DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Room 4613, Building 66
Silver Spring, MD 20993-0002

HR Pharmaceuticals, Inc.
c/o Jon P. Wiesman, President & Founder
221 West Philadelphia Street #17
York, PA 17401

Re: **Small Business Decision Number: SBD148065**
FY 2014 MDUFA Small Business Qualification
Approval Date: October 1, 2013
Expires: September 30, 2014

Dear Mr. Wiesman:

The Food and Drug Administration (FDA's) Small Business Determination (SBD) team has completed the review of your application eligibility as Small Business under the Medical Device User Fee Act (MDUFA). I am pleased to inform you that your firm qualifies under MDUFA as a Small Business for a reduced or waived fee for medical device submissions made during the fiscal year 2014.

Please include your Small Business Decision Number (see above) whenever you submit a Medical Device User Fee Coversheet (Form FDA 3601). This form is available at:
http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFeeandModernizationAct/ucm155274.htm
When completing the form, the **Business EIN Number** and the **user fee organization number 243053** must correspond to the **Business Name** in the mailing address above.

If you are registering as a new user to the User Fee System, please use this organization number to register as an existing organization. If you currently have a User Fee account and the organization number in your profile does not match this organization number, please contact the User Fees Help Desk for further assistance at 301-796-7200 or at userfees@fda.gov.

Your Small Business status expires at the close of business September 30, 2014. FDA will provide information on how to qualify as a Small Business for FY2014 in a FEDERAL REGISTER Notice to be published on or about August 1, 2014. We will also provide this information on our MDUFA website at:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeandModernizationActMDUFMA/default.htm

Sincerely,

Gene W. Allen
Small Business Reviewer
Division of Small Manufacturers, International
and Consumer Assistance
Center for Devices and Radiological Health
U.S. Food and Drug Administration