

-----START-OF-PETITION-TO-DOCKETS-MANAGEMENT----1-OF-13

I WOULD LIKE TO APPEAL THE DECISION MADE ON MY CITIZENS PETITION BY MS LESLIE KUX. THE APPEAL IS MADE TO THE COMMISSIONERS OFFICE, AND APPEAL IS MADE LESS THAN 60 DAYS AFTER MS. LESLIE KUX'S LETTER TO ME AND IS BASED ON LAW (21 CFR 12.125(a)).

ALSO I WOULD LIKE TO STATE THAT MS. KUX RESPONSE TO ME SEEMS TO ADDRESS BOTH MY PETITIONS HOWEVER IT DID NOT INCLUDE ITEMS FROM MY FIRST CITIZENS PETITION # FDA-2012-P-0119.

I PETITION THE DOCKETS FOLKS TO PLACE COPIES OF THIS LETTER IN BOTH MY CITIZENS PETITIONS # FDA-2012-P-0119 AND # FDA-2013-P-0735.

SUBMITTED BY
MARIO MORAIS



5

Home Phone number is [REDACTED]

MADE ON JULY 04, 2012

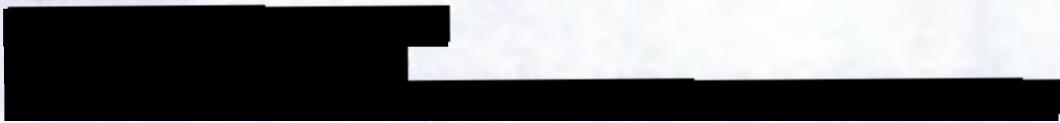
SUBMITTED TO THE U.S. FOOD AND DRUG ADMINISTRATION (HFA-305)

PETITION SENT TO

Division of Dockets Management,
DOCKET MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE, ROOM 1061
ROCKVILLE, MD. 20852
TEL: 240-402-7500 / Fax 301-827-6870 / Email fdadockets@oc.fda.gov,

JUL 15 P 107

Mario Morais



LETTER DATE JULY 04, 2014

Division of Dockets Management,
DOCKET MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE, ROOM 1061
ROCKVILLE, MD. 20852
TEL: 301-827-6860 / Fax 301-827-6870 / Email fdadockets@oc.fda.gov,
Mr. Ryan Cleaver 240-402-7500

RE: I WOULD LIKE THIS LETTER TO BE INCLUDED IN MY 2 PETITIONS. I WOULD LIKE THE DOCKETS MANAGEMENT FOLKS TO PUT A COPY OF THIS LETTER INTO BOTH MY FDA CITIZENS PETITION # FDA-2012-P-0119 AND #FDA-2013-P-0735. THANK YOU IN ADVANCE. (see above)

RE: I WOULD LIKE TO APPEAL, TO THE OFFICE OF THE COMMISSIONER, THE DECISIONS MADE ON MY CITIZENS PETITION NUMBER FDA-2013-P-0735 BY MS. LESLEY KUX. THE APPEAL IS BASED ON LAW (21 CFR 12.125(a)). I WOULD ALSO LIKE ALL FOLKS TO KNOW THAT MY FIRST CITIZENS PETITION (CP) # FDA-2012-P-0119, NOW 820 DAYS OLD, REMAINS UNANSWERED. THANK YOU (see above)

DEAR MR. RYAN CLEAVER AND MS. KAREN KENNARD AND TO THE FOLKS AT DOCKETS MANAGEMENT AT THE FDA:

FIRST I WOULD LIKE TO APOLOGIZE FOR TYPING IN ALL CAPS, BUT I HAVE MULTIPLE SCLEROSIS AND I AM IN A MOTORIZED WHEELCHAIR. BOTH MY LEGS ARE PARALYZED AND MY RIGHT HAND IS IN A FIST POSITION AND DOES NOT OBEY MY BRAIN, SO I TYPE USING MY LEFT HAND.

THE APPEAL LAW READS BELOW FOR YOUR REVIEW

Sec. 12.125 Appeal from or review of initial decision.

(a) A participant may appeal an initial decision to the Commissioner by filing exceptions with the Division of Dockets Management, and serving them on the other participants, within 60 days of the date of the initial decision.



