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Reclassification Petitions for Medical Devices; Proposed Collection

Comment On: FDA-2011-N-0776-0004
Agency Information Collection Activities; Proposed Collection; Comment Request; Reclassification Petitions for Medical Devices

Document: FDA-2011-N-0776-DRAFT-0002
Comment from Leroy Leslie Hamilton, NA

Submitter Information

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Organization: NA

General Comment

Re: Docket No. FDA-2011-N-0776

This comment is intended to reinforce my earlier communications to the FDA on the subject of Form FDA 3429, General Device Classification Questionnaire.

This form should be retained because it can be the simplest, quickest, and most efficient method to make an assessment of the appropriate class for a medical device. Classification questionnaires, in various versions, predate the enactment of the Medical Device Amendments in May 1976.

However, as FDA revised the Form, a serious logical error crept in, leading to Class III for some devices which did not satisfy the definition of Class III. This was addressed in Citizen Petition FDA-2012-P-0776. FDA responded by abruptly revising Form 3429 in July 2012, only one month after it had been renewed, unchanged, for 37 months. As I have explained in other communications to the FDA, the major change, stripping column 3 from the Form, rendered the Form useless for its intended purpose: column 3 contained all the logic for the form, including which questions to skip and the class of the device.

My Citizen Petition FDA-2014-P-0283 proposed a revised Form 3429 which would correct the defects. The petition, despite its obvious merits, was rejected by FDA by letter signed by Nancy Stade, dated May 16, 2014. That letter states the grounds for FDA denying the petition, repeating the misleading statements made by FDA to the OMB to explain and justify the abrupt changes made effective in July 2012.

March 3, 2014

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

[Docket No. FDA-2014-P-0283/CP1 filed 3/6/14]

Citizen Petition

The undersigned submits this petition under 21 CFR 10.30.

A. Action Requested

This petition requests the Commissioner to revise Form FDA 3429 to indicate the appropriate classification of a medical device. Petitioner believes that reinstating a corrected column 3 to the Form would be in the best interest of the FDA, the public, and the medical device industry.

B. Statement of Grounds

Form FDA 3429 is titled "General Device Classification Questionnaire." Classification Questionnaire is defined at 21 CFR 860.3

(f)*Classification questionnaire* means a specific series of questions prepared by the Commissioner for use as guidelines by classification panels preparing recommendations to the Commissioner regarding classification and by petitioners submitting petitions for reclassification. The questions relate to the safety and effectiveness characteristics of a device and the answers are designed to help the Commissioner determine the proper classification of the device.

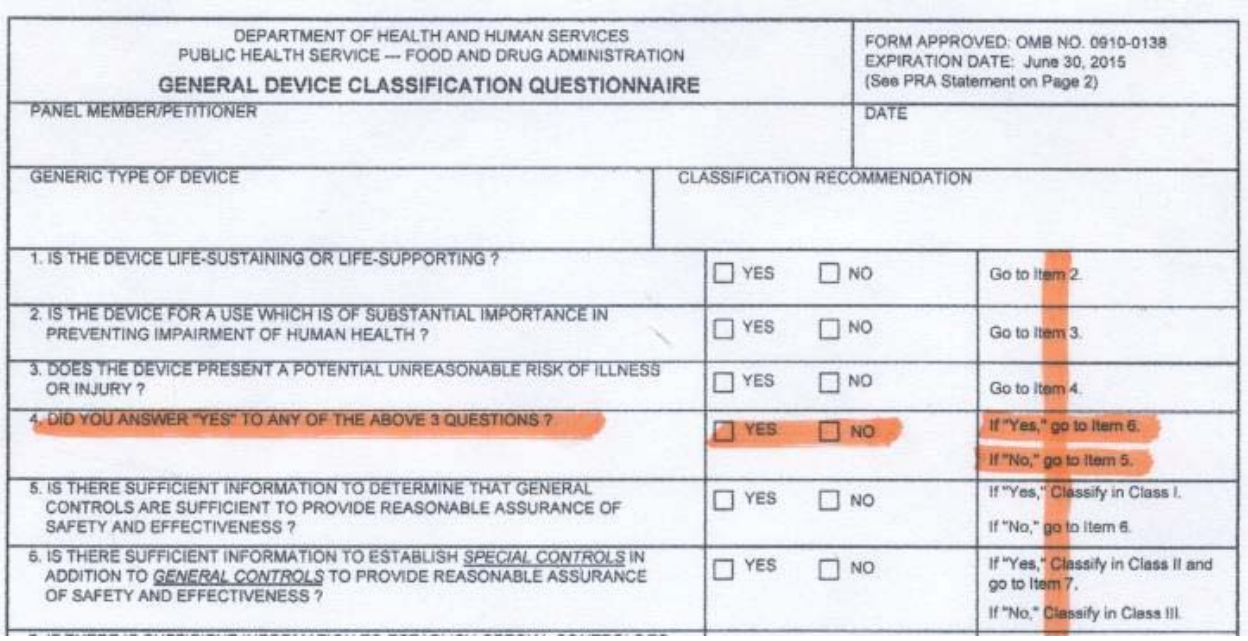
For years, the Classification Questionnaire specified the class for a device based on the answers to the questions. The current version (effective 7/12) was revised to eliminate a column which formerly provided logical instructions and listed the appropriate class for a device.

