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President
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Seattle, Washington

July 6, 2006

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Dear Sir or Madame:

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) have been asked by FDA staff to send written environmental impact and completeness statements to accompany the materials sent to the FDA on February 9, 2006, Petition to Exempt Cranial Orthoses from Premarket Notification Requirements.

To the best of our knowledge, there is no environmental impact statement required.

In addition, we have been asked to send an official certification of completeness statement which appears below:

I certify on behalf of the AANS and CNS that, to the best of my knowledge and belief, the petition submitted by the AANS and CNS on February 9, 2006, includes all information and views on which the petition relies, and that it includes any representative data and information known to the AANS and CNS which are unfavorable to the petition.

Thank you for your time and attention. If you require additional information, please contact me in the AANS/CNS Washington Office.

Sincerely,

Catherine Jeakle Hill

Catherine Jeakle Hill
Senior Manager, Regulatory Affairs
AANS/CNS Washington Office

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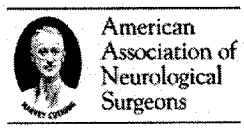

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February 9, 2006

0909 '06 MAY 26 P3:14

Dockets Management Branch
HFA-305, Food and Drug Administration
Dept. of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: Petition to Exempt Cranial Orthoses from Premarket Notification Requirements

Gentlepersons:

On behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), the AANS/CNS Section on Pediatric Neurosurgery and the AANS/CNS Drugs and Devices Committee, we are petitioning to exempt the Class II device "cranial orthoses" from the premarket notification requirements under section 510(m)(2), as provided by Food and Drug Administration (FDA) Modernization Act. Cranial orthoses are neurological devices that are reviewed under Part 882 by the Office of General, Restorative, and Neurological Devices.

Cranial orthoses are commonly used devices for the treatment of infant skull deformity and have been in documented use since 1978[3]. Since the 1998 FDA Class II designation for this type of device[9], access to the device has been significantly limited and the cost for the device has markedly increased. It is the expert opinion of our organizations that many patients who would benefit from the use of cranial orthoses are now unable to pursue this well accepted treatment due to financial and geographic access limitations. Furthermore, we believe that a premarket notification for this type of Class II device is not necessary to ensure the safety and effectiveness of the device. Our reasoning for this position is detailed below.

In a January 21, 1998 *Federal Register* notice (63 FR 3142), the FDA described the criteria the agency feels appropriate to determine which Class II device types should be exempt from the premarket notification (510(k)) requirements. A significant concern of the FDA is whether premarket notification for the device is necessary to provide reasonable assurance of safety and effectiveness of the device. We believe the cranial orthoses do not require premarket notification to ensure their safe application.

Background

Cranial orthoses are custom made devices designed to treat changes to an infant's head as a result of either intrauterine constraint, post-natal changes related to sleep position, or post-surgically after correction of prematurely fused skull bones[3,4,6,7,10,11]. There has been a true epidemic of this condition since the initiation of the "back to sleep" program by the American Academy of Pediatrics (AAP) in 1992[1]. This program, which has successfully reduced the incidence of Sudden Infant Death

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Syndrome, has had the unintended effect of a vast increase in the incidence of deformational plagiocephaly (aka. positional molding). The AAP, in a recent document[2], has reinforced the need for this sleep behavior, meaning that the incidence of infant skull deformity will likely increase. Prior to 1998, pediatric craniofacial and neurological surgeons treating this condition were often able to have the cranial orthotic devices made by local hospitals and orthotists. After the approval of a "de novo" application for cranial orthoses as Class II neurology devices by the FDA in 1998 (Federal Register, 63 FR: 40650-40652)[7,9], production of these orthoses were primarily reduced to large national conglomerates that had the resources available to pursue premarket notification. The net effect has been, on average, a 300-400% increase in helmet price, reduced willingness of insurance companies to pay for helmet therapy, reduced geographic access, and a significant increase in the number of families who are unable to pursue this treatment option for the condition after it has been diagnosed.

Cranial Orthoses Meet FDA's Exemption Requirements

The FDA considers the following four factors in deciding if a device can be exempt from premarket notification:

(1) The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials.

There now exists greater than 27 years of documented use of cranial orthoses[3]. They are, and always have been, produced and distributed only by prescription and under the direction of a physician. In standard practice, these devices are prescribed almost exclusively by neurosurgeons and plastic surgeons with expertise in pediatric craniofacial conditions, although other physicians may prescribe them. They are never available without the oversight of a physician. We have been unable to find any documented examples of false or misleading claims regarding their use. Even when these devices are produced by larger corporations, their use is always directed by a physician and they are serviced locally by qualified orthotists with expertise in using these devices.

The device design is such that it offers a protective shield to the flattened areas of an infant's skull[4,7,10] (i.e. a passive design which is not intended to limit skull growth, just allow growth to occur in the portions of the skull where growth was being limited by external forces). Studies have shown that head circumference growth is unaffected by helmet use[5]. The device is composed of standard synthetic materials commonly used in the manufacturing of orthoses for many parts of the body, including the cranium, extremities, and trunk. These materials are well tolerated and very inert, with little chance for negative reactions. The internal portion, which is the only portion which touches the cranium, is a cross-linked polyethylene foam which is commercially available. The external shell is a copolymer mix of polypropylene. The only other material used is Velcro to externally secure the orthosis. All of the materials which contact the child have been approved by the Occupational Safety and Health Administration (OSHA) for use and their OSHA status is "not considered hazardous under OSHA" (Material Safety Data Sheets, U.S. Department of Labor form OMB No. 1218-0072).

