

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12669



2 - LABEL SAMPLE

000001



1.2.1988 AND DATED 12.2.83 - 281
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Dai 89001



**HERBAL
 BALANCE**

DIETARY SUPPLEMENT
 SOLD EXCLUSIVELY BY
 AUTHORIZED DISTRIBUTORS

180 CAPSULES

THE HERBAL APPROACH TO WEIGHT LOSS

INGREDIENTS: Each capsule contains 480 mg of a proprietary blend of: Ephedra sinica (Ma Huang, stem, extract 1:4), Ilex paraguariensis (Mate, leaf), Arctostaphylos uva-ursi (Bearberry, Uva ursi, leaves), Astragalus membranaceus (Bai chi, root), Polygonum multiflorum (Fo ti, root), Valeriana officinalis (Valerian, root), Betaerolene, Crataegus oxyacanthoides (Hawthorn, berry), Lawsonia inermis (Henna, leaf), Rhamnus purshiana (Cascara sagrada, bark), Glycyrrhiza glabra (Licorice, root)

DISTRIBUTED BY SLIM FOR LIFE, INC., PLANTATION, FL 33418
 LOT # 139601C PRINTED IN CANADA
 EXP 5 98

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Daf 9001

98-755-227
10/29/97 1cm



DIRECTIONS: Begin with a low dose and build up to the most comfortable dose level. Take capsules with 8 oz (240 mL) of water.
Days 1-2: One (1) capsule 1 hour before lunch.
Days 3-4: One (1) capsule 1 hour before lunch, One (1) capsule 1 hour before dinner.
Days 5-6: Two (2) capsules 1 hour before lunch, One (1) capsule 1 hour before dinner. If you have not yet reached an optimum level, you may add a second capsule to dose before dinner after Day 6. Do not exceed four (4) capsules per day.

HERBAL BALANCE: should not be taken by pregnant women or nursing mothers. If you have heart or thyroid disease, diabetes, high blood pressure, difficulty in urination from prostate enlargement, or are taking an MAO inhibitor or any other prescription drug, consult your physician before taking this product. Do not take this product if you are taking appetite suppressants or products containing ephedrine or pseudoephedrine. Reduce or discontinue use if: nervousness, tremor, sleeplessness, severe loss of appetite or nausea occur. Not intended for use by persons under the age of 18.

KEEP OUT OF CHILDREN'S REACH

The Herbal Approach to W

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Herb
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DETAILED
Sole Distributor
Authorized
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Dal 84001

CAUTIONS: Begin with a low dose and build up to the most comfortable dosage level. Take capsules with 8 oz (240 mL) of water.

Dosage: Days 1-4: One (1) capsule 3 times per day.
Days 5-6: One (1) capsule 3 times per day.
Days 7-8: Two (2) capsules 3 times per day.
Days 9-10: One (1) capsule 3 times per day.

PRECAUTIONS: Do not take this product if you are pregnant, nursing, or have a history of seizures, kidney disease, diabetes, high blood pressure, or are taking any medication. Consult your physician before taking the product. Do not take the product if you are taking any medication or product containing ephedrine or pseudoephedrine. Do not take the product if you are taking any medication or product containing alcohol, caffeine, or other stimulants. Do not take the product if you are taking any medication or product containing aspirin, ibuprofen, or other NSAIDs. Do not take the product if you are taking any medication or product containing MAO inhibitors. Do not take the product if you are taking any medication or product containing MAO inhibitors. Do not take the product if you are taking any medication or product containing MAO inhibitors.

KEEP OUT OF CHILDREN'S REACH

The Herbal Approach to Weight Loss

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DIETARY SUPPLEMENT
SOLD EXCLUSIVELY BY
AUTHORIZED DISTRIBUTORS

180 CAPSULES

INGREDIENTS: Each capsule contains 480 mg of a proprietary blend of: Ephedra sinica (Ma Huang, stem, extract 1:4), Ilex paraguariensis (Mate, leaf), Astragalus membranaceus (Bei Ji, root), Polygonum multiflorum (Fo Ji, root), Valeriana officinalis (Valerian, root), B-carotene, Crataegus oxyacanthoides (Hawthorn, berry), Lawsonia inermis (Henna, leaf), Rhamnus purshiana (Cascara sagrada, bark), Glycyrrhiza glabra (Licorice, root).

