Chapter 8

CDRH Grants Citizen Petition

January – March 2013

Six months after submitting my Citizen Petition FDA-2012-P-0747 asking the Commissioner to initiate an impartial investigation into whether Form 3429 was in conformity with the law, I received an interim response. The letter[1], dated January 4, 2013 and signed by Nancy Stade[2] contained the following statement:

> FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen's petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

* * * * *

The letter made no mention of the fact that FDA had already revised Form 3429.

Petition Granted – Sort Of

It turned out that Dr. Shuren was correct when he said that CDRH would respond within a week to my Petition. The letter[3] signed by Nancy Stade was dated March 4, 2013, only four days after our telephone meeting on February 28.

CDRH had taken virtually no time to revise Form 3429, but required nearly eight months to draft and clear the four-page letter responding to my petition. The Form was revised with an effective date of July 2012, which was before the petition 0747 was logged in. Two likely explanations come to mind, but unless someone at the FDA speaks frankly, we'll never know what really happened.

1. My earlier petition 0493 – which had been rejected – and the subsequent conversation with Paul Gadiock got the ball rolling.

2. My second petition 0747, coupled with 0493, put them in high gear. However, if what I was told by PSC is correct, the mechanics of the revision weren't completed until September, but they still marked the effective date as July.

I suppose the exact timing of events isn't important, but it does seem strange to me.

On page 1, the March 4 approval letter stated:

> In accordance with 21 CFR 10.30(e)(3), we are granting your petition. FDA has investigated Form FDA3429 and has determined changes should be made to more closely align the form with section 513(a)(1)(C)of the Federal Food, Drug, and Cosmetic Act

> (FD&C Act). In addition, we respond to the questions you propose we address as part of an assessment of our use of the form.

Although the agency granted my petition, I consider it to be a hollow victory. The good news was that FDA agreed there was a problem with Form 3429, and they acted quickly (too quickly?) to change the form. But there was plenty of bad news to offset the good.

As discussed in previous chapters, I had good reason to be dissatisfied with the revisions to the Form.

Beginning on page 2, the letter addressed the questions I posed in the petition:

> FDA has re-evaluated the current Form FDA 3429. FDA agrees that form as it existed did not account for devices that are not for use in supporting or sustaining human life, are not for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, but are devices for which insufficient information exists to determine that general controls are sufficient to provide a reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance. In response to this petition, FDA has changed Form FDA 3429 to remove the information in the last column and the row enumerated four.

This wordy obfuscation conceals the simple truth: the form did not conform to the definition of Class III. FDA again tries to hide the fact that the Form erroneously led to Class III for certain devices that did not satisfy the definition of Class III in the law. In the paragraph quoted above, they wrote "FDA agrees that form as it existed did not account … ."

My petition asked that five additional questions be answered if the Classification Questionnaire was determined to not be in conformity with the definition of Class III in the law.

These questions are quoted below, one by one, along with the corresponding response from the FDA:

Question 2. Since Form 3429 does not conform to the definition of Class III, how long has this condition persisted?

FDA's answer to Question 2 was as follows:

> The earliest Form FDA 3429 with the same first six questions is listed as having a February 1997 creation date.

How does FDA know the date of the earliest Form FDA 3429 with the same first six questions? This implies that they had access to the form which presumably expired on January 31, 1997, and that it does not contain the same six questions. In that case, they had access to a version of a form they couldn't locate in response to my FOI request 2012-2021 which asked for all

versions of Form 3429. And, by extension, this concept would apply to each earlier version until one didn't.

In response to FOI request 2012-2021, FDA was unable to provide me copies of any of the Classification Questionnaires between 1977 and 1997.

The Office of Management and Budget maintains data on the submissions by other agencies concerning data collection activities. I was able to mine this data[4] to construct Table 8.1.

