

STATE OF FLORIDA  
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

<b>FILED</b>	
Department of Business and Professional Regulation	
Deputy Agency Clerk	
CLERK	Brandon Nichols
Date	2/10/2017
File #	2017-01091

KRS GLOBAL BIOLTECHNOLOGY, INC.,  
d/b/a KRS GLOBAL BIOTECHNOLOGY  
MANUFACTURING,

Petitioner,  
v.

DOAH CASE NO.: 16-2918  
DBPR CASE NOS.: 2016-017719  
2013-011474  
2016-013079

DEPARTMENT OF BUSINESS &  
PROFESSIONAL REGULATION,  
DIVISION OF DRUGS, DEVICES,  
AND COSMETICS,

Respondent.

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**FINAL ORDER**

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (Department), in accordance with the provisions of Section 120.57(4), Florida Statutes, hereby enters this Final Order incorporating and adopting, *in toto*, the Settlement Agreement entered into between KRS Global Biotechnology, Inc., d/b/a KRS Global Biotechnology Manufacturing, (Respondent) and the Department, attached hereto and incorporated by reference. This Final Order and Settlement Agreement are to resolve the alleged violation of Section 499.01(2)(a), Florida Statutes (2015), by failing to comply with current good manufacturing practices, as required by Section 499.01(1)(a), Florida Statutes (2015), and CFR Part 211; Section 499.005(14), Florida Statutes (2015), the purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient; Section 499.005(15), Florida Statutes (2015), the sale or transfer

of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug; Section 499.005(22), Florida Statutes (2015), the failure to obtain a permit or registration, or operating without a valid permit when a permit or registration is required by this part for that activity and Section 499.005(21), Florida Statutes (2015), purchase of prescription drugs from a private hospital or other health care entity or donated or supplied at a reduced price to a charitable organization. .

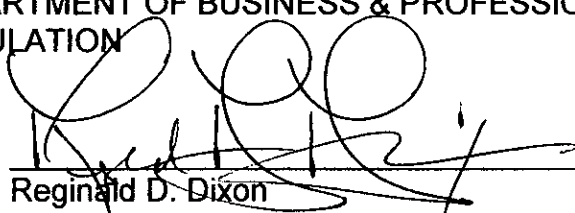
This Final Order is effective on the date it is filed with the Agency Clerk of the Department of Business & Professional Regulation as indicated on this Final Order.

DONE and ORDERED this 9th day of February, 2017 in Tallahassee, Florida.


MATILDE MILLER, INTERIM SECRETARY

DEPARTMENT OF BUSINESS & PROFESSIONAL  
REGULATION

By:

  
Reginald D. Dixon  
Division Director  
Drugs, Devices and Cosmetics

Prepared by:

  
Kathryn E. Amice  
Assistant General Counsel  
Division of Drugs, Devices and Cosmetics

**NOTICE OF RIGHT TO APPEAL**

Unless expressly waived, any party adversely affected by this Final Order may seek judicial review by filing an original Notice of Appeal with the Clerk of the

Department of Business & Professional Regulation, and a copy of the notice, accompanied by the filing fees prescribed by law, with the clerk of the appropriate District Court of Appeal within 30 days of the effective date of this order, in accordance with Florida Rule of Appellate Procedure 9.110, and Section 120.68, Florida Statutes.

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of this Final Order has been provided by United States Mail to: Counsel for Respondent, Sean Ellsworth, Esquire, Ellsworth Law Firm, P.A., 420 Lincoln Road, Suite 601, Miami Beach, Florida 33139, this 10<sup>th</sup> day of February, 2017.

By:   
Agency Clerk's Office