Chapter 3

The Problem with Form 3429

February – March 2012

The FDA uses around 640 different forms. One of these, Form FDA 3429 General Device Classification Questionnaire, was mentioned in the first two chapters. The version of the Form in use at the time I first learned of it bore an effective date of August 2010; the Form was set to expire on May 30, 2012[1] A search of the CDRH website uncovered a few earlier versions of Form 3429 which were essentially the same as the one I had. The effective and expiration dates appear to be the only way to identify any specific version of the Form. The earliest version I located initially was effective January 1997.

I should mention at this point that I had more than a passing acquaintance with a much earlier version of the Classification Questionnaire (CQ). From May, 1974 to December 1976 I was employed by the FDA in the new unit created to regulate medical devices. There were about 45 employees in the Office of Medical Devices and Diagnostic Products when I was hired in May 1974 to set up the Radiological Devices Classification Panel and serve as its Executive Secretary. The Panel met a few times before I left the FDA in December 1976 and during these meetings the Panel and I went through the Classification Questionnaire for hundreds of devices. I can say with confidence that the CQ of 2012 bore little resemblance to the one we used in 1976.

The idea behind the Classification Questionnaire (CQ) was quite simple: by answering a few questions, you are led to the appropriate Class for a device.

Simply stated, the problem with Form 3429 which I discovered is that it could lead to Class III for some devices which do not satisfy the definition of Class III in the law! This logical flaw apparently was overlooked or ignored for years until I came along and shook things up in 2012.

To understand the problem with Form 3429, let's take a more detailed look at the definition of class III. In Chapter 1, Figure 1.1 is an FDA slide which contains a greatly abbreviated statement which captures the essence of the definition. To be sure, we really need to go to the defining source document.

Definitions of Class III

There are actually two official definitions of Class III. The primary definition is the one which appears in the law, which in this case is the Federal Food Drug and Cosmetic Act, as amended. The Medical Device Amendments of 1976 (Public Law 94-295) is one of the major amendments to the Food Drug

and Cosmetic Act, and it is the source of the definition of Class III. In addition, the Safe Medical Devices Act of 1990 modified the definitions when Class II Standards was changed to Class II Special Controls.

The definitions which appear in the Code of Federal Regulations are less verbose and therefore easier to understand. These I call secondary definitions. They should be equivalent to the primary definitions in the law and I believe they are. (Appendix A contains more information about the three devices classes, including the definitions and the requirements they impose on manufacturers.)

Definition of Class III in the Law

The definition of Class III appears in the Federal Food Drug and Cosmetic Act (FFDCA) and can be found at Title 21 of the United States Code section 360c(1)(C) which states the following:

> (C) CLASS III, PREMARKET APPROVAL.—A device which because—
> (i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and ← NOTE "AND"
> (ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or
> (II) presents a potential unreasonable risk of illness or injury,

> is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

Definition of Class III in the Code of Federal Regulations

Here is the definition which appears in the Code of Federal Regulations (21 CFR)[2]:

> (3) *Class III* means the class of devices for which premarket approval is or will be required in accordance with section 515 of the act. A device is in class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls described in paragraph (c)(2) of this section would provide such assurance and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

You can take my word that they are equivalent or you can check for yourself.

As you may recall from Chapter 1, the important thing to understand is that the definition of Class III has two conditional clauses, joined by the conjunction "and." The first clause begins with the words "if insufficient information …" and the second clause begins with "if, in addition, … ."

Both clauses must be satisfied for a device to be eligible for Class III. The first clause essentially states that there is insufficient information for general controls by themselves, or general controls and special controls to provide reasonable assurance that the device is safe and effective. (You don't need to know what constitutes "general controls" or "special controls" at this point to understand the problem with the CQ. In any case, they are listed in Appendix A.)

The second clause has three parts. For this clause to be satisfied, at least one of the three following conditions must be true: (1) the device is life-supporting or life-sustaining, OR (2) the device is for a use which is of substantial importance in preventing impairment of human health, OR (3) the device presents a potential unreasonable risk of illness or injury.

One more definition from the CFR and we'll be ready to address the problem in the CQ.

> *Life-supporting or life-sustaining device* means a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

To me, to determine whether a device is life-supporting or life-sustaining, you simply answer the question: is the patient's life in imminent danger if the device fails or stops working? If not, the device is not life-supporting or life-sustaining.

Classification Questionnaire

Figure 3.1 shows the first six items for the Form which expired on May 30, 2012.

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: May 30, 2012 (See OMB 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.

Figure 3.1. First Six Items of Form 3429 Which Expired on May 30, 2012.

Testing the Logic of the Classification Questionnaire

Let's take a hypothetical device with the following properties:

1. It is not life-supporting or life-sustaining.

2. It is not for a purpose which is of significance in the prevention of impairment of human health.

3. It does not present a significant risk of illness or injury.

Turning to the CQ in Figure 3.1, we see that the answers to the first three items are "No." Therefore, the answer to item 4 is also "No." Since none of the conditions in the second clause of the definition of Class III is satisfied, our hypothetical device must be excluded from Class III.

Continuing, the logical instruction for Item 4, directs us to Item 5.

There are two possible answers to Item 5. If the answer is "Yes" the device is directed to Class I, as it should be. If the answer is "No" we are directed to item 6.

Here's where things get sticky. Answering the question in item 6 with confidence involves decision making that requires knowledge of the device, its use and the various special controls which could be applied. It can be complicated and requires judgment. For our purposes here, we really only need to examine the results of the possible answers to establish that the form has a logical flaw.

If we arrive at the answer "Yes" then the device is directed to Class II, Special Controls. So far so good.

However, if we decide that Item 6 should be answered "No" we are directed to Class III. By item 4, we already saw that our hypothetical device does NOT satisfy the definition of Class III, but the CQ puts it in Class III. THIS IS THE LOGICAL FLAW THAT I DISCOVERED IN FEBRUARY 2012.

It was this inconsistency that I tried to communicate to the Ombudsman and other CDRH employees during the period March to July 2012. But it seemed that no one (except Paul Gadiock as described in Chapter 5) was willing to discuss the issue.

The next few chapters document my efforts to get the FDA's attention about this problem and how they responded.

Another Problem with Form 3429

Up to this point, I had focused exclusively on the definition of Class III and how the CQ was not consistent with the definition. It turns out there was another problem with the CQ, this time having to do with the definition of Class I. I was totally clueless about this second problem for another year. We'll pick up that thread in Chapter 10.

In Chapter 4, the journey continues as I follow Dr. Buckles' advice and try to make the case at Panel meetings.

END NOTES FOR CHAPTER 3

[1] This particular version of Form 3429 expired on May 30, even though May has 31 days. All other versions of the form I located expired on the last day of the month. This may have been a typographical error or an editing oversight.

[2] 21 CFR 860.3(c)(3).