DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

Via UPS Next Day Air

January 20, 2016

Dennis King, Senior Director of Quality Assurance
PSS World Medical, Inc.
4345 Southpoint Boulevard
Jacksonville, FL 32216

Dear Mr. King:

This letter pertains to your company's sale of Wallcur LLC's "Practi-0.9% Sodium Chloride" product to medical care facilities, where the product was administered to patients. According to Wallcur, its products are intended for training purposes only. Their products are not manufactured under sterile conditions and are not safe for human use. Your firm nevertheless marketed and sold Practi-0.9% Sodium Chloride as a replacement for 0.9% sodium chloride IV human drugs, thereby causing the introduction of the product into interstate commerce for use in treating humans. Testing of Wallcur's products sold by your firm identified endotoxin and bacterial contamination in the samples. Wallcur Practi-0.9% Sodium Chloride products purchased from your company caused serious harm to patients.

FDA's investigation of the adverse events associated with the use of Wallcur's Practi-0.9% Sodium Chloride identified several ways in which your firm contributed to this simulation product getting into the human drug supply chain and being used in patients. These include, but are not limited to:

- Ordering procedures involving pull down menus or "pop-ups" on your website that misled purchasers into believing they were ordering drugs intended for human use

- Insufficient cautionary language on order areas in print or in website descriptions of products to clearly distinguish practice products from those that could safely and legally be used in patients

- Insufficient education for sales representatives to assure that they were familiar with the products being offered for sale and could advise buyers accurately on the intended use and regulatory status of the products.

Our investigation indicated that your practices caused the introduction into interstate commerce of a product that you advertised, marketed and sold as 0.9% sodium chloride IV for use in treating human patients, but which was actually a simulation product. Because the simulation product you advertised, marketed, and sold for use in treating human patients is not generally

recognized as safe and effective for use under the conditions recommended or suggested in the labeling (including information on your website at the time of the investigation), the product is a "new drug" within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or Act) [21 U.S.C. § 321(p)]. Under sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(a), (d) and 355(a)], a new drug may not be introduced into or delivered for introduction into interstate commerce unless an application approved by FDA under either section 505(b) or (j) of the Act [21 U.S.C. § 355(b) or (j)] is in effect for the drug. There are no FDA-approved applications on file for any of the products manufactured by Wallcur.

Furthermore, your firm contributed to the endangerment to health by selling simulation or practice products in the place of 0.9% sodium chloride IV human drugs. When used in the manner recommended or suggested in your promotional materials for the simulation product, such as your website from which orders for the products could be placed, such products were misbranded under section 502(j) of the FD&C Act. It is a prohibited act under section 301(k) of the FD&C Act to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being misbranded.

These drugs were also misbranded under Section 502(f)(1) [21 U.S.C. 352(f)(1)] in that their labeling failed to bear adequate directions for the use for which these drugs were represented or suggested. They are not exempt from this requirement under regulation 21 CFR 201.115, since they are new drugs within the meaning of Section 201(p) of the Act, 21 U.S.C. 321(p), and no approval of an application filed pursuant to Sections 505(b) and 505(j) of the Act[21 U.S.C. 355(b) and (j)] is effective for these drugs. It is a prohibited act under Section 301(a) of the FD&C Act to introduce or to cause introduction into interstate commerce of a misbranded drug.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that may exist in connection with your sale and marketing of "practice" or "simulation" products. In particular, violations cited in this letter are not necessarily limited to drug products manufactured by Wallcur and may apply to all drug products that you market without FDA-approved applications. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations.

FDA strongly recommends that your management immediately undertake a comprehensive assessment of your order fulfillment and website operations, including ordering procedures, product marketing descriptions and cautionary language, and training of sales personnel. You should fully implement necessary corrections in order to ensure that the drug product(s) marketed and sold by your firm conform to the basic quality standards that ensure safety, identity, strength, quality, and purity, and that any non-drug products are clearly identified as such.

Within fifteen working days of receipt of this letter, we request that you send to this office written documentation of the specific steps that you have taken to correct the violations discussed in this letter. Also please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation.

Your reply should be sent to U.S. Food & Drug Administration, CDER, Office of Drug Supply Chain Integrity, Security, and Response, 10903 New Hampshire Avenue, Building 51, Silver Spring, MD 20903, Attn: Karen Rothschild, Regulatory Counsel.

Sincerely,

/Thomas J. Christl/
Thomas J. Christl
Director, Office of Drug Supply Chain Security, Integrity, and Response