Received Date	Action Requested	Review Type[5]	Conclusion Action	Expiration Date
10/30/1981	New collection (Request for a new OMB Control Number)	Regular	Approved without change	12/31/1982
12/27/1982	Revision of a currently approved collection	Regular	Approved without change	12/31/1983
01/04/1984	No material or nonsubstantive change to a currently approved collection	Emergency	Approved with change	03/31/1984
08/06/1984	Reinstatement with change of a previously approved collection	Regular	Approved without change	10/31/1985
11/13/1985	Reinstatement with change of a previously approved collection	Regular	Approved without change	07/31/1987
04/30/1987		Emergency Extension	Approved	07/31/1987
05/05/1987	Extension without change to a currently approved collection	Regular	Approved without change	06/30/1990
05/02/1989	No material or nonsubstantive change to a currently approved collection	Emergency	Approved with change	09/30/1990
05/04/1990		Emergency Extension		
03/29/1991	Reinstatement with change of a previously approved collection		Approved without change	06/30/1994
03/03/1994		Emergency Extension		
12/11/1996	Reinstatement with change of a previously approved collection	Regular	Approved without change	01/31/2000
09/13/1998	No material or nonsubstantive change to a currently approved collection	Regular	Approved without change	01/31/2000
12/07/1999	Extension without change to a currently approved collection	Regular	Approved without change	01/31/2003
11/08/2002	Extension without change to a currently approved collection	Regular	Approved without change	03/31/2006
12/22/2005	Extension without change to a currently approved collection	Regular	Approved without change	05/31/2009
03/27/2009	Extension without change to a currently approved collection	Regular	Approved without change	06/30/2012
03/29/2012	Extension without change to a currently approved collection	Regular	Approved with change	06/30/2015
07/26/2012	No material or nonsubstantive change to a currently approved collection	Regular	Approved without change	09/30/2015
06/16/2015	Extension without change to a currently approved collection			

Table 8.1 History of OMB Actions Concerning Form 3429

This data provides an interesting insight into the process. The entry for 7/26/2012 states "No material or nonsubstantive change to a currently approved collection." This was the OMB review of the revisions to the CQ we have been discussing. Clearly, I disagree with this characterization on the grounds that the Form was gutted; it no longer serves the purpose for which it is intended. So CDRH and OMB both discount the importance of the change in this case.

We see the same language in connection with forms submitted to OMB for review on other dates, namely, 01/04/1984, 05/02/1989, and 09/13/1998. I suggest these point to the times when the CQ may have undergone significant revisions. AS STATED EARLIER, THE FORM USED IN 2012 BEARS LITTLE SIMILARITY TO THE FORM USED IN 1976.

The number of times the word "Emergency" appears in Table 8.1 is notable and one wonders about the circumstances.

Question 3. Which office or offices of the Center for Devices and Radiological Health (CDRH) have been responsible for maintaining Form 3429 during the time that it has been out of conformance?

Their answer to Question 3:

> The lead CDRH office responsible for maintaining Form FDA 3429 is the Office of Device Evaluation.

The Office of Device Evaluation employs hundreds[6] of people in numerous Divisions and Branches. I guess they couldn't (or wouldn't) be more specific.

Question 4. How can Form 3429 be revised to bring it into conformity with the definition of Class III and other applicable legal requirements?

Their answer to Question 4:

> FDA has changed Form FDA 3429. FDA removed the farthest right column in the form and the row enumerated four. This change will address the small number of devices for which insufficient information exists to determine that general controls are sufficient to provide a reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance that (1) are not for use in supporting or sustaining human life; (2) are not for a use which is of substantial importance in preventing impairment of human health; and (3) do not present a potential unreasonable risk of illness or injury.

This is more evasive bureaucrat-speak.

Question 5. Which devices may have been misclassified into Class III as a result of faulty version(s) of Form 3429?

Their answer to Question 5:

> FDA is aware of no devices that have been misclassified into class III as the result of Form FDA 3429. FDA considers the information supplied on Form FDA 3429 in proposing a classification. Typically the Form FDA 3429 is used by Classification Advisory Panels as part of their review and recommendation of a classification of a device or is included as part of a petition of reclassification (21 CFR 860.123(a)(4)). Form FDA 3429 is not binding and constitutes only part of the materials considered by

> FDA during the classification process, which includes review of available valid scientific evidence, appropriate regulatory controls given the risks presented by the device, and regulatory standards.
>
> In a footnote you pose product codes JXK and ILX as two devices that were incorrectly classified into class III. Product code JXK is identified as a cranial electrotherapy stimulator device (21 CFR 882.5800), which was classified into class III in 1979 (see 44 FR 51770; September 4, 1979. … Product code ILX is identified as a shortwave diathermy device (21 CFR 890.5290), which was classified into class III in 1983 (see 48 FR 53032; November 23, 1983). …

This lengthy paragraph at the bottom of page 3 continues by providing the history of these two device types, and concludes that both devices are properly in class III.

