Appendix C

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November 23, 2012

Ms. Nancy Stade, Deputy Director for Policy
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Registered Mail, Receipt Requested

Dear Ms. Stade,

I wish to go on the record concerning the revisions made to Form FDA 3429 earlier this year. The form which had expired on May 30, 2012, was renewed, unchanged, with an effective date of "6/12" and an expiration date of June 30, 2015. Within months, a revised form was published, with no fanfare, with an effective date of "7/12" and an expiration date of June 30, 2015. I discovered the existence of the revised form on October 15, 2012.

These comments are being directed to you as a responsible official of the Center for Devices and Radiological Health, with the title of Deputy Director for Policy, Center for Devices and Radiological Health.

The Classification Questionnaire is defined at 21 CFR 860.3(f). The original Classification Questionnaire was designed by David Link, who had been hired by the FDA to lay the groundwork for implementing the Medical Device Amendments of 1976. Link subsequently was appointed Director of the Bureau of Medical Devices. An early version of the Classification Questionnaire was used by the various Classification Panels, including the Radiological Devices Classification Panel which I served as Executive Secretary in 1976.

At some point in time, the form was designated as Form FDA 3429. The form evolved over the years. From the very beginning until the recent revision, the form could also be called a "logic tree" because it consisted of a set of questions along with directions based upon the answers to the questions. Until the recent revisions, discussed below, the form indicated the appropriate class for the device under consideration. This was the essential function of the form, to provide guidance so the person completing the form would know the device's classification based upon his or her answers to the questions. The form was intended for use by CDRH, advisory panels, industry and others. The form was used for advisory panels to develop their recommendations for classification, and a completed form is required to be part of any petition to reclassify.

The Revisions to Form 3429, effective July, 2012

Exhibit A shows the form as it was renewed in June, 2012. The first six questions have been answered for a hypothetical device which satisfies the following criteria:

a) The device is not life-supporting or life-sustaining;
b) The device is not for a use which is of substantial importance in preventing impairment of human health; and
c) The device does not present a potential unreasonable risk of illness or injury

Such a device does not satisfy the criteria for Class III under the definition at Title 21 U.S.C. § 360c(l)(C). However, when question 6 is answered No, the Form indicates the device should be classified in Class III. This is the logical flaw or intrinsic inconsistency which is the subject of my Citizen Petition FDA-2012-P-0747.

CDRH soon decided to revise the form, making them effective on "7/12." The revisions are highlighted on Exhibit A. The revisions are as follows:

1. Question 4 was omitted, and the subsequent questions renumbered.

Comment: This was a "collector" question, intended to highlight whether any of the first three questions was answered YES. These three questions are based directly on the definition of Class III in the law, and at least one YES answer is required for a device to qualify for Class III.

2. Column 3, containing the logical directions, was removed entirely.

Comment: This column contained the instructions of which item to answer next as well as stating the appropriate classification based on the previous answers. Indicating the appropriate classification is the reason the Classification Questionnaire was created. The removal of column 3 renders the form virtually useless for its intended purpose which is to indicate the appropriate classification.

Memorandum to OMB

Exhibit B is the memorandum from CDRH to the Office of Management and Budget which describes the changes and the reasons for making them. This document is of particular interest to me because it states the changes were made because Citizen Petition FDA-2012-P-0493 prompted "the agency to re-evaluate the information presented in FDA Form 3429 ... ." I was the author of that petition. I have reason to believe that Marjorie Shulman, assisted by Paul Gadiock, is responsible for the revisions to Form 3429 and possibly the memo to OMB.

The author(s) of the memo to OMB use words or phrases obviously intended to downplay the importance of the revisions: "nonmaterial/non-substantive change"; slightly modify a form";

"FDA has determined that unnecessary information has been included"; "extraneous information has proven confusing to readers"; "the extraneous information in the last column and row 4 describes merely one approach of understanding device classifications"; "has caused considerable confusion among FDA and stakeholders while providing little or no benefit."; "The information is being removed simply for clarity ... ."

Clearly, the changes do not "slightly modify" the form. The information removed was not "extraneous." The removal of column 3 is not a minor revision. For decades, Form 3429 was the principal tool for determining the proper classification for a device. As revised, the form is virtually useless for its intended purpose.