I HAVE TWO (2) OUTSTANDING CITIZENS PETITIONS. THE FIRST PETITION IS # FDA-2012-P-0119, AND CAN BE SEEN ON REGULATIONS.GOV AT WEBSITE:

<http://www.regulations.gov/#!searchResults;rpp=25;po=0;s=FDA-2012-P-0119;fp=true;ns=true>

MY SECOND PETITION IS # FDA-2013-P-0735 CAN BE SEEN AT WEBSITE:

<http://www.regulations.gov/#!searchResults;rpp=25;po=0;s=FDA-2013-P-0735;fp=true;ns=true>

THE LETTER THAT MS. KUX SENT TO ME ONLY COVERED MY SECOND PETITION # FDA-2013-P-0735. HER LETTER DID NOT RESPOND TO MY FIRST PETITION # FDA-2012-P-0119, THE FIRST PETITION IS STILL UNANSWERED.

THE SECOND PETITION IS JUST A POSITIVE COMMENT THAT I SENT TO MS. LINDSEY LLOYD IN 2011 AT THE CENTER FOR DEVICES AND RADIOLOGIC HEALTH (CDRH) REGARDING MY EXPERIENCE WITH THE PROCEDURE CCSVI.

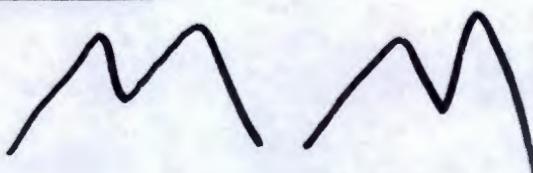
I WOULD LIKE THESE THREE (4) ITEMS GRANTED BY MR. MARGARET HAMBURG.

1. I WOULD STILL LIKE MY COMMENT TO BE INCLUDED IN THE FDA FOLDER FOR THE PROCEDURE CCSVI.

2. I WOULD LIKE THE CDRH TO FORMALLY ANSWER MY POSITIVE COMMENT BY TELEPHONE. MY THIRD REQUEST WAS THAT THE CDRH ANSWER MY COMMENT BY PHONE, AS I WAS TRYING VERY HARD TO OBTAIN A TRACKING NUMBER FROM CDRH, HOWEVER I HAD TO GO TO HHS TO GET A TRACING NUMBER. **YOU CAN HAVE THE FDA EXECUTIVE SECRETARIAT ISSUE ME A TRACKING NUMBER OR YOU CAN USE THE TRACKING NUMBER GIVEN TO ME BY HHS. THE TRACKING NUMBER IS # 0807-1412-913.**

3. I WOULD LIKE MY FIRST CITIZENS PETITION # FDA-2012-P-0119 ADDRESSED AND ANSWERED. THIS PETITION IS NOW APPROXIMATELY 820 DAYS OLD.

4. I WOULD LIKE THE COMMISSIONERS OFFICE TO ISSUE ME A CONTACT THAT WILL CONTACT ME AND ANSWER MY PHONE CALLS AND MY MESSAGES.



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THE REST OF THIS LETTER PROVES THAT MS. LESLIE KUX LETTER TO ME THAT CLAIMS TO ANSWER BOTH MY PETITIONS. HER LETTER DOES NOT AND HER LOGIC DOES NOT MAKE SENSE.

I HAVE SENT COPIES OF THIS LETTER TO MANY FOLKS IN THE OFFICE OF POLICY INCLUDING MS. LESLIE KUX.

IN MS. LESLIE KUX LETTER TO ME ADDRESSED ONLY MY SECOND CITIZENS PETITION, HOWEVER IN HER LETTER TO ME A SECTION IS COPIED BELOW FOR YOUR REVIEW, SHE SEEMS TO REFERENCE BOTH PETITIONS:

Mr. Mario Morais
[REDACTED]

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

Dear Mr. Morais:

This responds to 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-0'735. 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.

MS. KUX LETTER TO ME INCLUDED MANY 'ANDS', BUT MS. KUX LETTER DID NOT INCLUDE A RESPONSE TO MY FIRST CITIZENS PETITION # FDA-2012-P-0119, SO AGAIN, PLEASE ADVISE MS. KUX THAT CP # FDA-2012-P-0119 WAS NOT ANSWERED BY MS. KUX LETTER TO ME.

MS. KUX, I WOULD LIKE TO ASK YOU, HAVE YOU FULLY READ MY FIRST PETITION! FROM YOUR ANSWER, IN YOUR LETTER TO ME, I BELIEVE THE ANSWER IS NO, OR YOU ARE DENYING IT'S EXISTENCE. PLEASE DO NOT REGARD ME AS AN IDIOT.

