U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Praxair Inc. 1/7/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New York District
Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

January 7, 2015

WARNING LETTER NYK-2015-16

VIA UNITED PARCEL SERVICE

Mr. Stephen F. Angel, President, Chairman & CEO
Praxair Inc.
175 E. Park Drive
Tonawanda, NY 14150-7844
FEI: 1000448358

Dear Mr. Angel:

During an inspection of your firm located in Tonawanda, NY, on July 29, 2014 through August 8, 2014, an Investigator from the United States Food and Drug Administration (FDA) determined that your firm is a medical device specification developer of, in part, various 'gas flow regulators intended to administer oxygen to patients at a specific flow rate'. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are 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.

Quality System Violations

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, its 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 your firm's response dated August 29, 2014, regarding our investigator's observations included on the Form FDA-483 (FDA 483), List of Inspectional Observations, which was issued to you at the close of the inspection. We address this response below, in relation to each of the violations. These violations include, but are not limited to, the following:

1. Procedures for receiving, reviewing and evaluating complaints by a formally designated unit have not been established as required by 21 CFR 820.198. Specifically, complaint files associated with high pressure medical grade oxygen cylinders that reported leaks with use of your **(b)(4)** used to regulate the flow of oxygen, did not contain device identification and control numbers, results of investigation or replies to complainants. Additionally, your firm's procedure entitled: **(b)(4)**, has not been implemented to ensure a full complaint investigation is conducted. For example, your firm did not forward complaint information to the supplier of your **(b)(4)** to ensure an adequate investigation.

Your response to this observation is not adequate. In your response dated August 29, 2014 you indicate you will be revising complaint procedures to address this violation. Revised written complaint procedures have not been provided to date. Additionally, your response does not address correction to the above stated complaints.

2. Failure to establish procedures for corrective and preventive action, as required by 21 CFR 820.100(a). Specifically, written procedures have not been established for corrective and preventive actions as it pertains to devices (i.e. **(b)(4)** and quality data at your firm. This includes but not limited to the analysis and handling of: audit reports, service reports, product returns, trend analysis of complaints and trend analysis of non-conformances. Additionally, your procedure **(b)(4)**, does not require verification or validation of corrective and preventative actions to ensure any actions taken do not adversely affect the finished device.

Your response to this observation is not adequate. In your response dated August 29, 2014 you indicate you will be revising your CAPA procedures to address this violation. Revised written CAPA procedures have not been provided to date.

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 an agreement with its supplier, **(b)(4)**, that requires they notify you of changes in the product or service. Specifically, changes have been made to your **(b)(4)** by your supplier, **(b)(4)**, as referenced in drawings such as **(b)(4)**, however these changes were not reviewed or approved by your management prior to implementation.

Your response to this observation is not adequate. In your response dated August 29, 2014 you indicate you will be writing new procedures to address this violation. No procedures have been provided to date. In addition, your responses dated August 29, 2014 and September 24, 2014 do not include evidence to support changes made by your supplier to your **(b)(4)** have been reviewed and are acceptable.

MDR Violations

Our inspection also revealed that the **(b)(4)** 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 regarding the devices 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 deviations include, but are not limited to:

4. Failure to submit a report to FDA no later than 30 calendar days after the day that your firm received or otherwise became aware of information that reasonably suggests that a device that your firm markets has malfunctioned and this device or a similar device that your firm markets, would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, as required by 21 CFR 803.50(a)(2). For example:

a. The information included for MDRs **(b)(4)** and **(b)(4)** reasonably suggests that your firm's device malfunctioned, resulting in a flash fire in which the O-ring was a potentially contributing factor. A malfunction that results in a fire would be likely to cause or contribute to a reportable death or serious injury, if the malfunction were to recur. Your firm did not submit malfunction MDRs for these events within the required 30 calendar day timeframe.

b. The information included in your firm's document titled: **(b)(4)**, describes an event in which "an oxygen cylinder ruptured during the unloading from a truck and a fire resulted. The truck driver's helper burned his left arm. The helper received first aid at the hospital. The information included in the **(b)(4)** indicates that the O-Ring was a potentially contributing factor in the malfunction. A malfunction that results in a fire is a reportable event. Your firm did not submit a malfunction MDR for this event.

We reviewed your firm's response dated August 29, 2014, and conclude that it is not adequate. Your firm noted that it will submit a revised MDR procedure to address reporting problems. We have not received a copy of the revised procedure for review. In addition, we have not received a malfunction MDR for the event described above.

5. Failure to adequately develop, maintain and implement written MDR procedures as required by 21 CFR 803.17(a). For example, after reviewing your firm's MDR procedure, **(b)(4)** the following issues were noted:

a. Section **(b)(4)** does not establish internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements. For example:

i. There are no definitions of what your firm will consider to be a reportable event under 21 CFR Part 803. The exclusion of definitions from 21 CFR 803.3 for the terms "become aware," "caused or contributed," "malfunction," "MDR reportable event," and "serious injury," and the definition for the term "reasonably suggests," found in 21 CFR 803.20(c)(1), may lead your firm to make an incorrect reportability decision when evaluating a complaint that may meet the criteria for reporting under 21 CFR 803.50(a).

b. Section **(b)(4)** does not establish internal systems that provide for a standardized review process to determine when an event meets the criteria for reporting under this part. For example:

i. There are no instructions for how your firm will evaluate information about an event to make MDR reportability determinations in a timely manner.

c. Section **(b)(4)** does not establish internal systems that provide for timely transmission of complete medical device reports. Specifically, the following are not addressed:

i. The procedure does not include or refer to instructions for how to obtain and complete the FDA 3500A form.

ii. The circumstances under which your firm must submit initial or 30 day reports, supplemental or follow-up reports, and 5 day reports, and the requirements for such reports.

iii. The procedure does not include the address for where to submit MDR reports: FDA, CDRH, Medical Device Reporting, P. O. Box 3002, Rockville, MD 20847-3002.

We cannot determine the adequacy of your firm's response dated August 29, 2014. The response indicates that your firm is revising its MDR procedure to address reporting problems. We have not received a copy of the revised procedure for review.

The eMDR Final Rule requiring manufacturers and importers to submit electronic Medical Device Reports (eMDRs) to FDA was published on February 13, 2014. The requirements of this final rule will take effect on August 14, 2015. If your firm is not currently submitting reports electronically, we encourage you to visit the following web link for additional information about the electronic reporting requirements:

http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm (http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm)

If your firm wishes to discuss MDR reportability criteria or to schedule further communications, it may contact the Reportability Review Team by email at **ReportabilityReviewTeam@fda.hhs.gov (mailto:ReportabilityReviewTeam@fda.hhs.gov)**

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 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 occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) 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 written response should be sent the Food and Drug Administration; Attention:

LCDR Catherine Beer
Compliance Officer

U. S. Food and Drug Administration
One Winners Circle, Suite 110
Albany, NY 12205

If you have any questions about the content of this letter please contact: LCDR Catherine Beer at (518) 453-2314 x1015.

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/
Ronald M. Pace
District Director
New York District

Close Out Letter

- **Praxair Inc. - Close Out Letter 9/21/15 (/ICECI/EnforcementActions/WarningLetters/2015/ucm463626.htm)**

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