



DATE: August 20, 2013
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: Herbal Give Care LLC Recall [Drug]

**SUGGESTED
ACTION:**

Unclassified Recall; Herbal Give Care LLC is voluntarily recalling all lots of Esbelder man (30 capsules), Esbelder fem (30 capsules) and Esbelder siloutte (30 capsules) to the consumer level. The products have been found to contain undeclared Sibutramine, N-Desmethyilsibutramine, and N-di-Desmethyilsibutramine. The presence of these undeclared ingredients makes these products unapproved drugs. These products may pose a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the recalled products were distributed in the State of Indiana. Products were shipped nationwide to retail customers and via the internet. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-234-8569.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Herbal Give Care LLC Issues Voluntary Nationwide Recall of Esbelder Man Capsules, Esbelder Fem Capsules, and Esbelder Siloutte Capsules Vitamin Supplements Due to Potential Health Risks

Contact:

Consumer:

(972)602-6850

hgc-usa@hotmail.com

Media:

Omar Martinez

(972)602-6850

FOR IMMEDIATE RELEASE - August 16, 2013 - Grand Prairie, Texas, Herbal Give Care LLC is voluntarily recalling all lots of Esbelder man (30 capsules), Esbelder fem (30 capsules) and Esbelder siloutte (30 capsules) to the consumer level. The products have been found to contain undeclared Sibutramine, N-Desmethylsibutramine, and N-di-Desmethylsibutramine. The presence of these undeclared ingredients makes these products unapproved drugs.

These products may pose a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke. To date, Herbal Give Care LLC has not received any reports of adverse events related to this recall.

The Esbelder fem (30 capsules) is packaged in a white plastic bottle with a screw cap containing 30 capsules per bottle. All lots of this product are being recalled. The product was distributed Nationwide to retail customers and via the internet. UPC code for this product is 7502011000251.

The Esbelder man (30 capsules) is packaged in a white plastic bottle with a screw cap containing 30 capsules per bottle. The product was distributed Nationwide to retail customers and via the internet. UPC code for this product is 7502011000275.

The Esbelder Siloutte (30 capsules) is packaged in a white plastic bottle with a screw cap containing 30 capsules per bottle. The product was distributed Nationwide to retail customers and via internet. UPC code for this product is 7502011000268.

Herbal Give Care LLC is notifying its distributors and customers by calling and mailing a letter to all of them. Herbal Give Care LLC is making arrangements for the return of all recalled products. Consumers that have the affected product(s) should immediately stop using them and return them to the place of purchase.

Consumers with questions regarding this recall can contact Herbal Give Care LLC by calling to (972)602-6850 or email to hgc-usa@hotmail.com Monday- Friday from 9:00 am to 6:00 pm

