

Office of Nutritional Products
Labelling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway 8 5 OCT 28 P2:11
College Park, MD 20740
20th September 2005

Dear Sir or Madam,

This letter serves as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 (DSHEA), that Boots Retail USA Inc. is using the following statements on the label or in the labelling of

Boots Detox 5 Day Plan Apple Flavour Dietary Supplement Total Body Cleanse,

consisting of;

Vials (x 5)

(dietary ingredients: Grape vine leaf extra (*Vitis vinifera*) 700mg and Pine bark extract (*Pycnogenol*) 30mg)

"Help combat the effects with this 5 day plan that helps re-energise your detoxifying organs to leave you feeling revitalised."

"Made from a blend of ingredients that target your detoxifying organs, the plan helps to flush away impurities from your body. The plan contains ingredients that battle against toxic substances and help protect from the dangers of free radicals."

"If your body needs a rest from the stresses of a modern hectic lifestyle then this 5 day plan will help combat over indulgence to remove impurities and re-energise".

These statements are accompanied by the required disclaimer. To the best of my knowledge, the information contained in this notice is complete and accurate and the company has substantiation that these statements are truthful and not misleading.

Sincerely,



Adèle Pattie
International Regulatory Affairs

Boots Retail USA Inc.,
Stamford,
CT 06901

975 0162

LET

16787

05-7018

5 Day Plan

The Boots Detox product range works in harmony with your body to help flush away impurities and stimulate your body's natural detoxifying systems, leaving you purified and revitalised.

Do you need to detox?

Your body is designed to naturally flush out toxic substances. But a busy modern lifestyle can leave your system struggling to cope. Pollutants, pesticides, and other impurities can all find their way into the body. Help combat the effects with this 5 day plan to feel re-energised and revitalised.

Re-balancing and Harmonising

Made from a blend of ingredients that target your detoxifying organs, the plan helps to flush away impurities from your body. The plan contains ingredients that battle against toxic substances and help protect from the dangers of free radicals.

To Use: Each day, for 5 days, add the contents of a vial to a quart or litre of water and drink the pleasant tasting supplement throughout the day.

Please refer to the enclosed booklet for further information about the simple dietary and lifestyle changes you can make to increase the effectiveness of this plan.

WARNING: Not recommended for children or during pregnancy. Store in a cool, dry place away from children. Do not exceed stated daily intake.

Supplement Facts

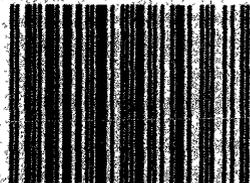
Serving size: 1 vial

Amount Per Serving		Contents	
		% Daily Value	
Grape vine leaf extract (Vitis vinifera)	700 mg		†
Pine bark extract (Pycnogenol)	30 mg		†

† Daily value not established

*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.

Other Ingredients: Water, Citric Acid, Flavouring, Grape vine leaf extract (Vitis vinifera), Sodium Citrate, Citric acid, Stabiliser (Xanthan gum), Ascorbic Acid, Pine bark extract (Pycnogenol), Sodium phosphate, Preservative (Sorbic acid)



5 000167 084368

Mfd in the UK for BEI Ltd NG2 6AA, UK
Dist in USA by Boots Retail USA Inc, Stamford CT 06901
USA: Questions? 1-866-75-BOOTS
www.boots.com

27-04-19
Expiry Date



detox

5 Day Plan

Apple flavour

DIETARY SUPPLEMENT

TOTAL BODY CLEANSE

Your body is designed to naturally flush out toxic substances. But a busy modern lifestyle can leave your system struggling to cope. Pollutants, pesticides and other impurities can all find their way into the body. Help combat the effects with this 5 day plan that helps re-energise your detoxifying organs to leave you feeling revitalised.*

