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March 23, 2009

Mr. Don St. Pierre
Acting Office Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health
U.S. Food and Drug Administration (FDA)
HFZ-440
2098 Gaither Road
Rockville, MD 20850 (240) 276-0450

Re: FDA should publish data to support new HPV test approval

Dear Sir:

I have just read the news on-line (enclosed), reporting that the Cervista HPV HR test has been approved for two uses:

- To screen patients with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results to determine the need for referral to colposcopy.
- Used adjunctively with cervical cytology to screen women 30 years and older to assess the presence or absence of high-risk HPV types.

In addition, the Cervista HPV 16/18 test has been approved for two uses:

- In women 30 years and older the test may be used adjunctively with the Cervista HPV HR test in combination with cervical cytology to assess the presence or absence of specific high-risk HPV types.
- Used adjunctively with the Cervista HPV HR test in patients with ASC-US cervical cytology results, to assess the presence or absence of specific high-risk HPV types. The results of this test are not intended to prevent women from proceeding to colposcopy.

Pursuant to 21CFR 814.9(e)**,** which stipulates "Upon issuance of an order approving, or an order denying approval of any PMA, FDA will make available to the public the fact of the existence of the PMA and a detailed summary of information submitted to FDA respecting the safety and effectiveness of the device that is the subject of the PMA and that is the basis for the order.", I

hereby request that the CDRH OIVD publish the clinical data to support the approved use of this device "(to) *screen patients with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results to determine the need for referral to colposcopy"* in terms of its positive predictive value (*ppv*) with precancer or cancer histology as the endpoint.

In addition, the scientific data used to support specific genotyping of HPV-16 without cross-reactivity with other closely related HPV genotypes should be published for maintaining transparency of the FDA reviewing process.

In view of the concerns expressed in my letter of December 23, 2008 which was addressed to Dr. Andrew von Eschenbach, the former Commissioner of the FDA (copy enclosed), and the FDA recognition of the fact that "Probe design is a critical process for HPV DNA testing because of the large number of closely related HPV genotypes" (page 14, line 3 of Dr. Steven Gutman's Reclassification Order on Docket No. 2007P-0210), the undersigned hereby requests that the FDA respond to this open letter in public to maintain the responsiveness and transparency of its reviewing process and to not cause more unnecessary biopsies on American women by its action.

Very truly yours,

Sin Hang Lee, M.D.
President
HiFi DNA Tech, LLC

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Encl:

www.medicalnewstoday.com : FDA Approves Two Hologic HPV Tests. 14 Mar 2009.

Copy of a letter to The Honorable Andrew C. von Eschenbach, M.D., dated December 23, 2008.

Cc:

Office of Inspector General
Department of Health and Human Services
Room 5541 Cohen Building
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