U.S. Department
of Transportation

**Pipeline and
Hazardous Materials Safety
Administration**

400 Seventh Street, S.W.
Washington, D.C. 20590

MAR 23 2006

Mr. Charles Atlas
President
Oxytec Medical Corporation
5150 East LaPalma Avenue
Anaheim Hills, CA 92807

Ref. No. 06-0048

Dear Mr. Atlas:

This is in further response to your letter dated September 26, 2005, and my reply dated November 30, 2005, regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 100-180) to a device that your company calls the OxyTec 900.

It has come to our attention that the *total* equivalent lithium content of the battery pack of the OxyTec 900 is 15.84 grams and not 7.92 grams as stated in our earlier response. That fact does not change the statement made in our earlier response that the OxyTec 900 is not subject to the HMR. However, I must inform you of the following two issues:

(1) In accordance with the 2005-2006 Edition of the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air, your device is regulated as a Class 9 material when transported as cargo on board passenger and cargo aircraft. However, the device may be authorized for transportation on board passenger aircraft as a consumer electronic device containing lithium ion batteries with up to 25 grams of equivalent lithium content when carried by passengers or crew for personal use and protected so as to prevent short circuits.

(2) In a notice of proposed rulemaking published under Docket HM-224C on April 2, 2002 (67 FR 15510), the Research and Special Programs Administration (predecessor to the Pipeline and Hazardous Materials Safety Administration) has proposed to eliminate the 25-gram exception for lithium batteries found under § 173.185(c)(2) of the HMR. Please refer to our website at hazmat.dot.gov under the Rules and Regulations icon, in the rulemaking and Federal Register Notices section.

I apologize for any inconvenience. Please do not hesitate to contact us for other inquiries concerning the Hazardous Materials Regulations.

Sincerely,

John A. Gale,
Chief, Standards Development
Office of Hazardous Materials Standards

173.185(c)(2)

060048

OxyTec™
Medical Corporation

Foster
§ 173.115
§ 173.185
§ 175.10
Applicability
05-0253

September 26, 2005

Ms. Susan Gorsky
U.S. Department of Transportation
Mail Stop THH-10
400 7th Street SW
Washington, D.C. 20590

Re: OxyTec™ 900 Portable Oxygen Concentrator (POC)

Dear Ms. Gorsky:

As a result of recent telephone conversations between John Gale at the DOT and Bob Mogue at OxyTec Medical Corporation we are sending you this letter.

Our goal is to gain approval from the DOT and eventually the FAA for the use of the OxyTec 900 on board aircraft (Reference: July 12, 2005, DOT/FAA 14 CFR Parts 11 and 12, Use of Certain Portable Oxygen Concentrator Devices Onboard Aircraft). The OxyTec 900 is similar to the Inogen One approved device.

The OxyTec 900 is scheduled for U.S. home care market introduction in late 2005. It is an FDA 510(k) pre-market notification cleared device. Our 510 (k) number is K043615.

The device can be briefly described as a 9-½ pound portable oxygen concentrator (POC) that includes two lithium ion batteries installed in the device. With the two batteries fully charged the 900 has a duration-of-use of 8 hours at a setting of 2, (which we understand will be a huge benefit to traveling patients compared to the currently approved products). One or two batteries can power the OxyTec 900, and both can be removed for quick replacement with spare/extra batteries should the patient desire. In addition, the device can be powered by use of either an AC or DC power cord. When using AC or DC power, the device operates and the batteries are charged. The carry case also serves as the devices protective cover and is integral to the device.

The device is intended for use by individuals requiring supplemental oxygen, by and on the orders of a prescribing physician. The user will be ambulatory. The interface with the user will be through a standard single-lumen nasal cannula. Typically, most of the users will be diagnosed with chronic obstructive pulmonary disease (COPD).

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During discussions with Mr. Gale, he outlined two areas of interest that needed to be addressed in this letter. Those areas were:

- Lithium Ion Equivalent
- System Pressure

We are pleased to provide the following information in regard to these two topics.

Batteries

The lithium ion batteries used in the 900 have received a Declaration of Conformance (see attached document). The declaration of conformance shows the 8 tests that are required in the DOT Test Matrix and the test results (all pass). This certificate was received from our battery manufacturer Inspired Energy, Inc. The lithium ion equivalent for our batteries is 7.92 grams (see attached document). Each battery is 14.4 volts and carries an Inspired Energy part number NL2024.

Pressure

When the device is new, the maximum pressure is controlled in software to 12 p.s.i. maximum pressure. As the device ages, or under adverse conditions, this could be adjusted to as much as 18 p.s.i. The diaphragm compressor, by its nature, is capable of generating a maximum pressure of approximately 20 p.s.i., when at full power and deadheaded (zero flow).

Outlet gas pressure (the connection point of the nasal cannula) is limited first by the product reservoir pressure (12 p.s.i. – 18 p.s.i. maximum as noted above). The delivery valve (0.045" orifice) restricts it, so that the actual pressure at the outlet gas port during flow is approximately 1 p.s.i. – 4 p.s.i.. It would be possible; however, to get full product reservoir pressure (12 – 18 p.s.i. maximum as noted above) in the oxygen cannula if the end of the cannula was occluded.

We look forward to your comments regarding the OxyTec 900 PAOS in these two areas. If I can provide you with further detail, please feel free to give me or Bob a call.

Sincerely,

OxyTec Medical Corporation

Charles Atlas

Charles Atlas
President

cc: L. Robert Mogue, Director
Sales and Marketing