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8335 '98 NOV 18 P2:12

Weber & Weber GmbH & Co. KG • Postfach 20 • 82263 Inning/Ammersee

October 29, 1998

RECEIVED  
11/9/98

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

**Re: Notification pursuant to 21 C.F.R. § 101.93**

Pursuant to the provisions of 21 C.F.R. § 101.93, please be advised that the undersigned has included on the label of product a statement listed in section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act.

1. Name and address of manufacturer, packer, or distributor:

Weber&Weber International GmbH & Co.KG  
Herschinger Str. 33  
D-82263 Inning/Ammersee

2. Text of the statement being made:

"Helps maintain proper muscle tone in cerebral blood vessels"

3. Name of the dietary ingredient or supplement that is the subject of the statement:

Extract of petasites hybridus (butterbur root)

4. Name of the dietary supplement, including brand name:

Petadolex™

97S - 0162

Weber & Weber GmbH & Co. KG  
Herschinger Str. 33  
D-82266 Inning/Ammersee  
HRA München 72263

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HRB München Nr. 119229  
Geschäftsführer: Dr. Reiner Rittinghausen

Sparkasse Starnberg  
Konto-Nr. 430 801 209  
(BLZ 700 540 80)  
Postscheckkonto München

LET 2370

5. Certification:

The undersigned hereby certifies that the information contained in this notice is complete and accurate, and that Weber&Weber has substantiation that the statement is truthful and not misleading.



Volker F. Gallichio  
Managing Director, US Operations