In February, 2012, I discovered a logical flaw in Form 3429 in use at the time. (The form's expiration date was May 30, 2012.) That version, and all previous versions dating back to at least 1997 led to Class III for some devices which did not satisfy the definition of Class III in the law. The Form was renewed, unchanged, in June 2012 with an expiration date of June 30, 2015.

In July, 2012, I filed a Citizen Petition (Docket No. FDA-2012-P-0747) requesting the Commissioner to initiate an impartial investigation into whether Form 3429 was in conformity with the definition of Class III in the statute. FDA's official response to my petition came in a March 4, 2013 letter signed by Nancy Stade, stating that my petition had been granted and that Form FDA 3429 was corrected by removing the information in the last column and row four.

Form 3429 was revised only a month after it had been renewed in June, 2012. The revised version of Form 3429 bears an effective date of 7/12 and an expiration date of June 30, 2015.

Figure 1 shows the first six questions of the Form as it was renewed in June; the highlighted areas show the revisions to the Form.



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.

FIGURE 1. Highlighted areas show material removed from Form 3429 effective June 2012.

For many years, the classification questionnaire included logical directions to assist the person completing the questionnaire, e.g., "Go to Item 2." Since these logical directions are missing from the present form, I believe the respondent completing the questionnaire is left without useful guidance.

More importantly, the Form also indicated the appropriate classification for the device in question, depending on the answers provided. The revised Form omits this vital information.

Although it can be argued that question 4 was redundant, petitioner believes that it had been included in previous versions of Form 3429 to serve as a "collector" question. IF THE ANSWER TO ITEM 4 IS "NO", THE DEVICE DOES NOT QUALITY FOR CLASS III.

Column 3 was removed, rendering the Form virtually useless for its intended purpose. As revised, the Form no longer indicates the appropriate classification for the device under consideration.

Petitioner is aware that CDRH has published various versions of a logic diagram intended to display in graphical form the process of device classification. The most recent version of this logic diagram of which the petitioner is aware was presented at a CDRH Panel meeting in February, 2014. The diagram appears in Figure 2 on the next page.