5 x 30 ml e 1 US Fl. Oz. Vials

Artwork Ref: HL8335	Version No.: 2	Comp Code: QCNZ9	Purchase Order No.: 406/4700011304
	Item Code: 27-53-197	Category Manager: Richard Thornhill	
Jupiter Design Ruddington Manor Manor Park, Ruddington Nottingham NG11 6DS	Date: 08/07/05	File Name: HL8332-VAL-WEWW4-Detox5DayPIApp	Packaging Team Approval: Cutter Guide <input type="checkbox"/> Colour Separation <input type="checkbox"/> Printability <input type="checkbox"/> Environment <input type="checkbox"/>
VAL JUPITER	Packaging Technologist: Ian Beadle	Print Process: Screen	



detox

Your pocket guide

The hows and whys, the benefits and the results. An easier, more natural way to look and feel better. This booklet contains comprehensive help and advice on the detox process. Everything from the nutritional and lifestyle changes you can make, through to why the simplest of things – like laughing more – can help. Hopefully its contents will answer many of your questions and at the same time give you advice on how to make detoxing a treat rather than a chore.

www.boots.com

08/01 002088 PJTT5

RANGE **detox** PAGE NO **16 & 1**



CUSTOMER & CONTACT		DESCRIPTION				COLOURS		PROOF		
BCM		Detox Leaflet Amends				Cyan Magenta Yellow Black				
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE	OPERATOR								
To Follow	A. Campbell	Gareth Prate								
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN	Total No. of Colours 4					
68244	1/8/04	No.2	77 x 77	150#						

*Approved
Ian Scudle
09 SEP 04*

Detox. How, why, what?

Pollutants, exhaust fumes, alcohol, smoke and pesticides are all everyday parts of 21st century life, and are all capable of contributing to the impurity build-up within our bodies. An increased exposure to these impurities can often leave you feeling less than 100% – lacking in energy and vitality, and can reduce your body's ability to digest food and eliminate waste. Detoxing is an excellent way to give your body a spring clean – reducing the level of excess waste and impurities built-up by everyday living. By watching what you eat and drink and with a few simple lifestyle changes, you should soon start to see and feel the benefits in both your body and mind.



RANGE **detox** PAGE NO **2 & 3**



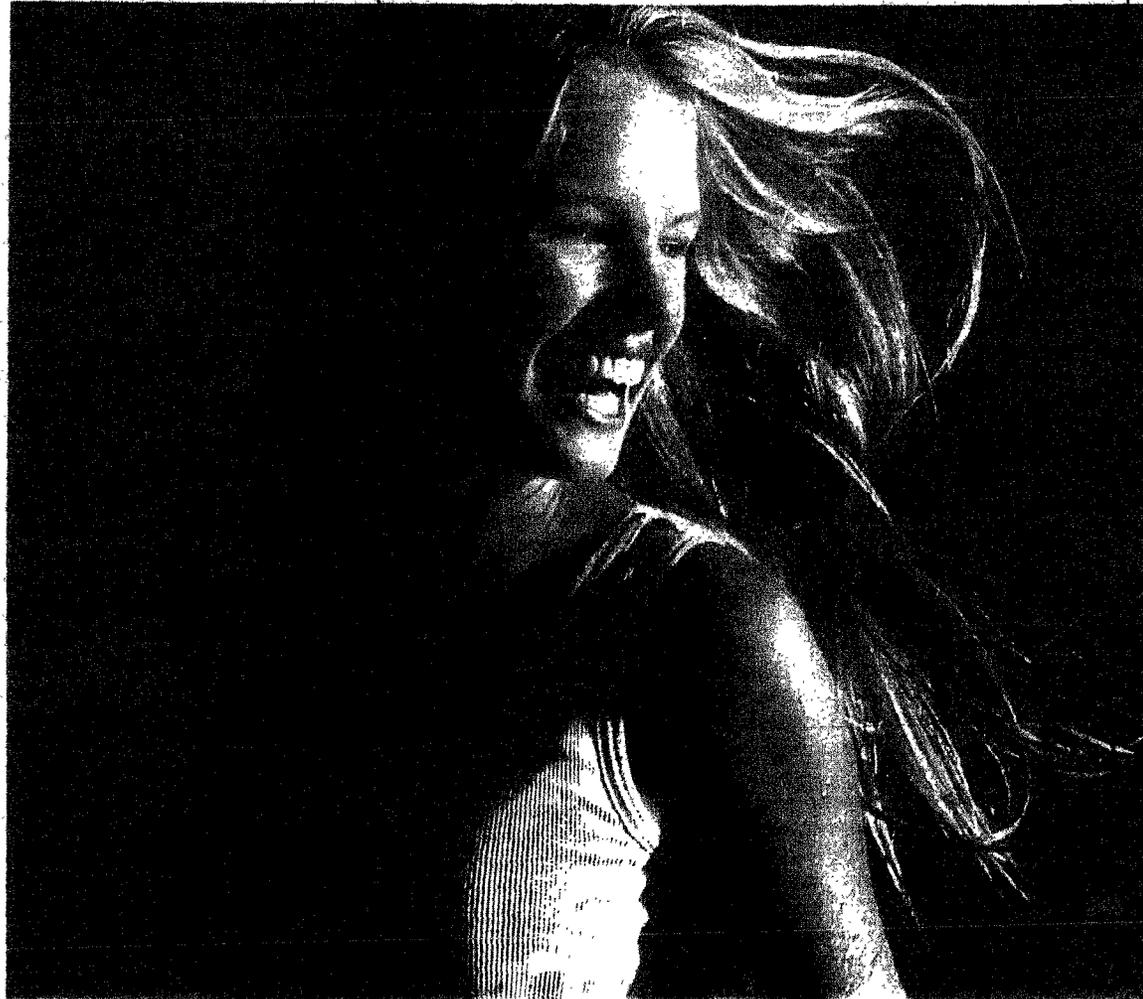
CUSTOMER & CONTACT		DESCRIPTION				COLOURS		PROG. Q.C.I.D.	
BCM		Detox Leaflet Amends				Cyan Magenta		100% PMS	
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE	OPERATOR				Yellow Black		USAS	
To Follow	A. Champbell	Gareth Prate							
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN	Total No. of Colours 4				
68244	1/6/04	No.2	77 x 77	150#					

