

NOUVEAU PROSTHETICS AND ORTHOTICS  
www.artificiallimbs.com

Corporate Offices &  
Patient Care Facilities:

Nouveau P&O, Inc.  
984 Highway 36  
Hazlet, NJ 07730  
(732) 739-0888  
Fax (732) 739-5351

Boro Park Office  
5422 Fort Hamilton Pky.  
Brooklyn, NY 11219  
(718) 871-2222  
Fax (718) 871-1478

Patient Care Centers:

501 Stillwells Corner Road  
Freehold, NJ 07728  
(800) 316-8330

158 South Main Street  
Hightstown, NJ 08520  
(800) 316-8330

1451 Route 88 West  
Suite 5  
Brick, NJ 08724  
(800) 316-8330

1100 Westcott Drive  
Suite 303  
Flemington, NJ 08822  
(800) 316-8330

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10 Parsonage Road  
Suite 508  
Edison, NJ 08837  
(800) 316-8330

South Shore Rehab  
4280 Hylan Boulevard  
Upper Level  
Staten Island, NY 10312  
(718) 871-2222  
Fax (718) 871-1478

November 15, 2006

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers lane, Room 1061  
Docket #2006P-0085  
Rockville, Maryland 20852

**Re: Docket # 2006P – Cranial Orthoses**

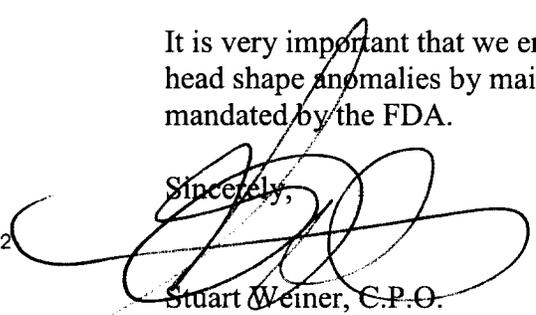
Dear FDA Officials:

I am writing in response to the Federal Register notice published by the Food and Drug Administration on October 24, 2006. Notice requested comments on the possibility of establishing an exemption from the premarket notification requirements for cranial remolding orthoses (headbands). These devices are used to improve cranial symmetry for babies with plagiocephaly.

As a clinician very actively involved in the treatment of infants with deformational plagiocephaly, I strongly oppose this change. I sincerely believe that if cranial remolding orthoses are exempted from premarket notification requirements, it will create safety and effectiveness issues for babies that require cranial remolding orthoses. These are risks inherent in applying cranial orthoses to an infant's rapidly growing cranium, and it is ill-advised to remove the current level of safeguards in place to protect this vulnerable population of patients.

It is very important that we ensure the utmost protection for babies with head shape anomalies by maintaining stringent regulation as presently mandated by the FDA.

Sincerely,

  
Stuart Weiner, C.P.O.

2006 P-0085

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