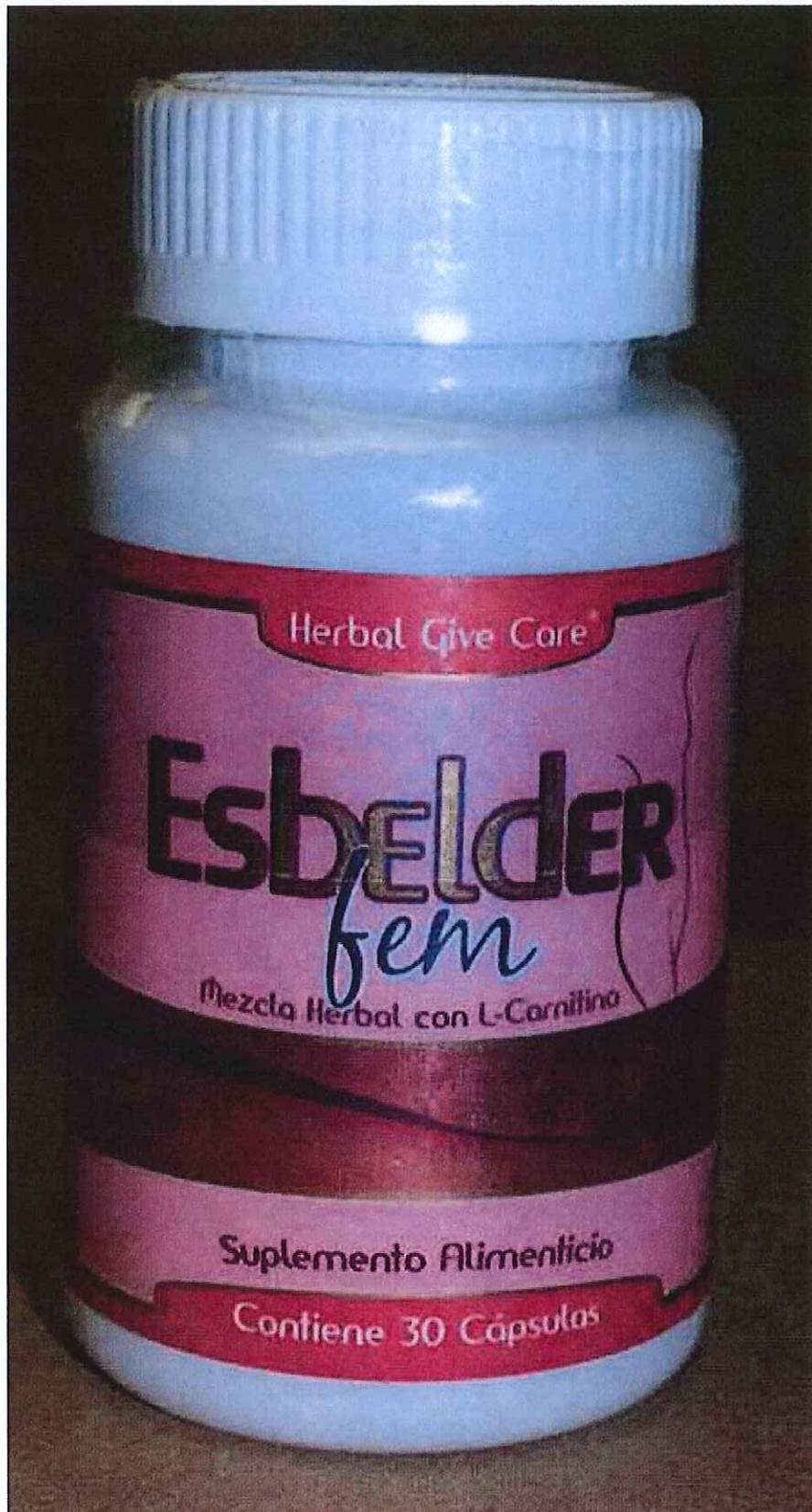
Central Daylight Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online:** <http://www.fda.gov/MedWatch/report.htm>¹
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: <http://www.fda.gov/MedWatch/getforms.htm>².
Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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Herbal Give Care®