*Approved
Ian Beadle
09 SEP 04*

The benefits of detoxing

Differences between individuals, in terms of metabolism and the patterns of previous lifestyle, will affect the degree to which you will be able to feel the benefits of detoxing, but there is little doubt that you will experience some beneficial changes.

As the impurity build-up is flushed away you will feel re-energised and revitalised as your body's systems are optimised. As your internal impurity levels reduce this can lead to clearer skin, healthier looking hair and increased energy levels. Detoxing is part of a healthier approach to life, rather than a diet programme. However the change in lifestyle may mean that weight loss is a side effect. What's more, abstaining from some of your usual bad habits can be the first steps to cutting down or giving up.



RANGE **detox** PAGE NO **4 & 5**



CUSTOMER & CONTACT		DESCRIPTION			COLOURS		ISO 9001		UKAS	
BCM		Detox Leaflet Amends			Cyan Magenta		ISO 9001		UKAS	
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE	OPERATOR			Yellow Black		PROG		Q.C.I.D.	
To Follow	A. Champbell	Gareth Prate					1			
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN	Total No. of Colours 4					
68244	1/6/04	No.2	?? x ??	150#						

Approved
Ian Beadle
09 SEP 04

How detoxing works

Detoxing is a way of removing excess waste and impurities from your body. The impurities we pick up in our everyday lives are carried around the body in our blood. They are carried to the liver, where they are filtered and converted into compounds that other organs are able to process and expel. When detoxing you should include elements for all the major organs involved in processing impurities. The Boots Detox range works in harmony with your body, helping the organs flush away impurities.

From plans for your whole body to products that target specific detoxifying organs, such as the skin, and the digestive system, our range can help both improve and supplement the cleansing process. Whilst our products will help to detoxify your body, the lifestyle changes described in this booklet will ensure that you get the most benefit from the time that you are investing. What's more, our products are designed to not only be effective, but also pleasant, and in some cases are decadently pampering, while still contributing to your detox. Sticking to the healthy lifestyle may not seem so bad when you can treat yourself to our gently warming face mask.

Our range contains plans and kits that will help you carry out a head to toe detox. They contain ingredients that target all the major detoxifying organs to give a general overhaul of your purifying processes.

