)
State	(b) (6)
Mail/ZIP code	(b) (6)
Have you reported the event to any of the following?	<blank>
Are you a healthcare professional?	No

Relevant Details

Patient/Consumer identifier	(b) (6)
Gender	Female
Age at time of event, if unknown, please enter Date of birth below	50
Select unit of measure	Year(s)
Date of birth	(b) (6)
Weight	235
Select unit of measure	Pound(s)
Height	66
Select unit of measure	Inch(inches)

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Problem Details

Outcomes attributed to adverse event (check all that apply)	A life-threatening experience

Please describe the event or problem	14oct2015 i saw flyer from(b) (6) advertising IT WORKS body wraps. i purchased and began program 16oct2015 with 2 fatfighter pills and a stomach wrap. i began feeling ill that night and vomited. 17oct2015, complained to(b) (6) after taking 2 more and eating heavy meal with lots of water. vomited shortly after. began burping, hiccupping and alternating between hot/cold. 18 and 19 oct no pills taken yet vomiting persisted each time anything ingested. went to emergency room 190ctober with product explaining symptons and physical complaints. given anti nausea sublinguals and water. vomiting stopped. diagnosed gastritis, stomach ulcer
Date of event	10/19/2015
Duration of adverse event	4
Select unit of measure	day
Please provide relevant medical history, including pre-existing conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) :	smoker, gerd
Do you have any relevant tests/laboratory data information to report?	No

Adverse Event Terms

Relevant Tests/Laboratory Data

Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	it works! advanced formula fatfighter with carb inhibitors. dietary supplement 60 tablets
Product manufacturer, packer, distributor	it works marketing,inc
Product strength	500
Select unit of measure	mg
Barcode identifier	0497G5
Select identifier type	Other
If other, please describe	number above exp date under bottle.
Diagnosis or reason for use (indication):	cut those diet-killing cravings and absorb less fat and carbs even after you've eaten them! claims of being all natural by representative(b) (6) . obese diagnosis, pre-diabetic
Lot number	0497G5
Expiration/use-by date	07/01/2017
Is the product available for evaluation by the FDA?	Yes

Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	10/16/2015
End:	10/17/2015
Duration of product use	2
Select unit of measure	day(s)
Frequency of consumption	2
Select unit of measure	day(s)
Amount consumed per serving	510
Select unit of measure	mg
Administration route	oral

Relatedness Details

Did the event stop when product use stopped or amount consumed was reduced?	No
Did the event reoccur when product use resumed?	Not Applicable
Please provide any notes describing the product's usage.	product is mixture of chromium glycinate 150mcg,neopuntia500mg,garcinia cambogia fruit extract50%,green tealeaf extract20%caffeine, white kidney bean extract, bitter melon fruit extract2.5%, banaba leaf extract, corosolic acid,gymnemicacids 25%,wheat amylase inhibitor and vanadyl sulfate. dicalcium phosphate,microcrystalline cellulose,croscarmellose sodium,stearic acid,magnesium stearate, silica film coat

Ingredient Details

Product Relevant Details

Concomitant Product Information

Select full name of product as it appears on the package label	Other

Full name of product as it appears on the package label	defining gel body contouring gel
Product manufacturer, packer, distributor or other responsible party	mark pentecost
Product strength	180
Select unit of measure	ml
Barcode identifier	508S04
Select identifier type	Other
If other, please describe	number in crimp of tube
Diagnosis or reason for use (indication):	defining and contouring
Lot number	508S04
Expiration/use-by date	<blank>

Concomitant Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	10/16/2015
End:	10/18/2015
Duration of product use	3
Select unit of measure	day(s)
Frequency of consumption/use	2
Select unit of measure	day(s)
Amount consumed per serving	1
Select unit of measure	oz
Administration route	topical
Please provide any notes describing the product's usage:	apply twice daily to problem areas ie. thighs, abdomen. ingred: water, witch hazel,glycerin,alcohol denat.,horse chestnut seed extract, urea,bladderwrack extract,hydrocotyl leaf extract,hedera ivy,butchers broom root extract,guarana seed extract,green tea,PEG-8 dimethicone, PEG-7glyceryl cocoate, triethanolamine, phenoxyethanol,carbomer,caprylylglycol, TEA-hydroiodide, methylsilanol mannuronate, rosmarinus officinalis,eucalyptus, sorbic acid BHT,limonene, linalool

Comcomitant Ingredient Details

Ingredient name	body contouring cream infused cloth
If other, please describe	body contouring cream infused cloth
Ingredient amount	<blank>
Select unit of measure	<blank>

Concomitant Product Relevant Details

I have reviewed the ingredients listed for each product, if available, and made any necessary corrections Yes

HL7 Batch Information

HL7 Batch Control Information

Submitting Organization Id SRPCIT

HL7 Batch Sender Information

Sender Id GuestAccount

HL7 Batch Receiver Information

Batch Receiver (Root) USFDA

Batch Receiver (Extension) US Food and Drug Administration

HL7 Message Information

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HL7 Message Control Information

Unique Sender Identifier SRPCIT

Profile Identifier FPSR.FDA.DSR.V.V1.GUEST.AE

HL7 Message Sender Information

Unique Sender Identifier ID-NOTGIVEN

Organization Name UNKNOWN

Title Voluntary Dietary Supplement Submitter

HL7 Message Receiver Information

Message Receiver Id USFDA

Attached Files

None

October 29, 2015

It Works! Inc.
4005 Newpoint Place, Suite 200
Lawrenceville, Georgia 30043

To Whom It May Concern:

This letter is to inform you that the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) has received a report of an illness or injury allegedly associated with the use of one of your products. This report has been entered in to the CFSAN Adverse Event Reporting System (CAERS). The agency uses CAERS to identify potential public health issues that may be associated with the use of a particular product. We have enclosed a copy of the redacted report, removing all information that could identify either the reporter or the person experiencing the adverse event.

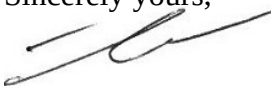
We are providing you with all of the information we have received to date. At this time, we have not yet evaluated this report, nor have we established a relationship between the reported event and your product. Information about FOIA can be found on FDA's web site, http://www.fda.gov/foi/foia2.htm.

Please note that there are now mandatory reporting requirements for serious adverse events alleged to be related to dietary supplements. More information about mandatory reporting may be found at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm171383.htm, the Guidance for Industry. For questions regarding the guidance document please call 240-402-2375.

To assist CFSAN in protecting consumer health, we encourage you to share with us information that is relevant and useful concerning any adverse events that you may be aware of involving your product. Please send your information to: CFSAN / CAERS Staff, (HFS-11), 5100 Paint Branch Parkway, College Park, MD 20740 or to CAERS@fda.hhs.gov. Future correspondence regarding this letter should reference CAERS # 190791.

If we can be of further assistance, please do not hesitate to contact the CFSAN/CAERS staff at 240-402-2405 or CAERS@fda.hhs.gov.

Sincerely yours,



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Office of Analytics and Outreach
Center for Food Safety and Applied Nutrition

Enclosure