DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JUN 19 2014

Mr. Mario Morais
[redacted]

Re: Docket Number: FDA-2012-P-0119 and
Docket Number: FDA-2013-P-0735

Dear Mr. Morais:

This responds to your citizen petition dated December 5, 2011, filed on February 29, 2012, and assigned docket number FDA-2012-P-0119 and your citizen petition dated June 1, 2013, filed on June 11, 2013, and assigned docket number FDA-2013-P-0735. In your petitions, you request that the Food and Drug Administration (FDA) acknowledge receipt of your positive comments on the chronic cerebrospinal venous insufficiency (CCSVI) procedure and request FDA take certain actions in response to your comments. We have carefully reviewed the arguments in your citizen petitions and for the reasons stated below we are partially granting and partially denying your requests.

1) Request that your comment be submitted to the Executive Secretariat

In your June 1, 2013, petition, you request that your comment be submitted to the Executive Secretariat. It appears that your "comment" refers to your citizen petitions dated December 5, 2012, and June 1, 2013. Copies of the two citizen petitions have been forwarded to the FDA Executive Secretariat. Therefore, we grant your request.

2) Include your comment in the U.S. Food and Drug Administration's (FDA's) folder for the agency's news release warning about the CCSVI procedure

In your June 1, 2013, petition, you request your comment be submitted "inside the FDA folder for the news release warning about this procedure know[n] as CCSVI." It appears that your reference to the "news release warning" refers to the Agency's FDA Safety Communication: Chronic Cerebrospinal Venous Insufficiency Treatment in Multiple Sclerosis Patients, issued on May 10, 2012.[1] Further, we assume that, by comment, you are referring to your citizen petitions dated December 5, 2011, and June 1, 2013. Please be advised that FDA does not post citizen petitions as part of its safety communications to the public. However, your citizen petitions, and the supplements, have been posted on Regulations.gov and are currently available to the public. Therefore, we are denying this request.

[1] http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm303318.htm.

3) Respond by telephone to your comment submitted to FDA and assigned tracking number 0807-1412-913

We are unable to find a document submitted to the Agency with tracking number 0807-1412-913. However, we believe you are referring to an email you sent on June 11, 2012, which is attached to this response. We are granting your request by commenting below.

While FDA appreciates your interest in alternative treatments for multiple sclerosis (MS), FDA is not aware of valid scientific evidence demonstrating that the CCSVI procedure is effective in treating MS. As outlined in FDA's May 10, 2012 Safety Communication: Chronic Cerebrospinal Venous Insufficiency Treatment in Multiple Sclerosis Patients (http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm303318.htm), data to support CCSVI as a clinical entity on its own or its relationship with MS are at times contradictory and therefore inconclusive. In addition, CDRH has received adverse event reports, including a fatal event, related to CCSVI procedures.[2] With respect to the information you have conveyed to us regarding your personal experience with CCSVI intervention, though we empathize with and share your desire for effective, FDA cleared or approved products for MS, personal anecdotes and testimonials do not constitute valid scientific evidence. See 21 CFR 860.7(c)(1) ("the agency relies upon only valid scientific evidence to determine whether there is reasonable assurance that the device is safe and effective") and 21 CFR 860.7(c)(2)(defining "valid scientific evidence").

Please also note that the requests you made in your December 11, 2011, citizen petition were previously addressed in the email from the CDRH Ombudsman David Buckles to you dated September 15, 2012. We are attaching copy of that email and incorporating it by reference into this response.

FDA has determined that the requests in your citizen petitions are either the same or substantially similar to numerous previous communications from you. The Agency has previously responded to your requests and has exercised due diligence in providing information responsive to the issues you have cited. The September 15, 2012, email from the CDRH Ombudsman is one example.

Further, you have been informed repeatedly that all contacts with the Agency be directed in writing to David Buckles, CDRH Ombudsman, at the address indicated in Dr. Buckles' September 15, 2012, email. Despite our attempts to direct your communications to Dr. Buckles, recently you have repeatedly contacted multiple individuals within CDRH and other components of FDA concerning the CCSVI procedures. In the past several months, you have called and emailed numerous individuals within FDA, leaving lengthy messages and sent many faxes.

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[2] http://www.cbc.ca/news/technology/ont-man-dies-after-ms-vein-opening-1.880586

For the reasons outlined above, we grant your requests to forward your comments to the FDA Executive Secretariat and to comment on your email dated June 11, 2012. We deny the remaining requests made in your citizen petition.

Sincerely,

Leslie Kux
Assistant Commissioner for Policy

Enclosures

1. June 11, 2012, email from you to FDA
2. September 15, 2012, email from CDRH Ombudsman David Buckles to you