RANGE **detox** PAGE NO **6 & 7**

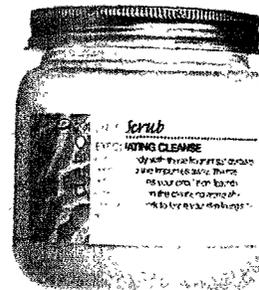


CUSTOMER & CONTACT		DESCRIPTION				COLOURS	
BCM		Detox Leaflet Amends				Cyan Magenta Yellow Black	
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE	OPERATOR					
To Follow	A. Campbell	Gareth Prate		PROG Q.C.I.D.			
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN	Total No. of Colours 4		
68244	1/6/04	No.2	77 x 77	150#			

*Approved
Ian Beadle
09 SEP 04*

Detox your skin and circulation

The major internal organs involved in removing toxins from your body are your lungs, liver, kidneys and digestive system. You breathe out impurities when you exhale, so deeper breathing is beneficial. By optimising your digestive process you will expel impurities more quickly and maximise your ability to absorb nutrients. The range contains specific products to help with this. Your kidneys are also important – drinking lots of water is the best way of helping them.



detox *range*
Amends

RANGE **detox** PAGE NO **8 & 9**



CUSTOMER & CONTACT		DESCRIPTION				COLOURS		PROG. Q.C.I.D.		
BCM		Detox Leaflet Amends				Cyan Magenta Yellow Black		1		
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE	OPERATOR								
To Follow	A. Campbell	Gareth Prate								
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN						
68244	1/6/04	No.2	77 x 77	150#	Total No. of Colours 4					

Approved
 Ian Beards
 24 SEP 04

The Essentials While Detoxing

Whilst our Detox range is undoubtedly a great way to aid the detoxifying process, there are many other things you can make part of your daily routine to help maximise the effects.

Drink more fluids

You should aim to drink at least 1.5 litres (3 pints) of fluids a day, preferably water. This will help flush your system and rehydrate your body.

Change your diet

A change to a more balanced, healthier diet can work wonders for your system and can also result in weight loss and increased energy levels. As a general rule, eat and drink natural, fresh produce.

Good detoxifying foods include:

Fruit – fresh or dried, Vegetables – preferably raw or steamed, Nuts, pulses and seeds, Fish, Brown rice, Wholemeal bread, Olive, walnut or sesame oil, Garlic, Herbal teas, Fruit juice – preferably not made from concentrate, Vegetable juice

Things to avoid or moderate

Dairy products (difficult to digest), processed or convenience food, artificially sweetened food, tea, coffee and alcohol (dehydrates your body), candy and chocolate

If possible you should also try to stop smoking and avoid smoky environments.

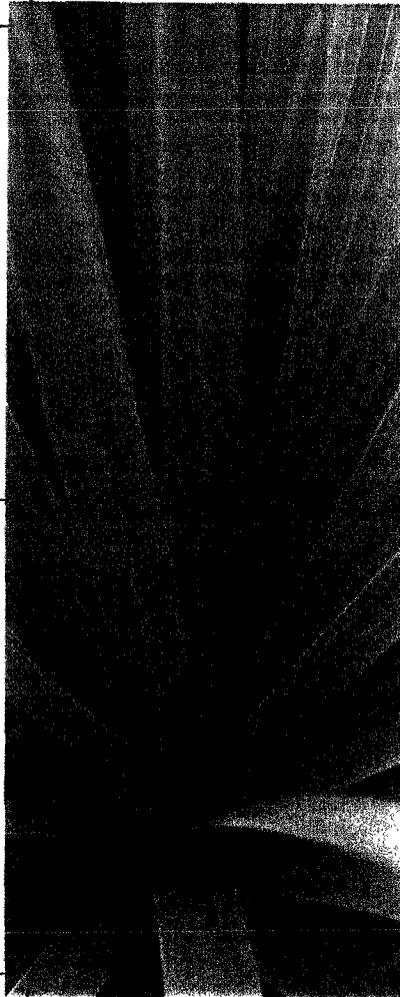


RANGE **detox** PAGE NO **10 & 11**



CUSTOMER & CONTACT		DESCRIPTION			COLOURS		 
BCM		Detox Leaflet Amends			Cyan Magenta Yellow Black		
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE	OPERATOR					
To Follow	A. Campbell	Gareth Prate					
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN	Total No. of Colours 4		
68244	1/6/04	No.2	77 x 77	150#			

Approved
Ian Beadle
09 SEP 04



Take the Holistic Approach

Exercise

One of the best ways of enhancing the detoxifying process is to take some form of regular exercise. Anything from visiting the gym to walking the dog will help improve both your circulation and metabolic rate and get internal organs working.

Deep breathing

Taking deep breaths can help to expel impurities from your lungs. You should try breathing deeply for at least 5 minutes every day.