The memo asserts that "the extraneous information in the last column and in row 4 describes merely one approach of understanding device classifications, albeit not the only approach, and has caused considerable confusion among FDA and stakeholders while providing little or no benefit." The Classification Questionnaire was the principal tool used by FDA, its 19 Classification Panels, and others for decades to determine the appropriate class for over 5800 devices. It was incumbent upon FDA to insure that the Classification Questionnaire was consistent with the law. This may have been the case in earlier versions of the Classification Questionnaire, but it has certainly not been the case since 1997. FDA needs to acknowledge the error and do what it can to ameliorate the damage instead of trying to cover it up.

The memo to OMB is a stark example of creative writing whose purpose is to mislead the unwary reader. I view the memo and the revisions as a ploy to defuse the criticism concerning Form 3429 raised in my two Citizen Petitions (FDA-2012-P-0493 and FDA-2012-P-0747). It is interesting that the form was essentially unchanged for at least 15 years and it was my bringing attention to the issue that brought on these changes.

In our previous communications concerning the "logical flaw" in Form 3429, I have repeatedly urged that CDRH give prompt attention to the issue because an as yet unknown number of companies are faced with having to meet the requirements of Class III for devices which do not belong in that classification. During our telephone conversation on July 23rd, you assured me that my Petition 0747 would generate a response "before too long." It seems an odd coincidence that the OMB memo is dated the very next day.

We're now approaching the six-month limit for an FDA response to my petition. The revisions to Form 3429 discussed in this letter seem to foreshadow a negative response to the petition. This would be unacceptable to me.

I hope that you and CDRH can do the right thing to resolve this issue without undue delay.

I look forward to your response.

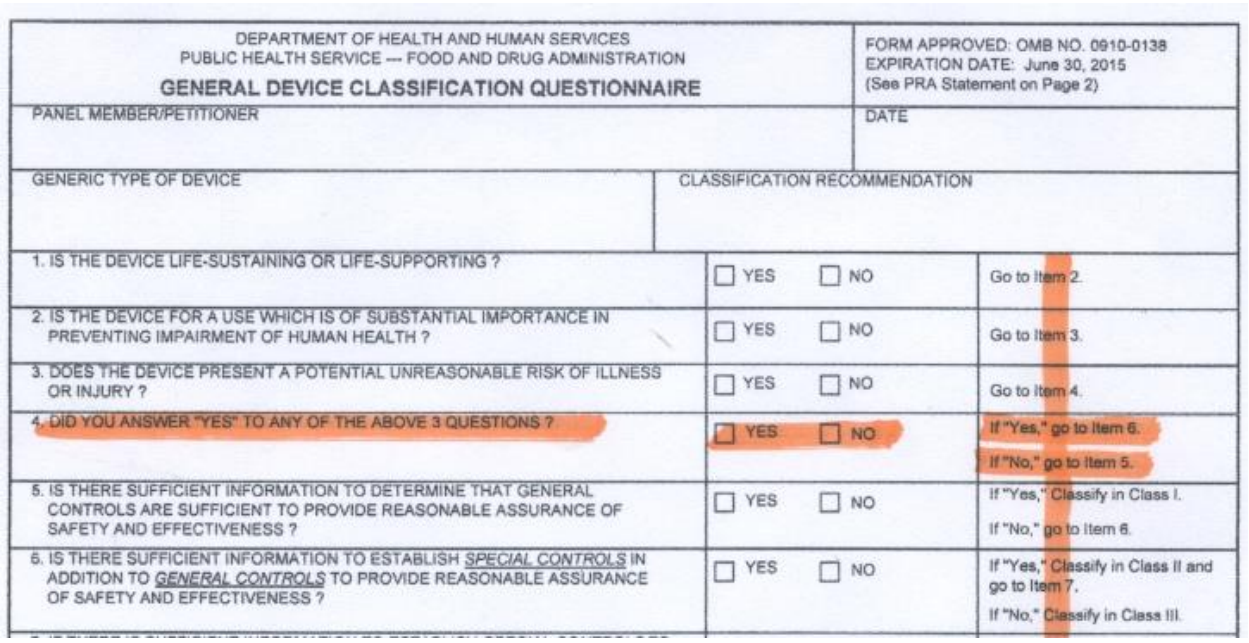
Sincerely,

Leroy L. Hamilton, Ph.D.

cc: Jeffrey Shuren, M.D., J.D.
Margaret Hamburg, M.D.
The Honorable Chris Van Hollen