MS. JANE A. AXELRAD SENT ME A LETTER (see item 1) TO STATE THAT MY FIRST PETITION WILL BE LATE. BUT I HOPE YOU CAN SEE THAT MS. AXELRAD'S LETTER CONTAINED MANY ISSUES THAT WERE NOT ADDRESSED BY MS. KUX LETTER TO ME. I HAVE A FULL COPY OF MS.



KUX LETTER TO ME FOR YOUR REVIEW (see item 2)

I APPRECIATE MS. KUX COMMUNICATION WITH ME BUT I DO NOT AGREE WITH MS KUX'S CONCLUSIONS. I DO NOT BELIEVE HER CONCLUSIONS WERE LOGICAL OR IN THE BEST INTEREST OF THE FDA OR THE SICK PERSONS NEEDS.

I HAD MADE THREE REQUEST IN MY SECOND CP # FDA-2013-P-0735. MY FIRST REQUEST WAS GRANTED-- I THANK MS. KUX, HOWEVER I WANTED MY COMMENT TO GO TO EXECUTIVE SECRETARIAT TO BE GRANTED A TRACKING NUMBER FOR MY COMMENT. THE CDRH WOULD NOT SEND MY COMMENT TO THE EXECUTIVE SECRETARIAT FOR A TRACKING NUMBER. THE CDRH OFFICE OF THE CENTER DIRECTOR AVOIDED ME. SO I ASKED THE COMMISSIONERS OFFICE AT THE TIME MS. KATHLEEN SEBELIUS AT HHS FOR ONE, I WAS GIVEN TRACKING # 0807-1412-913. THAT TRACKING NUMBER WAS GIVEN TO ME FOR MY COMMENT ABOUT CCSVI.

HERE IS PART OF MS. KUX LETTER TO ME BELOW

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.

IF MY REQUEST IS GRANTED THAN I WOULD LIKE A TRACING NUMBER FROM THE OFFICE OF THE EXECUTIVE SECRETARIAT AND WITH THAT TRACKING NUMBER I WOULD LIKE CDRH TO FORMALLY RESPOND TO MY COMMENT.

MY SECOND REQUEST WAS DENIED BUT I DISAGREE WITH MS. KUX'S CONCLUSION. HERE IS ANOTHER PART OF MS. KUX LETTER TO ME:

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.I



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.

I AM VERY SORRY MS. KUX BUT REGULATIONS.GOV AND THE FDA FOLDER HAVE ABSOLUTELY NOTHING TO DO WITH EACH OTHER AND ARE DEFINITELY NOT MUTUALLY EXCLUSIVE!

MS. KUX DENIED MY REQUEST THAT MY COMMENT BE INCLUDED IN THE FDA FOLDER BECAUSE MY COMMENT HAS BEEN POSTED TO REGULATIONS.GOV. THE ONLY REASON I EVEN OPENED A CITIZEN'S PETITION IS BECAUSE CDRH KEPT AVOIDING ME. AND I AM SURE THAT MY COMMENT BEING IN REGULATIONS.GOV DOES NOT DISQUALIFY MY COMMENT FROM GOING INTO THE FDA FOLDER.

I AM SURE, I HAVE THE RIGHT TO HAVE MY COMMENT IN THE FDA FOLDER. I WOULD STILL LIKE MY COMMENT TO BE INCLUDED IN THE FDA FOLDER FOR THE PROCEDURE CCSVI.

NO-ONE SHOULD NEED TO CREATE A CITIZENS PETITION TO GET A POSITIVE COMMENT REGARDING CCSVI ACKNOWLEDGED BY CDRH! AND NO-ONE SHOULD NEED TO WAIT TWO YEARS FOR A RESPONSE!

MY THIRD REQUEST WAS THAT THE CDRH ANSWER MY COMMENT BY PHONE, AS I WAS TRYING VERY HARD TO OBTAIN A TRACKING NUMBER FROM CDRH, HOWEVER I HAD TO GO TO HHS TO GET A TRACING NUMBER.

SO, I WOULD STILL WOULD LIKE CDRH TO FORMALLY ANSWER MY COMMENT BY PHONE.

MS KUX'S LETTER CONTINUES:

3) Respond by telephone to your comment submitted to FDA andassigned 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.

I HAVE BEEN INVOLVED WITH FDA PROCEDURES FOR YEARS SO, I AM VERY SORRY TO MS. KUX BUT I DO NOT WANT AN EXPLANATION OF HOW FDA WORKS. I THANK YOU FOR YOUR COMMENT, BUT I HAVE BEEN



READING FDA LAWS FOR YEARS!

