

**STATE OF FLORIDA  
DEPARTMENT OF HEALTH**

By:

*Rachul Bh*

Deputy Agency Clerk

Ornid Pharmaceuticals, Inc.,  
Petitioner,

vs.

Department of Health; Drugs,  
Devices, & Cosmetics Program;  
Respondent.

DOAH no. 08-5089

2009 APR 14 10:46 AM  
FILED  
DIVISION OF ADMINISTRATIVE HEARINGS

FINAL ORDER

This proceeding was initiated by a letter requesting an administrative hearing to challenge the Department of Health's intent to deny the Petitioner's application for a permit to operate as a prescription drug wholesale distributor. See **Florida Drug and Cosmetic Act**, Chapter 499, Part I, Florida Statutes. This matter was referred to the Division of Administrative Hearings for an adjudicatory proceeding pursuant to section 120.57(1), Florida Statutes. The Administrative Law Judge (hereinafter the ALJ) has entered a recommended order, and returned this matter to the Department of Health (hereinafter the Department) for disposition.

Counsel for the Department filed exceptions to the ALJ's findings on whether the Petitioner's sole owner was an affiliate of Worldwide Medical Supplies and Pharmaceuticals, Inc., an entity which was disciplined less than a year ago by **revocation** of its permit to operate as a prescription drug wholesale distributor in this State. Counsel maintains that the ALJ gave insufficient weight to discovery admissions of the Petitioner's sole owner. In considering the exceptions to an ALJ's findings of fact the general rule of deference is that an agency may reject or modify a finding of fact only if a challenged finding is not supported by competent, substantial evidence. Section

120.57(1) (ℓ), Florida Statutes. It is the role of the ALJ as fact finder to weigh conflicting evidence, to resolve conflicts in the evidence, to judge the credibility of witnesses, and to draw permissible inferences from the evidence. Correlatively, the referring agency has no authority to reweigh the evidence. See e.g. Heifetz v. Dept. of Bus. Regulation, 475 So.2d 1277, 1281, (Fla. 1<sup>st</sup> DCA 1985). The ALJ's findings of fact are entitled to as much weight and respect as the verdict of a jury. See Gruman v. Department of Revenue, 379 So.2d 1313, 1316 (Fla. 2<sup>nd</sup> DCA 1980). In Lawnwood Medical Center, et al., vs. Agency for Healthcare Administration, et al., 678 So.2d 421, 425 (Fla. 1<sup>st</sup> DCA 1996), the Court reversed a sister agency's final order on the basis that the agency reweighed the evidence by recasting as policy matters the ALJ's findings of fact on criteria for a certificate of need. Accordingly, these exceptions must be denied.

The disposition recommended by the ALJ is that the Department enter a final order denying the Petitioner's permit application based on the failure of the applicant to satisfy a critical requirement of licensure, the choice of a competent and trustworthy individual to serve as the Petitioner's "certified designated representative"<sup>1</sup>. The ALJ continues with a suggestion that application at issue be returned to Department staff to allow the Petitioner to propose another individual to serve as "certified designated representative". The effect of this suggestion would be to reopen the "free form"<sup>2</sup> consideration of this permit application.

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<sup>1</sup> The "certified designated representative" is a full-time manager certified by the Department of Health and actively involved in the day-to-day operation of a prescription drug wholesale distributor. See section 499.012(16), Florida Statutes.

<sup>2</sup> A "free form decision" is a decision by an agency's staff, which has ripened to the point where written notice to the substantially affected person must be given along with notice of the right to initiate an adjudicatory proceeding under 120.569 and 120.57. See e.g., Capeletti Brothers v. Dept. of Transportation, 362 So2d 346 (Fla. 1<sup>st</sup> DCA 1978)(Free form proceedings are the "every day" way that an agency makes its regulatory decisions, as distinguished from legally structured adjudicatory proceedings under the *Administrative Procedure Act*.)