Esbelder *fem*

Mezcla Herbal con L-Carnitina

Suplemento Alimenticio

Contiene 30 Cápsulas

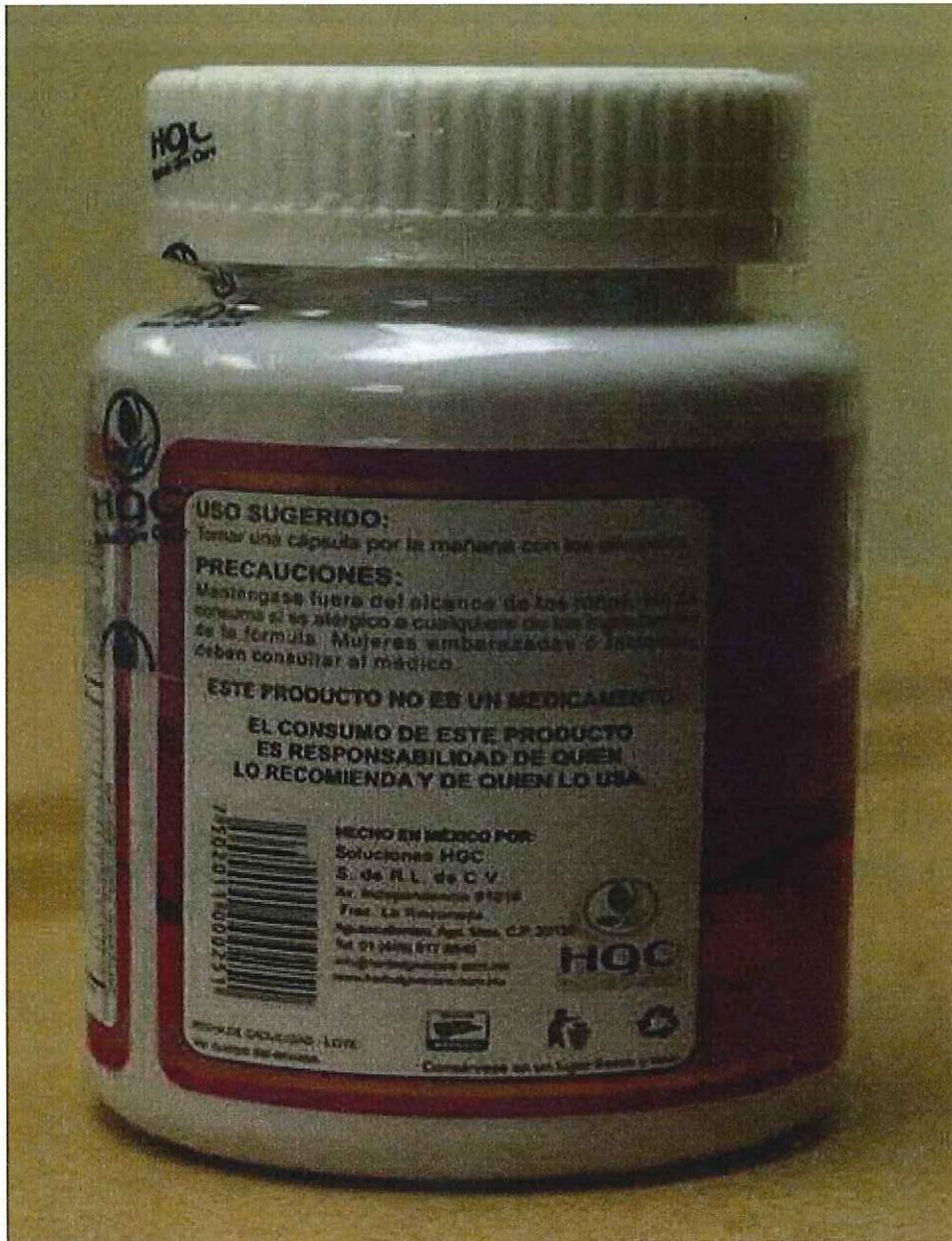
HOC

INFORMACIÓN NUTRIMENTAL

Tamaño de la porción: 1 Comprimido
Porciones por frasco: 30

	Por 100 g	Por porción
Contenido Energético	280 kcal	1.40 kcal
Proteínas	70 g	3.50 g
Grasas	4 g	0.20 g
Carbohidratos	54 g	2.70 g
Sodio	4 g	0.20 g
Fibra dietética	78 g	3.90 g
L-Carnitina	20 g	1.00 g
Masca Especial		550 mg
Alcachofa (<i>Cynara scolymus</i>) (hoja)		100 mg
Té Verde (<i>Camellia sinensis</i>) (hoja)		100 mg
Slimerina (<i>Silybum marianum</i>) (extracto)		100 mg
Isóflavonas de Soya (<i>Glycine max</i>) (semilla)		100 mg
Black Kehosh (<i>Cimicifuga racemosa</i>) (raíz)		100 mg
Mangostán (<i>Garcinia mangostana</i>) (fruta)		100 mg
Espirulina (<i>Spirulina maxima</i>) (alga)		100 mg
Cancerina (<i>Hippocrates sycalata</i>) (leche)		100 mg
Coccoloba (<i>Millettia quinquiflora</i>) (raíz)		100 mg
Tenchalagus (<i>Erithaea tetramera</i>) (planta)		100 mg
Ben (<i>Cassia argyrafolia</i>) (hoja)		100 mg
Tolu		100 mg

* El HOC está registrado en el Libro de Marcas de la Oficina de Patentes y Comercio de Colombia.
* El HOC es un producto de la industria farmacéutica de Colombia.
* El HOC es un medicamento.



