NCS Pearson 8/20/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

WARNING LETTER
AUG 20, 2015

Mr. Russell A. Gullotti
CEO and President
Pearson Education, Inc.
NSC Pearson
239 Littleton Road
Suite 6A
Westford, Massachusetts 01886

Re: Quotient ADHD System
Refer to CMS 471631

Dear Mr. Gullotti:

The United States Food and Drug Administration (FDA) has learned that your firm is marketing the Quotient ADHD System in the United States without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Under section 201(h) of the Act, 21 U.S.C. § 321(h), this product is a device because

it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

The FDA has reviewed your firm's website at http://www.quotient-adhd.com and determined that the Quotient ADHD Systemis adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g) for the device as described and marketed. The Quotient ADHD Systemis also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm introduced or delivered for introduction into interstate commerce for commercial distribution this device with major changes or modifications to the intended use without submitting a new premarket notification to FDA as required by section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR 807.81(a)(3)(ii).

Specifically, the Quotient ADHD System(originally named OPTAx System) was cleared underK020800with the indications for use as a device that provides clinicians with objective measurements of hyperactivity, impulsivity and inattention to aid in the clinical assessment of ADHD. OPTAx results should be interpreted only by qualified professionals. However, your firm's promotion of the device provides evidence that the device is intended to measure motion and analyze shifts in attention state, monitor response to treatment, help to optimize treatment in weeks instead of months, and help to determine the effectiveness of a new treatment or continued effectiveness of ongoing treatment when clinically indicated**.** This would constitute a major change or modification to its intended use for which your firm lacks clearance or approval. Examples include:

- "….monitor response to treatment.."
- "…objectively measures micro-motion and analyzes shifts in attention state."
- "Follow-up tests help to assess whether the patient is getting the right intervention."
- "…optimize treatment in weeks instead of months."
- "….helps to achieve clinical efficacy sooner."

These indications fall outside of the cleared indications for the Quotient ADHD System and provide evidence of a new intended use for which FDA's clearance or approval is required.

For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b). The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/defau
FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

Our office requests that NSC Pearson immediately cease activities that result in the misbranding or adulteration of the Quotient Attention ADHD System, such as the commercial distribution of the device for the uses discussed above.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within fifteen (15) business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from recurring. Include documentation of the corrections and/or corrective actions (which must address systemic problems) your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Field Inspections Support Branch
White Oak Building 66, Rm 2609
10903 New Hampshire Ave.
Silver Spring, MD 20993

Refer to the identification number CMS # 471631 when replying. We remind you that only written communication is considered as official. If you have any questions about the contents of this letter, please contact: Debra Demeritt, Chief, Surveillance and Enforcement Branch II at (301) 796-5770 or fax (301) 847-8137.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm. It is your firm's responsibility to ensure compliance with the

applicable laws and regulations administered by FDA.

Sincerely yours,
/S/
Jan B. Welch, MHS, MT (ASCP) SBB
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

More in 2015

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

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