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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 6 1997

WARNING LETTERVIA FEDERAL EXPRESS

Bill Tidmore
President
DePuy Motech
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Dear Mr. Tidmore:

The Center for Devices and Radiological Health of the Food and Drug Administration (FDA) received a letter dated October 20, 1997, from Cheryl Hastings, Manager, Regulatory Submissions, DePuy, Inc. (DePuy), advising us that the International Marketing Department of DePuy Motech had placed in a U.S. journal an advertisement promoting a DePuy product for a use not cleared by FDA. The letter stated that the individual who placed the ad thought that there was an international edition of the journal as well as a domestic edition.

The ad is for DePuy's PEAK Cervical Plate Systems and it appeared in the October, 1997 issue of the Journal of Neurosurgery. Ms. Hastings' letter referred to the Channeled Plate described in the ad and noted that FDA's marketing clearance for the plate in response to the company's premarket notification submission, k963350, was limited to "... use in treating fractures of small bones such as the metacarpals, ulna, radius, humerus and metatarsals and in treating fractures of the lateral malleolus, olecranon, and intraarticular distal tibia." The PEAK Fixation System, also identified in an addition to the 510(k) dated November 5, 1996, as the PEAK Channeled Plate Fixation System, is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act.)

The advertisement has resulted in the misbranding and adulteration of DePuy's PEAK Channeled Plate Fixation System because it advertises the Posterior Channeled Plate as being associated with or part of Depuy Motech's Peak Cervical Plate Systems. Readers of the ad can therefore make a connection between the cleared PEAK Channeled Plate Fixation System and the claim, unapproved in the United States, for use of the Posterior Channeled Plate for cervical use. The advertisement therefore, changes the intended use of the U.S. cleared device and promotes it in the U.S. for an off-label use. The agency's regulations at 21 CFR 801.4 provide that the term "intended use" refers to the objective intent of the persons legally responsible for the labeling of the device. That intent may be

shown by labeling claims or advertising matter or oral or written statements by such persons or their representatives. United States users of the PEAK Channeled Plate Fixation System may be encouraged to use the device in the cervical area.

The device is misbranded within the meaning of section 502(o) because no notice or other information respecting the modification of the intended use was provided to FDA as is required by 21 CFR 807.81(a)(3)(ii) and the device was not found substantially equivalent to a predicate device for the uses implied in the ad.

The device is adulterated within the meaning of section 502(f)(1)(B) of the Act in that it is a class III device within the meaning of section 513(f) of the Act and does not have an approved premarket approval application in effect pursuant to section 515(a) or an approved application for an investigational device exemption under section 520(g).

This letter is not intended to be an all-inclusive list of deficiencies associated with your PEAK Channeled Plate Fixation System. It is your responsibility to ensure adherence to each requirement of the Act and the Federal regulations. The specific violations discussed in this letter may represent practices used in other promotional or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to ensure compliance with applicable regulations.

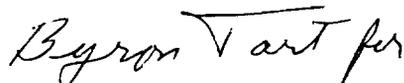
While Ms. Hastings' letter indicated that the employee in your International Marketing Department who placed the recent ad did so without following the company's review process, the company remains responsible for the resulting publication. We acknowledge that your letter brought the ad to our attention and that Ms. Hastings indicated that the company had discontinued the ad. It is important that you take prompt action to correct any other violations and to ensure that the advertisement does not appear again in the Journal of Neurosurgery or in any other publication or setting. Failure to correct these deviations may result in FDA's initiating regulatory action without further notice. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product and assessing civil money penalties.

As noted above, we acknowledge that the company indicated that it intended to remove this ad from publication and we note that it does not appear in the November issue of the journal. Please notify this office in writing within 15 working days of your receipt of this letter of the specific steps you have taken to prevent similar violations in the future, including any violations that may be posed by other materials pending publication. Such steps may include educating marketing and sales personnel on the appropriate distribution of materials. If corrective actions cannot be completed in 15 working days, please state the reason for the delay and the time within which the actions will be completed.

Send your response to Deborah Wolf, Regulatory Counsel, Promotion and Advertising Policy Staff, Office of Compliance (HFZ-302), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Detroit District Office. Please forward a copy of your response to the District Director, Food and Drug Administration, (HFR-MW200), 1560 East Jefferson Avenue, Detroit, Michigan 48207.

Sincerely yours,

A handwritten signature in cursive script that reads "Byron Tart for".

Lillian Gill

Director

Office of Compliance

Center for Devices and

Radiological Health