HOC
MÁS EN ORO

HOC
MÁS EN ORO

USO SUGERIDO:

Tomar una cápsula por la mañana con los alimentos.

PRECAUCIONES:

Manténgase fuera del alcance de los niños. No consumir si es alérgico a cualquiera de los ingredientes de la fórmula. Mujeres embarazadas o lactantes deben consultar al médico.

ESTE PRODUCTO NO ES UN MEDICAMENTO

**EL CONSUMO DE ESTE PRODUCTO
ES RESPONSABILIDAD DE QUIEN
LO RECOMIENDA Y DE QUIEN LO USA.**



HECHO EN MÉXICO POR:
Soluciones HOC
S. de RL. de CV
Av. Independencia 91214
Frac. La Rotonda
Aguascalientes, Agt. Sta., CP 20124
Tel 01 444 877 8840
www.solucioneshoc.com.mx

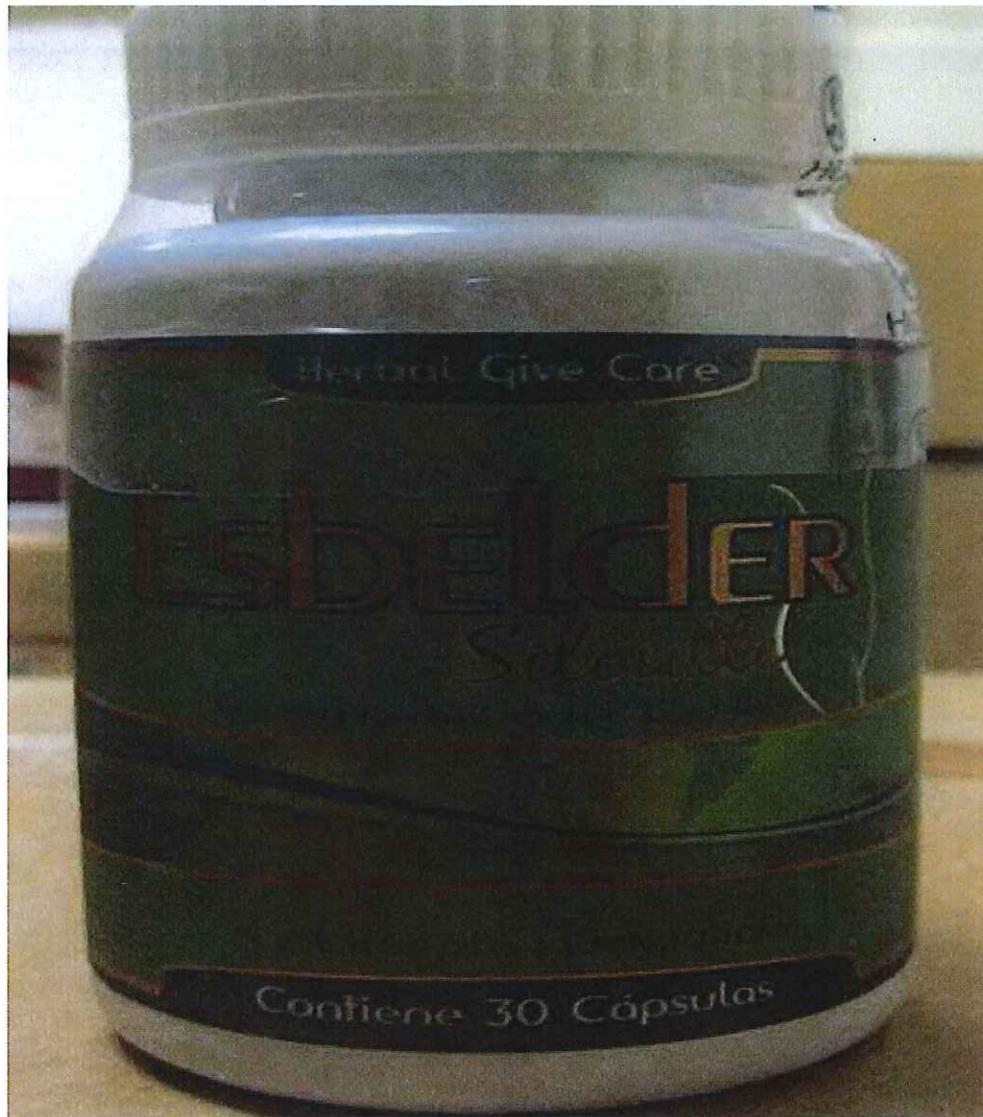


HOC

PROXIMA SOLUCIÓN: LITE
por Grupo Soluciones



Contiene 30 cápsulas de 300 mg



INFORMACION NUTRIMENTAL

Tamaño de la porción
Porciones por bote

1 Cápsula (500 mg)

	Por 100 g	Por porción	% DR*
Contenido Energético	300 kcal	1,5 kcal	**
Proteínas	10 g	50 mg	< 1%
Grasas	4 g	20 mg	< 1%
Carbohidratos	54 g	270 mg	< 1%
Sodio	4 g	20 mg	< 1%
Fibra dietética	16 g	80 mg	< 1%
L-Carnitina	40 g	100 mg	**
Mezcla Especial		400 mg	
Cha De Bugre (<i>Cordia alliodora</i>) (Hoja)			**