Enclosures: Exhibit A: Form 3429 (Eff. 6/12) mark-up
Exhibit B: CDRH memo to OMB July 24, 2012

Exhibit A



DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE — FOOD AND DRUG ADMINISTRATION

GENERAL DEVICE CLASSIFICATION QUESTIONNAIRE

FORM APPROVED: OMB NO. 0910-0138
EXPIRATION DATE: June 30, 2015
(See PRA Statement on Page 2)

PANEL MEMBER/PETITIONER		DATE
GENERIC TYPE OF DEVICE	CLASSIFICATION RECOMMENDATION	
1. IS THE DEVICE LIFE-SUSTAINING OR LIFE-SUPPORTING ?	☐ YES ☐ NO	Go to Item 2.
2. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE IN PREVENTING IMPAIRMENT OF HUMAN HEALTH ?	☐ YES ☐ NO	Go to Item 3.
3. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY ?	☐ YES ☐ NO	Go to Item 4.
4. DID YOU ANSWER "YES" TO ANY OF THE ABOVE 3 QUESTIONS ?	☐ YES ☐ NO	If "Yes," go to Item 6. If "No," go to Item 5.
5. IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☐ YES ☐ NO	If "Yes," Classify in Class I. If "No," go to Item 6.
6. IS THERE SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* IN ADDITION TO *GENERAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☐ YES ☐ NO	If "Yes," Classify in Class II and go to Item 7. If "No," Classify in Class III.

The FDA renewed Form 3429 which expired on May 30, 2012. Shown are the first six questions of the renewed Form which became effective June, 2012, to expire on June 30, 2015.

Abruptly, without fanfare or public notice, the agency revised the Form effective July, 2012, to expire June 30, 2015.

Only the first six questions of Form 3429 effective June, 2012, are shown. The highlighted areas show the parts of the form which were removed by the FDA. (The entirety of column 3 was removed effective July, 2012.

"Reclassification Petitions for Medical Devices"
(OMB Control Number 0910-0138)

Change Request (83-C)

July 24, 2012

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) in order to slightly modify a form associated with OMB control number 0910-0138.

FDA received a citizen petition prompting the agency to re-evaluate the information presented in FDA Form 3429 (FDA-2012-P-0493-0001/CCP). After careful consideration, FDA has determined that unnecessary information has been included in FDA Form 3429 and that the extraneous information has proven confusing to readers. The extraneous information in the last column and in row 4 describes merely one approach of understanding device classifications, albeit not the only approach, and has caused considerable confusion among FDA and stakeholders while providing little to no benefit. The information is being removed simply for clarity and does not bear on the underlying program or on the hour or cost burden associated with the collection of information. For consistency, we made minor conforming changes in the instructions on page 3.

* * *

My Comments on Memo to OMB:

The FDA memo trivializes the importance of the changes by using words and phrases such as "nonmaterial/non-substantive"; "slightly modify"; "unnecessary information"; "extraneous information has proven confusing to readers."

Although the question in row 4 may seem to be redundant, I think it served an important role as what I would call a "collector question." As I interpret the definition of Class III, at least one of the first three items in the second part of the definition must be answered "Yes" for the device to even be considered for Class III.

If the answer to question 4 is "No" then the device should be precluded from Class III!

Most importantly, removal of column 3 rendered the Form useless for its intended purpose which is described in the regulation[1] defining "Classification Questionnaire." It appears that the

[1] 21 CFR 860(f)

author of this document is purposely trying to conceal the existence of the logical flaw in the Form and to avoid acknowledging that there may have been consequences of that mistake.

The memo cites a Citizen Petition (Docket Number FDA-2012-P-0493) as the reason the agency re-evaluated the form. **This was my petition requesting FDA to reclassify cranial electrotherapy stimulators from Class III to Class II. This petition had been denied on the basis that it should have been filed instead as a petition to reclassify. It is interesting that this petition is cited as the reason CDRH revised Form 3429; I'm confident that the telephone conversations I had with Paul Gadiock had an impact too.**

From the document I received from Mr. Gittleson, it would appear that he was the author of the notice to OMB. However, I think he was merely a link in the chain. It seems illogical that he would be in a position to originate the change. He may have created the document based on guidance provided to him orally or in a memo. When I spoke in October 2014 with Mr. Gittleson about the fact that his name appears in the metadata for the Word document which he sent to me, he did not offer any explanation.

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