The suggestion violates the interest of finality of litigation and is rejected.<sup>3</sup>

The recommended order of August 15, 2008 is adopted and incorporated by reference except for the modification of the disposition recommended by the ALJ. The recommended order is attached as exhibit A. The denial letter of September 8, 2008, is attached as exhibit B.

Based on the foregoing, the application of the Petitioner, Ornid Pharmaceuticals, Inc., for a permit to operate as a prescription drug wholesale distributor is denied. This proceeding is closed.

**DONE** and **ORDERED** this 20 day of April 2009 in Tallahassee, Leon County, Florida.

Ana M. Viamonte Ros, M.D., M.P.H.  
State Surgeon General

By: Jean L. Kline  
Jean L. Kline, R.N., B.S.N., M.P.H.  
Deputy Secretary for Health

**NOTICE**

A PARTY ADVERSELY AFFECTED BY THIS FINAL ORDER IS ENTITLED TO JUDICIAL REVIEW PURSUANT TO SECTION 120.68, FLORIDA STATUTES. A REVIEW PROCEEDING IS GOVERNED BY THE FLORIDA RULES OF APPELLATE PROCEDURE. A REVIEW PROCEEDING IS COMMENCED BY FILING A NOTICE OF APPEAL WITH THE CLERK OF THE DEPARTMENT OF HEALTH AND A COPY ACCOMPANIED BY THE FILING FEE WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE PARTY RESIDES OR THE FIRST DISTRICT COURT OF APPEAL. THE NOTICE MUST BE FILED WITHIN 30 DAYS OF THE FILING DATE OF THIS FINAL ORDER.

Copy furnished to each of the following:

Robert E. Meale  
Administrative Law Judge  
Division of Administrative Hearings  
The DeSoto Building  
1230 Apalachee Parkway  
Tallahassee, Florida 32399-1550

Rebecca R. Poston  
Department of Health  
Drugs, Devices, & Cosmetics Program  
4052 Bald Cypress Way, bin C-19  
Tallahassee, Florida 32399-1739

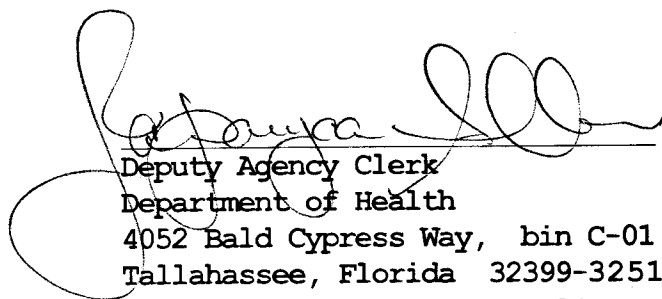
<sup>3</sup> In *Lawnwood Medical Center, et al., vs. Agency for Healthcare Administration, et al.*, 678 So.2d 421, 425 (Fla. 1<sup>st</sup> DCA 1996), the Court remarked that "to allow a party to produce additional evidence after the conclusion of an administrative hearing below would set in motion a never ending process of confrontation and cross-examination, rebuttal, and surrebuttal evidence, a result not contemplated by [Chapter 120]."

Gary L. Asbell, Esquire  
Department of Health  
4052 Bald Cypress Way, bin A-02  
Tallahassee, Florida 32399-1703

Ornid Pharmaceuticals  
c/o Alexander Valdes  
14052 S.W. 80<sup>th</sup> Street  
Miami, Florida 33183

CERTIFICATE OF SERVICE

I CERTIFY that a copy of the foregoing FINAL ORDER has been sent by the United States Postal Service, inter-office mail, or by hand delivery to each of the above-named persons this 23 day of April 2009.

  
Deputy Agency Clerk  
Department of Health  
4052 Bald Cypress Way, bin C-01  
Tallahassee, Florida 32399-3251  
phone: (850) 245-4121

**Deputy Agency Clerk**