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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-04-24

March 24, 2004

Margaret S. Bennett
President, Encore, Inc.
7696 15th Street, East
Sarasota, Florida 34243-3213

Dear Ms. Bennett:

During the Food and Drug Administration's (FDA) inspection of Encore, Inc., located in Sarasota, Florida on November 4-5, 2003, we determined that your establishment is a finished device manufacturer and own-label distributor of vacuum erection systems (VTU-1 and VTU-E) in the United States. These vacuum erection systems are intended to aid in the production and maintenance of a penile erection in individuals suffering from impotence. They are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that your vacuum erection systems are adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, the manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System (QS) regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Your firm failed to establish and maintain procedures for implementing corrective and preventive actions are required by 21 CFR 820.100. Your General Manager, Jack Bennett, stated that he was responsible for all investigations, but that there was no procedure or documented evidence of investigations, corrective actions and preventive actions. Mr. Bennett stated that the only documentation were notes on the distribution records in cases where the company sent the customer a new device or special instructions.
2. Your firm failed to establish and maintain procedures for receiving, reviewing and evaluating complaints to ensure complaints are processed in a uniform and timely manner as required by 21 CFR 820.198. Mr. Bennett stated that he was responsible for handling all complaints and any investigations and that there was no procedure for complaint handling. As noted above, the only documentation of

these activities are notes on distribution records on the occasion of sending a customer a new device or special instructions.

3. Your firm designed the device, but failed to establish any design control procedures or to maintain a Design History File (DHF) for the identification, documentation, validation or where appropriate verification, review and approval of design changes prior to the implementation as required, 21 CFR 820.30(i). Your firm changed vendors of the pump and has no documentation that the current pump meets the specifications of the original pump manufacturer. In addition, an O-ring on the electric pump was changed without following any procedures for such a change. As a result, there was no evaluation conducted, documented or approved to ensure the change in the pump or O-rings did not have any effect on the safety or effectiveness of the device.
4. Your firm failed to establish and maintain purchasing control procedures to ensure that all purchased or otherwise received product and services conform to specified requirements as required by 21 CFR 820.50. For example:
 - According to Mr. Bennett, there is no procedure or documentation of any assessment of your contract manufacturer, [REDACTED]
 - According to Mr. Bennett, Encore orders all components for [REDACTED] and is responsible for qualifying all vendors before the components are shipped to [REDACTED] but there is no procedure or documentation of any supplier evaluations or control of purchasing data.
5. Your firm failed to adequately establish and maintain procedures or specifications in conjunction with your contract manufacturer, [REDACTED] in order for production processes and controls to be established that would ensure that a device conforms to its specifications as required by 21 CFR 820.70. During the FDA inspection, a telephone conference was held between the FDA investigator, Mr. Bennett and Mr. [REDACTED] from [REDACTED]. Mr. [REDACTED] stated that requirements were made verbally and not placed in writing except the pump test procedure that was written by [REDACTED]. No other specifications or process controls were documented.
6. Your firm failed to establish and maintain procedures for the acceptance of incoming product as required by 21 CFR 820.80(b). Mr. Bennett stated that he is responsible for vendor qualification and component purchasing, but he does not have specifications developed for the components. If there are no specifications developed, then acceptance activities cannot be properly conducted at Encore or [REDACTED]. The only control of components is that some components are tooled

with tooling equipment supplied by Encore. Further, [REDACTED] appears to only have testing procedures for the pump.

7. Your firm failed to ensure that management with executive responsibility has fully implemented and maintained an adequate and effective quality system at all levels of your organization as required by 21 CFR 820.20. Your General Manager, Jack Bennett, stated that there is no quality plan in place that relates to your Florida facility.
8. Your firm failed to establish and document procedures for conducting quality audits as required by 21 CFR 820.22. No internal quality audit procedures are in place to evaluate the quality system at your facility.

Additionally, no external penile rigidity devices to date have received marketing clearance from FDA for claims found in your advertising brochure, your web sites at <http://www.impoaid.com> and <http://www.revivesystem.com>, and labeling, including the information panels on the device cartons and user manual, that include being effective for improving blood flow to the penis, allowing many men to achieve normal erections on their own, removing plaques and cholesterol building up, and to open penile arteries and possibly restore them to their natural elasticity. The Condom Loc ring claims state "holds condom secure" and "keeps the condom securely in place." The trade name "Condom Loc" also implies this function.

These claims significantly modify the intended use(s) of the devices, as defined under 21 CFR 801.4, and would require the submission and prior clearance of a new 510(k) as required by 21 CFR 897.81(a)(3)(ii). In addition, with these claims, the vacuum erection systems are adulterated within the meaning of section 501(f)(1)(B) of the Act in that they are Class III devices under section 513(f), and do not have an approved application for premarket (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The vacuum erection systems are also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the devices was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the devices were not found to be substantially equivalent to a predicate device.

Your web site material also states "F.D.A. registered equipment" and "It is a medical grade F.D.A. registered product." Title 21 CFR, Part 807.39 specifically provides that [any] representation that creates an impression of official approval because of registration [of a device establishment] or possession of a registration number is misleading and constitutes misbranding." The registration of your establishment is just

one requirement that must be met for you to conduct the type of activities in which are engaged. Registration is also not a determination of FDA approval as to the status of the device, as clearly stated in 21 CFR 807.35(c).

Any reference of regulatory compliance, whether for registration or any other statutory requirement, provided for under the authority of the Federal Food, Drug, and Cosmetic Act (the Act) or promulgated pursuant to the Act, may not be used to denote FDA approval or compliance.

Your vacuum erection systems are also misbranded within the meaning of section 502(t)(2) in that your firm failed or refused to furnish material or information required by or under section 519 respecting the device and 21 CFR Part 803 (Medical Device Reporting regulation). Specifically, your firm failed to develop, maintain, and implement written MDR procedures and failed to establish and maintain MDR event files, which are material and information required under section 519 and 21 CFR 803.17 and 803.18. Under 21 CFR 803.17, written MDR procedures must include the following requirements:

1. Internal systems that provide for:
 - a. Timely and effective identification, communication, and evaluation of events that may be subject to medical device reporting requirements;
 - b. A standardized review process/procedure for determining when an event meets the criteria for reporting under this part; and
 - c. Timely transmission of complete medical device reports to FDA and/or manufacturers;
2. Documentation and record-keeping requirements for:
 - a. Information that was evaluated to determine if an event was reportable;
 - b. All medical device reports and information submitted to FDA and manufacturers.
 - c. Any information that was evaluated for the purpose of preparing the submission of annual reports; and
 - d. Systems that ensure access to information that facilitates timely follow-up and inspection by FDA.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We have reviewed your firm's response signed by Jack Bennett, General Manager, dated December 1, 2003, and find that the response is inadequate because it only promises to make the necessary corrective actions. Also for new procedures included, there was no evidence that they have been implemented and are effective. Your response has been made part of the Florida District file.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Please direct your response to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderely Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4728.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", written in a cursive style.

Emma R. Singleton
Director, Florida District