Improve your environment

Your home or office can be as prone to impurities as the outside. Green plants are an excellent way of removing airborne pollutants, and ionisers, humidifiers and oil burners are all great ways of improving the atmosphere.

Potential side effects

When detoxing you may experience certain minor side effects. These often depend on your lifestyle prior to detoxification. For example, someone who usually drinks a lot of coffee may experience mild headaches as their body adjusts to the change in caffeine levels.

Common side effects

Mild headaches – caused by your body learning to live without chemicals such as alcohol, sugar and caffeine. These usually appear on day 2 or 3 of the detox and can last for up to 24 hours. Drink lots of fluid and make time for relaxation.

Spots – The skin is the body's biggest organ of elimination, so the appearance of spots during a detox is not uncommon. They can appear as early as day 3 and can last throughout the detox process – drinking plenty of water will help.

Increased bowel movements – this is completely normal and is a sure sign that your body is starting to cleanse itself.

A furry tongue – Again a sure sign that the body is removing impurities. Use a mouthwash or try scraping your tongue with a toothbrush.

Lulls in energy during the first few days – Your body will be used to instant energy snacks. It will take a few days to adjust to the more gradual energy release replacements. These side effects should be minor in nature, and only last for a few days.

Why not try detoxing with a friend?
It's a great way to overcome any potential pitfalls and gain the extra resolve that's sometimes needed to stick it out.

RANGE **detox** PAGE NO **12 & 13**



CUSTOMER & CONTACT		DESCRIPTION			COLOURS		ISO 9001	
BCM		Detox Leaflet Amends			Cyan	Magenta		
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE	OPERATOR		Yellow	Black			
To Follow		A. Campbell	Gareth Prate				PROG	Q.C.I.D.
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN				
68244	1/6/04	No.2	77 x 77	150#	Total No. of Colours 4			

*Approved
Ian Beadle
09 SEP 04*

Did you know?

Laughing helps – a good laugh not only gives your internal organs a workout, it also reduces stress levels – an important factor in detoxification.

Cold showers can help you detox – they increase your circulation and kick-start lymph flow.

Many aromatherapy oils have cleansing properties that can help with detox, for example juniper, lemon grass and rosemary.

Frequently asked questions

Q. How often should I detox?

A. Everyone's lifestyle and metabolism is different. It will depend on your impurity intake, and your body's natural efficiency at detoxing. When you have detoxed you will feel clearer and re-energised. As impurities start to build up again this feeling will lessen. It's then time to detox again!

Q. When should I detox?

A. We recommend that you detox when you feel you need it. For example, after prolonged periods of over-indulgence, or before a big event so that you look and feel your best e.g. summer holidays. It is best not to detox when you are experiencing a hectic time at work or socially. Coping with the change in lifestyle can be time consuming until you are familiar with it.

Q. Who shouldn't detox?

A. Anyone who is pregnant or breastfeeding should not detox. We also do not recommend detoxing for children. Check the individual products in the range for warnings that are specific to that product.

Q. Where can I get further information?

A. There are numerous books, magazine articles and internet sites that offer detox advice – some of which is conflicting, and some even dangerous. Anything that sounds extreme is probably best avoided. Take care to use reputable sources only.

Q. Which plan should I do?

A. It depends! The 5 day plan is more suitable if you want to boost your body's detoxifying systems to get a quick result, particularly in reducing the impurity build-up in your liver. The 28 day plan builds up over time, so the benefits are more gradual but more thorough.

Changes to a more healthy lifestyle will have become ingrained if you do them for a month – leading to less impurity exposure in the future.

Q. Can I take both plans at once?

A. We do not recommend that you do both plans at once. You may wish to do the 28 day plan the first time, and then when you next feel the need, do a 5 day detox.

Q. Will I be hungry?

A. Just because you are detoxing, it is no reason to deprive yourself of food, providing you eat natural and fresh produce.

RANGE **detox** PAGE NO **14 & 15**



CUSTOMER & CONTACT		DESCRIPTION				COLOURS		PROOF		Q.C.I.D.	
BCM		Detox Leaflet Amends				Cyan Magenta Yellow Black		ISO 9001 9002		MEAF	
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE	OPERATOR									
To Follow	A. Campbell	Gareth Prate									
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN							
68244	1/6/04	No.2	77 x 77	150#	Total No. of Colours 4						

Approved
Ian Beadle
09 SEP 04