

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

ALL FLORIDA MEDICAL SUPPLIES,)
INC.,)
)
Petitioner,)
) Case No. 08-2553
vs.)
)
DEPARTMENT OF HEALTH,)
)
Respondent.)
_____)

RECOMMENDED ORDER

A final hearing was held in this case, pursuant to notice, on June 24, 2008, by video teleconference at sites in West Palm Beach and Tallahassee, Florida, by Eleanor M. Hunter an Administrative Law Judge of the Division of Administrative Hearings.

APPEARANCES

For Petitioner: Javier Talamo, Esquire
Kravitz & Talamo, LLP
7600 West 20th Avenue, Suite 213
Hialeah, Florida 33016

For Respondent: Jennifer L. Condon, Esquire
Department of Health
4052 Bald Cypress Way, Bin A-02
Tallahassee, Florida 32399-2202

STATEMENT OF THE ISSUE

Whether Petitioner is entitled to a permit to operate a medical oxygen retail establishment.

PRELIMINARY STATEMENT

On April 10, 2008, Respondent, Department of Health ("Respondent" or "DOH"), sent notice of its intent to deny the application filed by Petitioner, All Florida Medical Supplies, Inc., for a permit to operate a medical oxygen retail establishment. On May 23, 2008, the Division of Administrative Hearings received a request to assign an administrative law judge to hear issues raised in the Petition for Formal Administrative Hearing dated April 29, 2008. The final hearing was held on June 24, 2008.

At the hearing, Petitioner submitted its Exhibits 1-6, but presented no witnesses in its case-in-chief. Respondent presented the testimony of Bridget Coates and Denean Merritts, and submitted Respondent's Exhibits 1 and 2.

The Transcript of the final hearing was received on July 22, 2008. Proposed Recommended Orders were filed on July 28, 2008.

FINDINGS OF FACT

1. Petitioner, All Florida Medical Supplies, Inc. located in Delray Beach, Florida, is the applicant for a permit to operate a medical oxygen retail establishment. The application was filed due to a change in the ownership of Petitioner.

2. Respondent, Department of Health (DOH), is the agency authorized to regulate medical oxygen retail establishments, as provided in Chapter 499, Florida Statutes (2008).

3. On November 14, 2007, DOH received Petitioner's Application for a Permit under Chapter 499, Florida Statutes, to operate as a medical oxygen retailer. The applicant's address was given as: "601 N. Congress Ave. Bldg. 6 Suite Number 606, Delray Beach, FL 33445."

4. The handwritten mailing address given appeared to be "128 Van Gown Way, Royal Palm Beach, FL 33411-1580." The name given for the emergency contact at the mailing address was David L. Ford.

5. On December 11, 2007, and on December 31, 2007, DOH sent letters to the 128 Van Gown address requesting additional information to complete the application.

6. On January 8, 2007, one of the owners of Petitioner, Ellen Gust, sent an address correction to DOH by facsimile, along with a corrected application providing a new address. The corrected address was the 601 North Congress Avenue address.

7. On January 11, 2008, another letter citing an application deficiency was sent to the original Van Gown mailing address not the corrected mailing address. In the meantime, the assigned DOH permitting staff person and Mrs. Gust, for

Petitioner, had some telephone and email contacts that eliminated the remaining deficiency.

8. On January 18, 2008, DOH notified Petitioners that is application was complete.

9. A DOH inspector received the completed application from the permitting office and, on February 7, 2008, conducted an inspection of the business at its location at 601 North Congress Avenue in Delray Beach.

10. The inspector saw approximately 60 cylinders of oxygen at the inspection site and determined that they were full, based on the color of the tape used to seal them. She testified that Mrs. Gust told her that the cylinders had been filled on site.

11. The inspector found that the full oxygen cylinders were improperly labeled. That is, the labels on the cylinders lacked the name of the company and location where filled, as required by the Food and Drug Administration's compressed medical gases guidelines. In addition, the expiration date on the cylinders was December 2007, and there was no way to determine the oxygen content because Petitioner failed to produce any stability testing records. Mrs. Gust told the investigator that the date on the cylinders was the date they were filled.

12. The inspector observed cylinders inside a delivery van that also had an expiration date of December 2007. The lot

numbers on the cylinders inside the business and in the van were the same, but the validity of the lot numbers could not be verified by reference to any corresponding business records or fill logs. Mrs. Gust's husband told the inspector that the lot numbers were the numerical date of the year and month the tanks were filled, which is acceptable except that the methodology was not listed in any of Petitioner's policies and procedures.

13. Based on the inability to verify that the oxygen was safe and effective for use by patients, or to determine the useful life in the absence of stability test records or fill logs, the inspector ordered the removal of the seals on the cylinders and the release of the oxygen.

14. The inspector also found unclear signage to designate a quarantine area in the warehouse.

15. The inspector recommended, and DOH agreed that Petitioner failed the site inspection and that its permit application should be denied.

CONCLUSIONS OF LAW

16. The Division of Administrative Hearings has jurisdiction over the parties to and subject matter of this proceeding. §§ 120.569 and 120.57, Fla. Stat. (2008).

17. In license and permit application cases, the burden is upon the applicant to demonstrate its entitlement by a preponderance of the evidence. Department of Transportation v.

J.W.C. Company, Inc., 396 So. 2d 778 (Fla. 1st DCA 1981); Balino v. Department of Health and Rehabilitative Services, 348 So. 2d 349 (Fla. 1st DCA 1977); State ex rel. Glaser v. Pepper, 155 So. 2d 383 (Fla. 1st DCA 1963).

18. Petitioner, in this case, argues that it is entitled to the permit for one reason, the requirement in Florida Administrative Code Rule 64F-12.015(3)(d) that follows:

(d) The department will request from the applicant written documentation to evidence compliance with the requirements of Chapter 499, F.S., when an on-site inspection cannot be completed within 30 days of receipt of a completed application for a permit requiring an on-site inspection or a written request for a change of address.

19. Petitioner claims that its application, having been filed on November 14, 2007, should be deemed to have been complete 30 days later, because it did not timely receive a deficiency letter and have an opportunity to correct any omissions, or have the required on-site inspection within 30 days.

20. Petitioner's argument ignores three compelling facts. First, that it was Petitioner that provided an incorrect mailing address to DOH, and cannot now benefit from its mistake. Second, that the rule requires "receipt of a completed application." The application was not complete until January 18, 2008. Finally, despite DOH's error in continuing to

use the original rather than the corrected mailing address when it sent the deficiency letter of January 11, 2008, Petitioner was being given the same information by email and telephone calls to one of its owners, and the inspection was conducted on February 7, 2008, within 30 days of the receipt of the completed application.

21. Petitioner has failed to demonstrate entitlement to a permit to operate a medical oxygen retail establishment.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law it is RECOMMENDED:

That the Department of Health enter a final order denying the application of All Florida Medical Supplies, Inc., for a permit to operate a medical oxygen retail establishment.

DONE AND ENTERED this 15th day of August, 2008, in Tallahassee, Leon County, Florida.



ELEANOR M. HUNTER
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Filed with the Clerk of the
Division of Administrative Hearings
this 15th day of August, 2008.

COPIES FURNISHED:

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NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

All parties have the right to submit written exceptions within 15 days from the date of this Recommended Order. Any exceptions to this Recommended Order should be filed with the agency that will issue the Final Order in this case.