(2) Characteristics of the device necessary for its safe and effective performance are well established.

There are many published articles in peer-reviewed medical literature documenting the indications for the device and the characteristics needed for safe and effective performance[3,4,6,7,10,11]. General routines include 12-22 hours of helmet use per day for an average treatment course of two-four

months, depending on clinical response as judged by the treating health care professional. The device requires regular follow up by the orthotist during the course of use to avoid pressure points from developing as the cranium grows, but no other ongoing maintenance.

(3) Changes in the device that could affect safety and effectiveness will either: (a) be readily detectable by users by visual examination or other means such as routine testing before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment.

The manufacturing profile for these devices is well established. Through casting or laser scanning a negative of the cranium is made. This is followed by a positive mold of the cranium, and then the manufacturing of the orthosis itself. Few changes to the device are likely based on the effective profile of the current device. The effects of any changes that would be made will be easily detectable by inspection of the cranium and scalp for pressure points. Anthropometric measurements of the skull using simple caliper measuring devices or topographic laser scanning easily determine the effectiveness of the device. Misdiagnosis of craniosynostosis (premature fusion of the skull sutures) as deformational plagiocephaly, although rare, would not be adversely affected by the device. Craniosynostosis leads to an intrinsic lack of skull growth and therefore a cranial orthosis applied to uncorrected craniosynostosis will have no impact either positively or negatively.

(4) Any changes to the device would not be likely to result in a change in the device's classification.

Few changes to this device are anticipated. The orthosis is so simple and effective that we do not anticipate any alteration to its basic design. The device is a passive system which allows growth of deficient areas of the skull by shielding these areas, without a reduction of other parts of the skull (i.e. it does not lead to active compression of the skull, it only allows for growth of the skull). We do not anticipate any changes in the device profile that could change the devices classification. Of course, even if these devices are exempted, they would still be subject to the limitations on exemptions.

Limitation on Exemption

As per the limitation on exemptions described by the FDA, an exemption from the requirement of premarket notification for a cranial orthosis is only to apply to those devices that have characteristics of commercially distributed devices described above. A cranial orthosis would not be exempt from premarket notification if it (1) has an intended use that is different from the intended use of a legally marketed device in that generic type; e.g., the device is intended for a different medical purpose, or the device is intended for lay use instead of use by health care professionals; or (2) operates using a different fundamental scientific technology than that used by a legally marketed device in that generic type.
In addition, an exemption from the requirement of premarket notification does not mean that the device is exempt from any other statutory or regulatory requirements. We propose that all cranial orthoses remain available only on the advice of a physician and by prescription, that inappropriate applications of the device by avoided by close oversight of the device by health care professionals, and that labeling accompany all orthoses. The labeling should include instructions for the parents on appropriate application of the device, care and cleaning recommendations, and warning signs of an ill-fitting device.

Conclusion

In summary, we believe that cranial orthoses for remolding of the infant skull are benign biocompatible devices that should be exempt from the premarket Class II notification requirements. They will remain available by prescription only, under the care of a qualified physician and orthotist, and be accompanied by appropriate labeling. We strongly believe that this exemption will greatly increase the availability of these devices to children-at-need, whose access to the device has been greatly reduced by current requirements.

Thank you for considering our request. If you have any questions or require addition information please contact us.

Sincerely,

Fremont P. Wirth, MD, President
American Association of Neurological Surgeons

Richard G. Ellenbogen, MD, President
Congress of Neurological Surgeons

Rick Abbott, MD, Chairperson
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cc: CDRH
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References:

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11. Ripley, et al. Treatment of positional plagiocephaly with dynamic orthotic cranioplasty. J Craniofac Surg. 1994 Jul;5(3):150-9; discussion 160.

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April 23, 2006

Dockets Management Branch
HFA-305, Food and Drug Administration
Dept. of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: Petition to Exempt Cranial Orthoses from Premarket Notification Requirements

To whom it concerns:

Apparently there has been some confusion related to the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) Petition to Exempt Cranial Orthoses from Premarket Notification Requirements filed February 9, 2006. This letter serves to clarify this matter.

I had attempted to submit a personal letter in support of the AANS and CNS petition, but was informed that I was unable to do so without additional documentation and so I submitted the attached notification withdrawing my personal petition. Unfortunately, as a result of my personal correspondence, the FDA withdrew the entire AANS and CNS petition.

Please note that the American Association of Neurological Surgeons does indeed support the above reference petition, a copy of which is attached, and respectfully requests that the FDA reinstate it for consideration.

Thank you in advance for correcting this error. If you have any questions or need additional information, please let me know.

Sincerely,

Fremont P. Wirth, MD
President

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President
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May 26, 2006

0908 '06 MAY 26 P3:14

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Dear Sir or Madame:

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) have been asked by FDA staff to send a written notice of release for all of the materials included in our February 9, 2006, Petition to Exempt Cranial Orthoses from Premarket Notification Requirements.

All of the material in our letter and the accompanying documents are releasable and may be used and forwarded by the FDA as appropriate and necessary in their regulatory review of the petition.

Thank you for your time and attention. If you require any additional information, please contact me in the AANS/CNS Washington Office.

Sincerely,

Catherine Jeakle Hill

Catherine Jeakle Hill
Senior Manager, Regulatory Affairs
AANS/CNS Washington Office

American
Association of
Neurological
Surgeons

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