When I served as Executive Secretary to the Radiological Devices Classification Panel in 1976, the Classification Questionnaire (before it was designated as Form 3429) was the principal tool used by most of the nineteen Panels to arrive at their recommendations for classification. There were discussions about certain devices, yet the CQ weighed heavily. (The Panel mentioned lead letters frequently as the archetype of devices that the Panel felt needed little if any regulation. Lead letters are pieces of lead metal formed into the shapes of letters and numbers; they block X-radiation thus leaving a shadow on x-ray plates. The Panel's reasoning was simple: Any company whose lead letters didn't work wouldn't remain in business for long.)

It seemed reasonable to me that the recommendations of the other Classification Panels would have relied heavily for their recommendations on the Classification Questionnaires they completed.

Now, FDA says "FDA is aware of no devices that have been misclassified into class III as the result of Form FDA 3429." I suspect that whoever wrote the March letter was not aware of any devices that have been misclassified into class III regardless of the reason.

In retrospect, I shouldn't have made the connection between alleged misclassifications and Form 3429. That doesn't change the fact that unless a device satisfies the definition of Class III, it shouldn't be in Class III.

Question 6. Which companies currently have devices listed with CDRH which may have been misclassified into Class III?

> As stated above, FDA is not aware of any devices that have been misclassified into class III as the result of Form FDA 3429. Given the role of Form FDA 3429 in the procedure FDA uses to classify a device, FDA has no reason to believe any device has been misclassified into class III.

FDA Changes Its Tune

In less than ten weeks, CDRH reversed itself concerning the classification of nonthermal shortwave diathermy (Product Code ILX)[7] devices, saying that they could be in Class II. This startling development appeared in the FDA Executive Summary[8] prepared for a meeting of the Orthopaedic and Rehabilitation Devices Panel held on May 23, 2013. This meeting is discussed in Part 3 of this book.

Reversal of the Cranial Electrotherapy Stimulator devices took longer. On June 12, 2014, CDRH announced in the Federal Register they were withdrawing the proposed order to require the filing of a premarket approval or a notice of completion of a product development protocol for cranial electrotherapy stimulators (Product Code JXK).

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During the telephone conference with Dr. Shuren on February 28, Ms. Stade made the point that she did not know which version of the Classification Questionnaire was used during the classification of each particular device into Class III. I agreed with her, saying I did not have that information either.

Since FDA is unable to provide the completed Classification Questionnaires for any of the Class III devices on my tentative list[9], nor are they able to provide blank Classification Questionnaires for the 20-year period from 1977 to 1997, we are left in a quandary.

My experience through this entire episode has provided an unsettling insight into the FDA bureaucracy. It is certainly not in keeping with the agency's public relations efforts. CDRH advertises its Mission, Vision, and Shared Values on the FDA website[10]. Under the heading **Accountability** appears the statement "We hold ourselves accountable for the actions we do and do not take. We acknowledge our errors and learn from them."

Lessons learned:

FDA is quite capable of making mistakes but appears to be incapable of admitting mistakes. Of course, I'm looking at a complex organization through a very small window.

In the next chapter, I'll describe my efforts to obtain more information about the people responsible for the revisions to the CQ. The reason for the changes seems rather clear: they accepted my complaint in Citizen Petition FDA-2012-P-0493 that the CQ was not in conformity with the definition of Class III in the law and that some change was needed to remove or neutralize the intrinsic logical flaw. At every step, the agency has thwarted my efforts to learn the rationale for the revisions they adopted who made the decision to remove row 4 and column 3 from Form 3429.

END NOTES FOR CHAPTER 8

[1] See Docket Number FDA-2012-P-0747-0003 at www.regulations.gov
[2] Deputy Director for Policy, CDRH
[3] See Docket Number FDA-2012-P-0747-0004 at www.regulations.gov
[4] http://www.reginfo.gov/public/do/PRASearch Search for OMB control number 0910-0138.
[5] Review Type extracted from OMB records "NOTICE OF OFFICE OF MANAGEMENT AND BUDGET ACTION"
[6] In September 2015, there were 550 names listed in the Office of Device Evaluation
[7] ILX devices are known by various names, including nonthermal shortwave diathermy and shortwave diathermy for other uses.
[8] The Executive Summary, which can be found at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/UCM352560.pdf
[9] FOI request 2012-1839, March 12, 2012 for classification questionnaire for JXK devices
FOI request 2012-1840, March 12, 2012 for classification questionnaire for ILX devices
FOI request 2012-2021, March 18, 2012 for copies of all versions of the Classification Questionnaire/Form 3429.
[10] http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/ucm297377.pdf