THE REASON I WANT A FORMAL TELEPHONE RESPONSE TO MY COMMENT IS BECAUSE THE RELEASE BY THE FDA HAD INCORRECT INFORMATION AND IF THE FDA DOES NOT ANSWER A COMMENT. THEN NOTHING CAN CHANGE AT THE FDA!

TRACKING NUMBERS ARE USED FOR THE PUBLIC TO HAVE INTERACTIONS WITH THE FDA, AND HELP THE FDA BECOME MORE SENSITIVE TO SICK PEOPLES NEEDS. IF ALL PUBLIC COMMENTS WERE ANSWERED BY FDA COMMENTS, THEN NOTHING AT THE FDA COULD EVER CHANGE.

AND I KNOW WE BOTH WANT THE FDA TO TRULY BE RESPONSIVE TO SICK PEOPLE'S NEEDS. SO THE FDA CAN REACT IN A POSITIVE WAY TO SICK PEOPLES NEEDS.

MY FIRST CITIZENS PETITION # FDA-2012-P-O119 HOPES TO GET THE FDA TO BETTER SERVE THE SICK PEOPLE, THATS WHY I AM SURE YOU DONT WANT THAT CITIZENS PETITION TO FALL THRU THE CRACKS.

HERE IS PART OF THE LETTER MS. AXELRAD SENT ME REGARDING MY FIRST PETITION. YOUR LETTER TO ME (see item 2) DID NOT ANSWER THESE QUESTIONS

requests that the Agency: (1) issue a statement that "checking" (e.g., through imaging technology) and "fixing" blood flow to the brain (i.e., using "liberation therapy") may benefit patients who have neurological problems; (2) create an "unapproved drugs" category of drugs, to which patients could receive access at their own risk; (3) permit all interested patients to participate in clinical trials, and let all participants receive the drugs being tested; (4) make available the drug identified as BB:7075 to HIV patients, and ask the National Institutes of Health (NIH) to test it; (5) permit patients to have more influence in drug approval decisionmaking; and (6) provide safety information from investigational new drug trials.

ON ANOTHER SUBJECT. MR. DAVID BUCKLES WANTS TO BE MY CONTACT AT THE FDA BUT MR. BUCKLES DOES NOT ANSWER MY PHONE CALLS AND MR. BUCKLES ALSO DOES NOT RETURN MY PHONE MESSAGES. AND LASTLY MR. BUCKLES DID NOT ANSWER MY REGISTERED MAIL.

SO, WHY IS MR. BUCKLES MY FDA CONTACT?



IT MAKES NO LOGICAL SENSE ONLY THAT THE FDA WANTS ME TO GO AWAY, BUT ONLY WISH IS TO MAKE THE FDA MORE RESPONSIVE TO SICK FOLKS AS I AM SICK.

**AFTER MY CCSVI PROCEDURE, MY BRAIN IS MUCH SHARPER
THE SAME PROCEDURE THE FDA WANTS TO BAN AS TOO DANGEROUS!**

LET ME EXPLAIN THE PROCEDURE, CCSVI STANDS FOR 'CHRONIC CEREBROSPINAL VENOUS INSUFFICIENCY' THE BRAIN OBTAINS ITS BLOOD FROM THE HEART. THEN THE BRAIN DRAINS THE BLOOD THRU 3 MAIN VEINS, THE TWO JUGULAR VEINS AND THE AZYGOS VEIN, IF ANY ONE OF THE 3 VEINS BECOMES RESTRICTED OR TANGLED OR CLOGGED THERE WILL BECOME A REFLUX OF BLOOD BACK INTO THE BRAIN, WHICH CAUSES A LAYER OF BLOOD IN THE BRAIN, WHICH BECOMES IRON DEPOSITS AND IRON DEPOSITS ON THE BRAIN CREATE AN AUTO IMMUNE REACTION JUST LIKE IN MS.

AS FOR ME, I HAD ALL THREE VEINS EITHER RESTRICTED OR CLOGGED, THE DOCTOR PLACED, WHAT I CALL A SNAKE, IN A SMALL INCISION MADE IN MY GROIN AREA, I WAS AWAKE THRU THE WHOLE PROCEDURE, THE PROCEDURE LASTED ABOUT 1 TO 1 1/2 HOURS AND I SLEPT IN MY HOTEL ROOM THAT NIGHT. IT WAS THE BEST PROCEDURE I HAVE EVER HAD. AND THE PROCEDURE INCREASED MY QUALITY OF LIFE TREMENDOUSLY, I FEEL THAT IF I HAD THIS PROCEDURE 10 YEARS AGO, I WOULD NOT BE IN A WHEELCHAIR TODAY!

