



HR Pharmaceuticals, Inc.
Jon P. Wiesman
Founder & CEO
2600 Eastern Boulevard, Suite 201
York, PA 17402

December 11, 2018

Re: FY 2019 MDUFA Small Business Qualification
Small Business Decision Number: SBD198396
FDA User Fee Organization Number: **335772**
Approval Date: December 11, 2018
Expires: September 30, 2019

Dear Mr. Wiesman:

The Center for Devices and Radiological Health's (CDRH's), Small Business Determination (SBD) team has completed the review of your business' eligibility as a Small Business under the Medical Device User Fee Amendments (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 2019.

Please include your business' Small Business Decision Number (see above) whenever your business submits a Medical Device User Fee Coversheet (Form FDA 3601). This form is available at:

<http://www.fda.gov/forindustry/userfees/medicaldeviceuserfee/ucm452525.htm>

If you have issues with your business' User Fee account, please contact the User Fees Help Desk for further assistance at 301-796-7200 or at userfees@fda.gov.

Your business' Small Business status expires at the close of business September 30, 2019.



For information on the Small Business Program please reference the Device Advice website, [Reduced Medical Device User Fees: Small Business Determination \(SBD\) Program](#) and the [The Medical Device User Fee Small Business Qualification and Certification: Guidance for Industry, Food and Drug Administration Staff and Foreign Governments](#). For information on the FDA user Fee Program please see the [MDUFA User Fees](#) website.

Sincerely,

Gene W. Allen -S Digitally signed by Gene W. Allen -S
Date: 2018.12.11 08:19:51 -05'00'

Gene W. Allen
Public Health Advisor
Premarket Programs Branch
Division of Industry and Consumer
Education
Office of Communication and Education
Center for Devices and Radiological Health
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