DISTRIBUTED BY: S.W. GREENE, INC., 13500 N. 10th Ave., Scottsdale, AZ 85258

LOT # 135491C
EXP. DATE 11/01/03

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98-7
10/29

1. FLAG SURVEILLANCE <input type="checkbox"/> COMPLIANCE <input checked="" type="checkbox"/> Consumer Complaint Sample		2. TYPE SAMPLE		3. SAMPLE NUMBER 98-227	
4. CF NO. NOCFN		5. DATE COLLECTED 10/29/97		6. PRODUCT CODE 54FHG09	
7. RESP FIRM M		8. PROGRAM ASSIGN CODE 1. 21R801		9. HOURS 1. 8 hours	
10. RELATED SPL none		11. PC 2	12. COLL NO. 140	13. SPLING DIST DAL-DO	14. COLL DIST DAL-DO
15. PRODUCT NAME AND IDENTIFICATION (Quote pertinent labeling including firm name and address) Dietary supplement in poly bottle labeled in part: "The Herbal Approach To Weight Loss Herbal Balance Sold Exclusively by Authorized Distributors 180 Capsules INGREDIENTS: Ephedra sinica (Ma Huang stem, LOT# 139601C EXP. 5 98) DISTRIBUTED BY: SLIM FOR LIFE, INC., PLANTATION, FL 33313"					
16. REASON FOR COLLECTION (Indicate analysis needed & document assignment. Include CP No. and/or Assignment No. if applicable.) Sample collected as a F/U to DAL 89001. Analyze for Ephedra (Ma Huang) per memo dtd 3/13/96.				17. MFG CODES (Labels, pkg, shipping containers) Lot # "139601C" Exp. date "5 98"	
18. MANUFACTURER (Name, address & ZIP) DISTRIBUTED BY: Slim for Life, Inc. 4350 W. Sunrise Blvd. Suite 122 Plantation, FL 33313		19. SHIPPER (Name, address & ZIP) unknown		20. DEALER (Name, address, ZIP & telephone) 	
21. SIZE OF LOT FROM WHICH SAMPLED n/a		22. EST VALUE n/a	23. RECEIPT ISSUED FDA472 <input type="checkbox"/> FDA484 <input checked="" type="checkbox"/> NONE <input type="checkbox"/>		24. DATE SHIPPED & DOC REF n/a
25. DESCRIPTION OF SAMPLE AND METHOD OF COLLECTION (Number and size of units, etc.) Sample collected from Dealer and consists of an unopened poly bottle with screw cap, containing 180 capsules of Herbal Balance.					
26. HOW PREPARED Sample ID per #27, placed in a poly bag, stapled & officially sealed per #28, FD525 att. Sample kept in locked govt. locker until shipped per #29.					
27. COLL IDENT ON PKG AND/OR LABEL "98-755-227 10/29/97 ICM"		28. COLLECTOR'S IDENTIFICATION ON SEAL "98-755-227 10/29/97 Iris MacInnes"			
29. SAMPLE DELIVERED TO Denver Lab via FEDEX - Austin, TX Airbill No. 4506417764		30. DATE DELIVERED 11/7/97		31. LAB DEN-DO	
		32. LAB W/SPLIT SAMPLE n/a		33. ORIG C/R & RECORDS TO FLA-DO	
34. RCDS OBTAINED	a. INVOICE NO. AND DATE n/a		b. SHIPPING RECORD (B/L, F/B, Waybill, Affidavit, etc.) NO. AND DATE n/a		
	c. OTHER DOCUMENTS (Affidavits from dealers, etc.) SIGNER'S NAME AND DATE Affidavit from  Dal 89001 signed on 10/31/97. Copy of Complaint 89001 is attached to orig. C/R.				
	35. REMARKS (If additional space is needed, attach Form FDA 464a, C/R Continuation Sheet) 20. Dealer purchased product at  as part of a diet program. The clinic verbally said that the product 'increased your metabolism to help you lose weight'. See copy of complaint.				
36. CONSUMER COMPLAINT NO. OR RECALL NO. DAL 89001		37. AMT. \$ n/c CRED. CD. C <input type="checkbox"/> V <input type="checkbox"/> B <input type="checkbox"/>		38. 704(d) SPL YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	
39. COLLECTOR (Typed name and signature)  Iris C. MacInnes					

FORM FDA 464 (11/85) PREV ED MAY BE USED.

COLLECTION REPORT

SAMPLE RECORD COPY 4

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ARMS# 12669

PRODUCT Herbal Balance Capsules		2 SAMPLE NO 98-755-227	
3a SAMPLE CLASSIFICATION		b LABORATORY CONCLUSIONS	
14 2CODE	PAC NO	Sample consisted of one bottle containing 160 capsules of product. HPLC Analysis by LIB 3996 found:	
4	21R801		
c NAME AND TITLE Janet L. Burke, Chemist		d SIGNATURE <i>Janet L. Burke</i>	DATE 12/1/97
4a DISTRICT CONCLUSIONS			
b NAME AND TITLE		c SIGNATURE	d DATE

FORM FD 465 (4/78)

SAMPLE SUMMARY

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