Té Verde (<i>Camellia sinensis</i>) (Hoja)			**
Garcinia (<i>Garcinia cambogia</i>) (Corteza Fruta)			**
Mangostán (<i>Garcinia mangostana</i>) (Fruto)			**
Goji (<i>Lycium barbarum</i>) (Fruto)			**
Acai (<i>Euterpe oleracea</i>) (Fruto)			**

* El DR Es Basado En Una Dieta De 2,000 Calorías. Estos Valores Pueden Ser
Máximos o Mínimos Dependiendo De Su Metabolismo De Calorías.
**% DR No Especificado.

Otros ingredientes: Capsula de Quitina Dura

USO SUGERIDO:

Tomar una capsula por la mañana con los alimentos.

PRECAUCIONES:

Manténgase fuera del alcance de los niños. No se consuma si es alérgico a cualquiera de los ingredientes de la fórmula. Mujeres embarazadas o lactando, deben consultar al médico.

ESTE PRODUCTO NO ES UN MEDICAMENTO.

**EL CONSUMO DE ESTE PRODUCTO
ES RESPONSABILIDAD DE QUIEN
LO RECOMIENDA Y DE QUIEN LO USA.**



HECHO EN MÉXICO POR:

Soluciones HGC
S. de R.L. de C.V.
Av. Independencia #1016
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Aguascalientes, Ags. Mex. CP 20136
Tel: 01 (449) 917 6530
info@herbalgrecant.com.mx
www.herbalgrecant.com.mx