ALL I WANTED TO DO WAS MAKE A POSITIVE COMMENT ABOUT MY EXPERIENCE. HOWEVER THE CDRH WANTS TO TOTALLY IGNORE ME TO THE POINT THAT I HAD TO CREATE CITIZENS PETITION NUMBER FDA-2013-P-0735, MY SECOND PETITION).

THE CORRECT QUESTION TO ASK IS WHY DID IT TAKE 2 YEARS AND A PETITION TO GET A RESPONSE TO A COMMENT. WHY DIDN'T THE CDRH FOLLOW THE FDA'S OWN RULES AND REGULATIONS?

I HAVE DONE NOTHING ILLEGAL. I FOLLOW ALL FDA RULES AND REGULATIONS. THE FDA NEEDS TO FOLLOW ITS OWN RULES AND REGULATIONS.

FROM ALL MY YEARS DEALING WITH THE FDA, I WAS TOLD THAT WE WANT TO CHANGE BUT WE CANNOT, BECAUSE NO-ONE ASKS US TOO.

WELL NOW I'M TRYING AND THE FDA WANTS ME TO JUST GO AWAY. SO, I'M COMING TO THE CONCLUSION THAT THE FDA DOES NOT WANT TO BETTER THE LIVES OF SICK PEOPLE, CERTAIN FOLKS AT THE FDA JUST



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WANT TO PROTECT THE PHARMACEUTICAL COMPANIES. IT'S
THE REGULATOR PROTECTING THE REGULATED (OR)
IT'S THE CLASSIC STORY OF THE WOLF GUARDING THE HEN HOUSE.
THANKING YOU IN ADVANCE FOR YOUR TIME.

SINCERELY YOURS,

MARIO MORAIS

FAXED TO 301-827-6870 AND SENT REGISTERED MAIL TO THE FOLKS AT
DOCKETS MANAGEMENT, AND EMAILED TO SAME FOLKS AT
fdadockets@oc.fda.gov, TO THE FOLKS AT THE U.S. DEPARTMENT OF
FOOD AND DRUG ADMINISTRATION (FDA),



----- (ITEM 1) -----

10-OF-13

HERE IS A COPY OF A LETTER MS. JANE A. AXELRAD SENT ME
REGARDING MY FIRST CITIZENS PETITION # FDA-2012P-0119

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration
Rockville MD 20857

AUG - 1 2012

2012 AUG - 2 A 9:56

Mr. Mario Morais

Re: Docket No. FDA-2012-P-0119

Dear Mr. Morais:

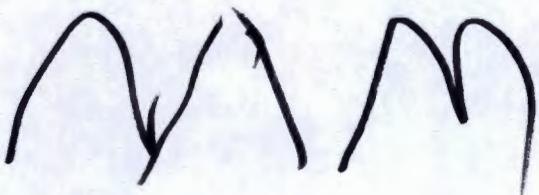
I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition and supplement, received on February 3, 2012 and April 18, 2012, respectively. Your petition requests that the Agency: (1) issue a statement that "checking" (e.g., through imaging technology) and "fixing" blood flow to the brain (i.e., using "liberation therapy") may benefit patients who have neurological problems; (2) create an

"unapproved drugs" category of drugs, to which patients could receive access at their own risk; (3) permit all interested patients to participate in clinical trials, and let all participants receive the drugs being tested; (4) make available the drug identified as BB:7075 to HIV patients, and ask the National Institutes of Health (NIH) to test it; (5) permit patients to have more influence in drug approval decisionmaking; and (6) provide safety information from investigational new drug trials.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research



-----11-OF-13

HERE IS A COMPLETE COPY OF MS. KUX LETTER. I HOPE YOU CAN SEE THAT SHE DID NOT ADDRESS THE ABOVE ISSUES.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

JUN 19 2014

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

Mr. Mario Morais

[REDACTED]

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

M M

Dear Mr. Morais:

This responds to 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-0'735. 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.

I) 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.I

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.

Page 2 Mr. Mario Morais

3) Respond by telephone to your comment submitted to F DA andassigned 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.



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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.

Page 3 - Mr. Mario Morais

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

