



**Alva-Amco Pharmacial Companies, Inc.**

*Fine Pharmaceuticals Since 1904*

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March 5, 2001

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

MAR 8 2001

**Re: Ultra-Fiber® Regularity Balance™  
Insoluble Fiber Supplement**

Ladies/Gentlemen:

This letter notifies the Food and Drug Administration pursuant to 21CFR101.93, that within the past 30 days our company has begun to market Ultra-Fiber® Regularity Balance™ Insoluble Fiber Supplement with the following statements on the label and/or in labeling for the product.

Helps maintain natural regularity.

Helps promote natural regularity and natural laxation . . . helping avoid occasional constipation.

A higher fiber diet provides added bulk allowing foods to move more surely through the gastro-intestinal tract thus reducing the time food is in contact with the intestinal walls.

The dietary ingredient of the product that is the subject of the above statements is: Dietary Fiber (as microcrystalline cellulose from natural plant sources, oat bran fiber, natural chicory fiber, apple fiber, psyllium powder and prune powder).

It is hereby certified that the information in this notification is complete and accurate and that our company has substantiation that the above statements are truthful and not misleading.

Very truly yours,  
Alva-Amco Pharmacial Cos., Inc.

Grace Burbulys  
Technical Affairs Manager

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