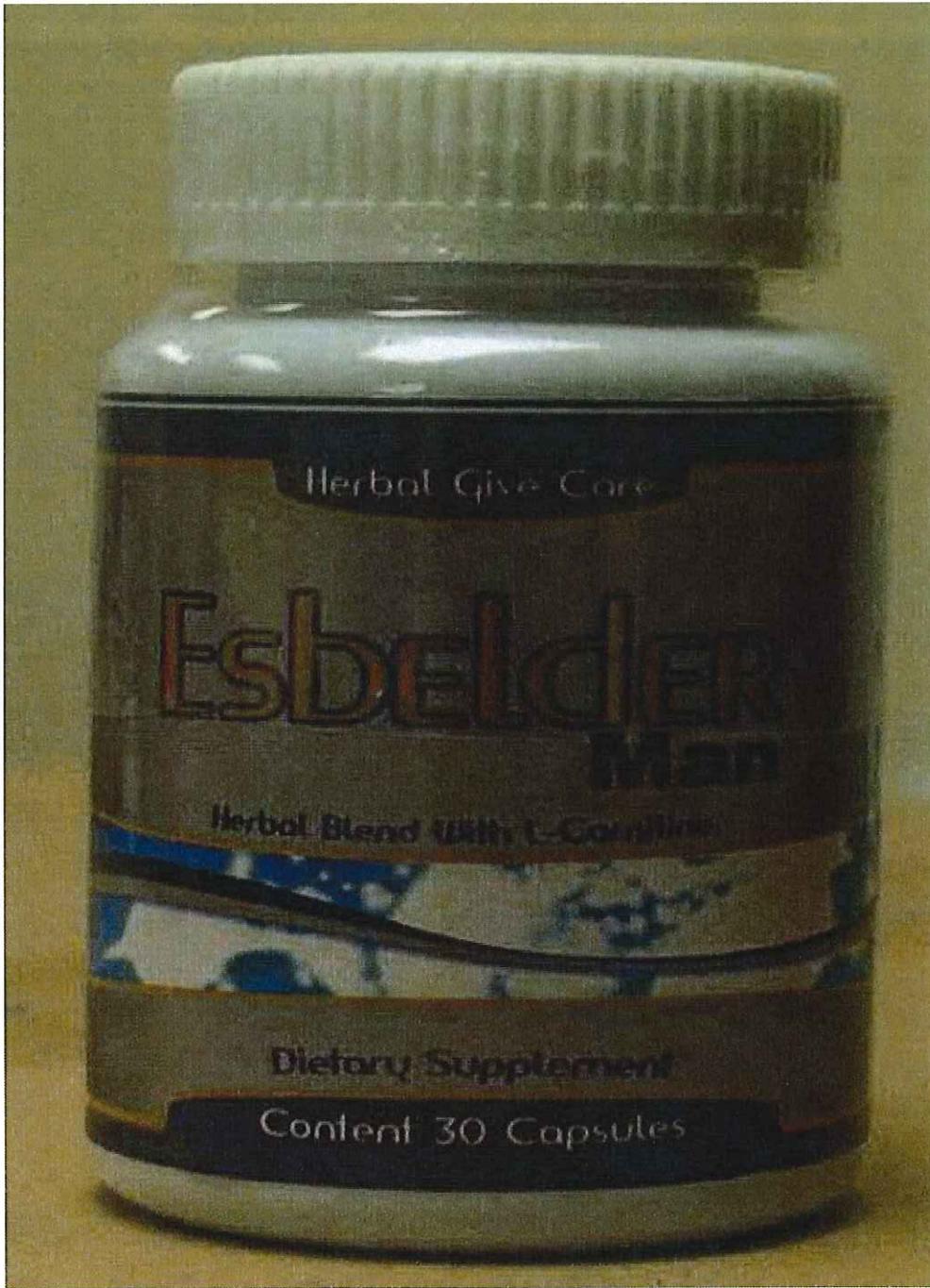


HGC

FECHA DE CADUCIDAD - LOTE:
Ver cuerpo del envase



Conservese en un lugar fresco y seco



Herbal Give Care

Esbeldier MAN

Herbal Blend With L-Carnitine

Dietary Supplement

Content 30 Capsules

SUPPLEMENT FACTS

Serving Size
Servings Per Container

Amount per Serving

L-Teanine 20 mg

Resveratrol 50 mg

L-Carnitine 100 mg

Proprietary Blend 330 mg

Cha De BuGre (Cordia alliodora) (Leaf)

Green tea (Camellia sinensis) (Leaf)

Wolfberry (Lycium barbarum) (Fruit)

Acai (Euterpe oleracea) (Fruit)

*Percent daily values are based on a diet of 2,000 calories per day.

**Daily value not established.



SUGGESTED USE:

Take one capsule at breakfast.

WARNING:

Do not consume if you are allergic or intolerant to ingredients, pregnant or lactating women should consult a doctor.

Keep out of reach of children.

THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.

THE CONSUMPTION OF THIS PRODUCT IS RESPONSIBILITY OF ITS USER AND WHO RECOMMENDS IT.



MADE IN MEXICO:
Soluciones HQC
S. de R.L. de C.V.
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Frac. La Finca
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Phone: 449 917 8540
info@herbalgivecare.com.mx
www.herbalgivecare.com.mx



LOT, EXP. DATE:
See body of package



Store in a cool and dry place.