

**NOTICE TO THE OFFICE OF NUTRITIONAL PRODUCTS, LABELING AND  
DIETARY SUPPLEMENTS OF STRUCTURE/FUNCTION CLAIM**

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The undersigned hereby files this Notice of dietary supplement structure/function claim, pursuant to 21 C.F.R. Section 101.93, with the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, and states:

1. The label of the product "Prunelax" bears the following information:

**PRUNELAX**

Natural laxative for occasional constipation.\*  
Dietary Supplement.

AUG - 1 2005

Manufactured by Laboratorios Garden House S.A.  
Avda. Pdte. Jorge Alessandri Rodriguez 12310 - Sn Bdo.Chile  
Imported by Luis Garratón, Inc  
Carretera 869 Zona Ind. Las Vegas Barrio Palmas  
Cataño Puerto Rico 00962 Tel.: (787) 788-6100

**KEEP OUT OF REACH OF CHILDREN  
STORE IN A DRY AND COOL PLACE  
NOT TO BE USED AS FOOD  
NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN**

**Prunelax (Ciruelax)** contains dried plums and herbs which help you maintain bowel regularity.\*  
**Directions:** Adults and children 15 years of age and over take one teaspoon (0.53 oz) before bedtime. Follow with a glass of water or juice. Do not exceed recommended dosage.  
Children under 15 years of age consult a doctor.

**WARNINGS:** This product contains Senna. Read and follow package direction carefully. Stop use the product if diarrhea, loose stools or stomach pain develop. If you have noticed a sudden change in bowel habits that persists over two weeks, consult a doctor before using laxatives. Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult a doctor. Laxative products should not be used for a period longer than one week unless directed by a doctor. Consult a doctor before using this product if you are pregnant, nursing, taking medication or have medical conditions.

<b>SUPPLEMENT FACTS</b>		
Serving size : 1 tsp (0.53 oz/15 g)		
Servings Per Container: 10		
<b>Amount per serving</b>		<b>% Daily Value</b>
Calories	37.9	< 2%**
Total Fat	0.17g	0%
Sodium	10 mg	< 0.5%***

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Total Carbohydrates	9.6g	3%
Sugar	8.5 g	†
Dietary Fiber	1.1g	4.4%
Proteins	0.19 g	< 1%****
Dried Plums (prunes) (Prunus domestica fruit)	3.6mg	†
Senna Leaves (Cassia angustifolia Valh)	660 mg	†
Alexandrian Senna Pods (Cassia senna L.)	330 mg	†
** Percent Daily Value are based on 2,000 calories diet. *** Percent Daily Value are based on 2,400 mg of Sodium. **** Percent Daily Value are based on 56 g of proteins † Daily Value not established.		

**Other Ingredients:** Raisins, Sucrose, Purified Water, Bee Honey, Linseed, Caramel Color, Citric Acid, Guar Gum Powder, Potassium Sorbate and Sodium Benzoate added as preservatives.

**\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.**

2. The address of the distributor for Puerto Rico is Luis Garraton Inc., Carretera 869-Zona Ind. Las Vegas, Barrio Palmas-Cataño Puerto Rico 00962.

3. The undersigned can certify the accuracy of the information presented and contained in the foregoing notice. The foregoing information is complete and accurate, and the undersigned represents that the statements contained in this notice are truthful and not misleading.

Signed this 7 day of July, 2005.

  
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San Bernardo  
Santiago, Chile  
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