

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

3 2 5 5 5 AUG 18 P 2 :21

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:

AUG - 1 2005

**PRUNELAX**

Gentle yet effective laxative.  
Dietary Supplement. 60 Tablets

Manufactured by Laboratorios Garden House S.A.  
Avda. Pdte. Jorge Alessandri Rodriguez 12310 - Sn Bdo.Chile  
Imported by Healthtex Distributors, Inc.  
3555 N.W. 41 St. Miami - Florida 33142  
www.prunelax.com

**Supplement Facts/Nutrition Information:**

<b>SUPPLEMENT FACTS</b>		
Serving size : 2 tablets		
Servings Per Container: 30		
<b>Amount per serving</b>		<b>% Daily Value</b>
Calories	0.74	< 1%**
Total Fat	0.02g	0%
Sodium	0 mg	0%
Total Carbohydrates	1 gram	0%
Proteins	0.02 g	< 1%***
Dried Plums Extract (prunes extract)	125 mg	†
Senna Leaves (Cassia angustifolia Valh)	960 mg	†
Alexandrian Senna Pods (Cassia senna L.)	180 mg	†
** Percent Daily Value are based on 2,000 calories diet.		
*** Percent Daily Value are based on 56 g of proteins		
† Daily Value not established.		

**Other Ingredients:** Sodium Starch Glycolate, Polyvinylpyrrolidone, Copolyvidone, Padry NS Clear® (Coating), Colloidal Silicon Dioxide, Sodium Lauryl Sulphate.

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**\*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.**

**KEEP OUT OF REACH OF CHILDREN  
STORE IN A DRY AND COOL PLACE  
NOT TO BE USED AS FOOD  
NOT USE IF THE BLISTER PACK  
ALUMINUM IS BROKEN**

**Prunelax (Ciruelax) Tablets** contain dried plums extract and herbs which help you maintain bowel regularity.\*

**Directions:** Adults and children 15 years of age and over take 2 to 3 tablets before bedtime. Follow with a glass of water or juice. Do not exceed recommended dosage.

Children under 15 years of age consult a doctor.

Prunelax takes effect within 8 to 12 hours.

**Natural laxative for occasional constipation.\***

**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.

2. The address of the distributor is Healthtex Distributors, INC. 3555 N.W. 41 Street, Miami, Florida 33142.

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 16 day of June, 2005.



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