U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Rainbow LTD, Inc. dba PN Medical 11/1/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Florida District
555 Winderley Place, Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
FLA-12-04
November 1, 2011

Marguerite K. Nicholson
President
Rainbow Ltd, Inc. dba PN Medical
3340 Chatsworth Lane
Orlando, FL 32812-6005

Dear Ms. Nicholson:

During an inspection of your firm located in Orlando, Florida,on June 23, 2011, through June 23, 2011, an investigator from the United States Food and Drug Administration (FDA) determined that your firm is a specification developer and repacker of a therapeutic (incentive) spirometer, "The Breather." Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (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 is intended to affect the structure or function of the body.

This inspection revealed that this device is adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in tha the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

We received a response from you dated July 8, 2011, concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations that was issued to your firm. We reviewed your response to each observation and conclude that it is not adequate. Although it was noted in the response that your firm has hired an outside consulting firm to help establish a Quality System including procedures that conform to the regulation, no evidence of those procedures or their projected implementation is included in your firm's response. Further, no evidence of specific corrections, corrective actions, or systemic corrective actions was included in your firm's response. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a).

For example:

Your firm has not established CAPA procedures.

2. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i).

For example:

a. Your firm lacks written procedures for design change.

b. Although your firm has changed the device's package insert and website material in response to violations cited in the 483, the claims that remain promote your device for uses beyond those cleared in **(b)(4)** and K972824. Specifically, your firm's package insert and web materials claim the device can be used to treat dysphagia, dysarthria, smoking cessation and other new uses. These changes were not made in accordance with design change requirements of the Quality System regulation.

3. Failure to establish and maintain 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:

Your firm does not have a purchasing control procedure and has not evaluated the contract manufacturer to ensure that manufacturing processes are appropriately validated. In addition, there are no maintenance procedures in place, nor has you firm established procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

4. Failure to establish and maintain procedures for acceptance activities, as required by 21 CFR 820.80(a).

For example:

Your firm has not established procedures for acceptance activities and has no documentation to support that incoming inspection activities have been conducted.

5. Failure to establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a).

For example:

Your firm failed to review and evaluate complaints, specifically, you noted a situation when you received a complaint of loos mouthpieces for the device and satisfied the complainant by shipping other product to her client. Additionally, your firm has not documented oral and written complaints on the "Complaint Record Form" as required by your firm's complaint procedure.

6. Failure to establish and maintain procedures for quality audits and conduct such audits to assure that the quality system is i compliance with the established quality system requirements and to determine the effectiveness of the firm's quality system, as required by 21 CFR 820.22.

For example:

Your firm has not established an internal audit procedure and has not conducted any internal audits.

Our inspection also revealed that your firm's The Breather device is misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting. Significant violations include, but are not limited to, the following:

7. Failure to develop, maintain and implement a written MDR Procedure, as required by 21 CFR Part 803.17.

For example, when the investigator requested the MDR procedure for review, you noted that you did not know what an MDR procedure was. Upon explanation by the investigator you confirmed that your firm had not established an MDR procedure.

Your firm obtained the following 510k clearances for the Breather, **(b)(4)** and K972824. The Breather, cleared under **(b)(4)**, is intended as a device that indicates a patient's breathing volume or flow and that provides an incentive to the patient to improve his or her ventilation. That is, it is an inspiratory/expiratory breathing exerciser for respiratory muscles, and used as an expiratory resistance device, positive expiratory pressure to substitute for pursed lip breathing and to assist in mucous clearance. The Breather, as cleared under K972824, is intended to assist the patient in the coordination of breathing during nebulization treatments via hooking the device up with medication delivery systems i.e., metered does inhalers and electronic nebulization therapy. It is to be used in addition to, and not in place of, the medication delivery device provided by the manufacturer for nebulization treatments.

8. On September 21, 2011, a review of your firm's website, www.pnmedical.com/patient, found the following claims that are not

supported by your firm's cleared 510(k)'s. On the PN Medical patient webpage, your firm makes the following claims:

- It is the only FDA approved breathing device;
- Optimizes lung power;
- Induces relaxation via slow, deep breathing;
- Improves cardiovascular endurance;
- Improves Dysphagia (swallowing); and
- Improves Dysarthria (imperfect phonation).

At the bottom of your firm's PM Medical patient webpage, we also found a reference to your website, www.betterairways.com, whicl we were also able to review during the inspection. On your firm's "betterairways" website, there is a webpage dedicated to chronic obstructive pulmonary disease (COPD) where your firm makes the following claims:

> This site is for people with COPD, emphysema, chronic bronchitis, and asthma. . . In addition to treating COPD, many professionals use the Breather for cystic fibrosis, bronchiectasis, asbestosis, black lung disease. . . post polio syndrome, cerebrovascular accidents (including stroke), quadriplegia, postoperatively – especially for abdominal surgeries, and any time a person is short of breath or suffers from panic attacks.

We reviewed your firm's response and conclude that it is not adequate. Although your firm removed your firm's "Home" pages from both websites, misleading and inappropriate information is still available on pages such as,www.pnmedical.com/speech.html and www.betterairways.com/asthma.html.

These statements represent a major change or modification in the intended use of your firm's device that requires a new premarket notification. 21 CFR 807.81(a)(3)(ii). Therefore, the Breather device is 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 under section 520(g) of the Act, 21 U.S.C. § 360j(g). The device is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce it into commercial distribution for the intended uses discussed above, as required by section 510(k) of the Act, 21 U.S.C. § 360(k).

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 C.F.R. 807.81(b). The kind of information that your firm needs to submit in order to obtain approval or clearance for your device is available through the Internet at http://www.fda.gov/cdrh/deviceadvice /3122.html. The FDA will evaluate the information your firm submits and decide whether the product may be legally marketed.

The PN Medical device is also misbranded under 501(a) of the Act (21 U.S.C.§ 352(a)) in that the labeling for the device at http://www.betterairways.com/asthma.html, contains statements such as "It is the only FDA approved breathing device…." which suggest that the device has been approved by FDA for uses listed on your firm's website, which statements are false.

Under section 510 of the Act (21 U.S.C. § 360), manufacturers of medical devices are required to annually register with the FDA. In September 2007, section 510 of the Act was amended by the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85) to require domestic and foreign device establishments to submit their annual establishment registration and device listing information to FDA by electronic means [section 510(p) of the Act (21 U.S.C. § 360(p))] during the period beginning October 1st an ending December 31st of each year. Our records indicate that your firm has not fulfilled annual registration and listing requirements for fiscal year 2011.

Therefore all of your firm's devices are misbranded within the meaning of section 502(o) of the Act (21 U.S.C. § 352(0)), in that the devices were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under sectio 510 of the Act (21 U.S.C. § 360) and were not included in a list required by section 510(j) of the Act (21 U.S.C. § 360(j)).

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. Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen business days from the date your firm 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 occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that 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: Salvatore Randazzo, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida

32751. Refer to the Unique Identification Number (CMS 213973) when replying. If you have any questions about the contents of thi letter, please contact: Salvatore Randazzo at (407) 475-4712.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely,
/S/
Emma R. Singleton
Director, Florida District

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