FDA U.S. FOOD & DRUG ADMINISTRATION

Dec. 21, 2016

Valerie Palmieri
President and CEO
Vermillion, Inc.
12117 Bee Caves Road
Austin, Texas 78738

Dear Ms. Palmieri:

Thank for you for contacting me regarding FDA's Center for Devices and Radiological Health's September 7, 2016 safety communication, alerting women about the risks associated with tests marketed as ovarian cancer screening tests.

We agree that this safety communication does not apply to Vermillion's FDA-cleared tests, OVA1 and Overa, which are not screening tests for ovarian cancer.

FDA cleared OVA1/MIA and Overa/MIA2G as aids to further assess the likelihood that malignancy is present when the physician's independent clinical and radiological evaluation does not indicate malignancy. The intended uses of the two assays are the same—to help physicians more reliably identify which patients would benefit from consultation with or referral to a gynecologic oncologist. OVA1 and Overa are indicated for women who present with an adnexal mass. As the product labels clearly state, these tests are not intended as screening tests for asymptomatic women, or standalone diagnostic assays.

You may use this communication as you see fit to help health care professionals understand that OVA1 and Overa are not included in the tests referred to in our safety communication.

Sincerely,

Jeffrey Shuren, M.D., J.D.
Director
Center for Devices
and Radiological Health

cc: Alberto Gutierrez, Ph.D.

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