



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

HR Pharmaceuticals, Inc.
5470 Mt. Pisgah Road
York, PA 17406

October 1, 2011

To: Jon P. Wiesman, Owner, President/CEO
Subject: Request for Qualification as a Small Business

Small Business Decision Number: **SBD128064**

Expires: **September 30, 2012**

This responds to your request for eligibility for Small Business Qualification on Form FDA 3602.

After review of your submission, I am pleased to inform you that your firm does qualify under MDUFMA as a small business for reduced or waived fees for medical device submissions made during the fiscal year 2012.

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 https://fdasfinapp8.fda.gov/OA_HTML/fdaCCtdMinisites.jsp?language=US In completing the form, the **Business EIN Number** and the **user fee organization number 243053** must correspond to the Business name in the top line of 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 userfees@fda.gov.

Your Small Business status expires at the close of business September 30, 2012. FDA will provide information on how to qualify as a Small Business for FY 2013 in a Federal Register Notice to be published on or around August 1, 2012. We will also provide this information on our MDUFMA website, at:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

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