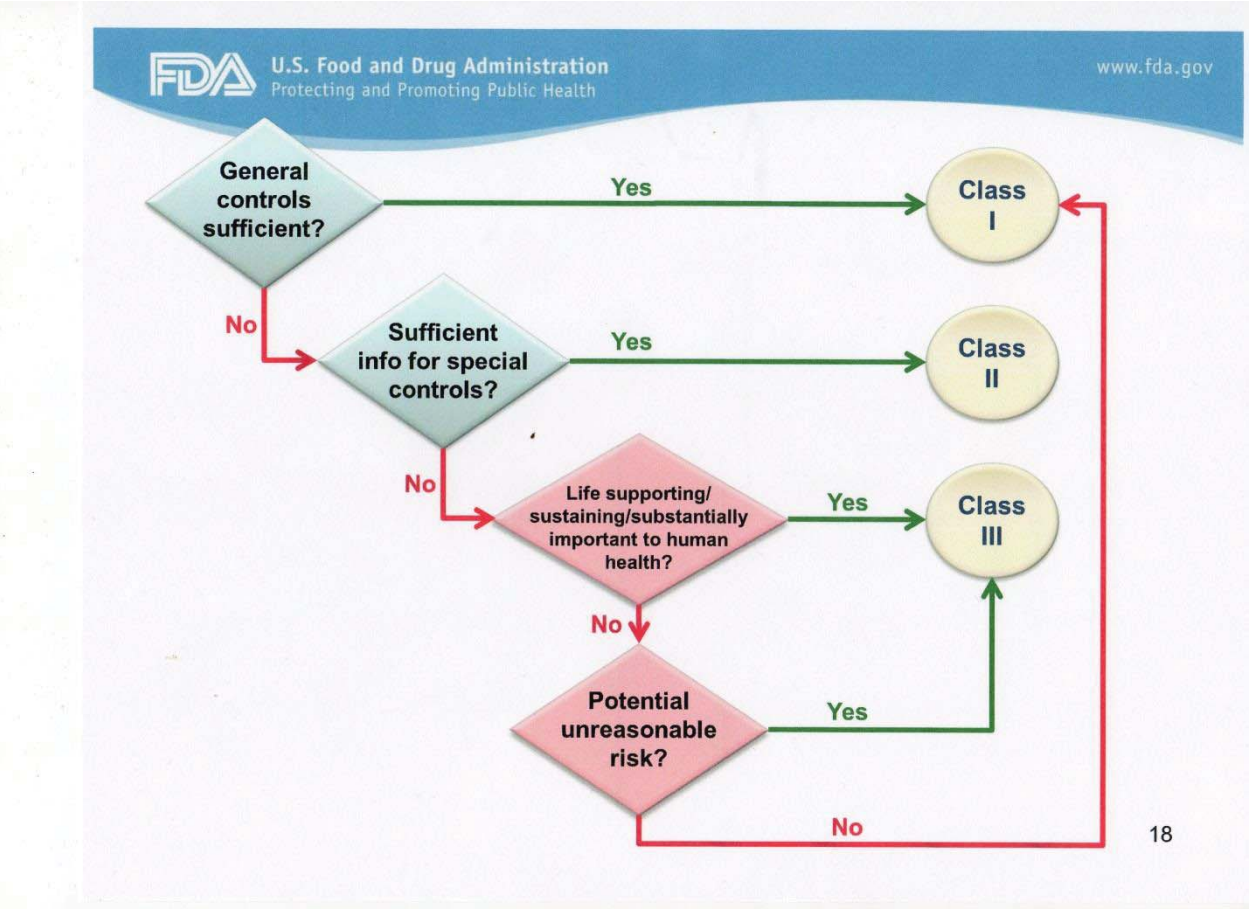


FIGURE 2. Logic Diagram for Classification/Reclassification

Petitioner believes that this diagram conforms to the definitions of Class I, Class II and Class III in the statute.

One aspect of the logic diagram in Figure 2 requires discussion. There are two pathways to Class I. The first pathway, where the answer to the question "General controls sufficient" is "Yes" is clear-cut, and it comes from clause (i) of the definition of Class I, which appears below. The second pathway, where the answer to the question "Potential unreasonable risk?" is "No" is also valid. This can be seen by examining clause (ii) of the definition of Class I.

Class I is defined at 21 USC § 360c:

> (A) **Class I, General Controls.—**
>
> (i) A device for which the controls authorized by or under section 351, 352, 360, 360f, 360h, 360i, or 360j of this title or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.
>
> (ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—

(I) is not 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, and

(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

The convoluted language in clause (ii) was apparently included as a safety net to assure that devices which did not meet the criteria in clause (i) or the definitions of Class II and Class III would be subject at least to General Controls. Without clause (ii), such devices would be in some sort of limbo.

It does seem strange that a device can be in Class II if there is sufficient information to establish special controls but only in Class I if there is insufficient information to establish special controls. The implication is that as we learn more about a device that "fell through" to Class I might then be reclassified to Class II. BUT THIS IS THE LANGUAGE OF THE STATUTE AND FDA SHOULD BE BOUND BY IT OR REQUEST CONGRESS TO CHANGE THE LAW.

Petitioner believes that Figure 2 can serve as a template to create an improved version of Form 3429 General Device Classification Questionnaire. Petitioner offers Exhibit A, the proposed Classification Questionnaire which restores the logical directions and leads to the appropriate class.

Most of the language of the current Form 3429 is retained in the proposed revision in Exhibit A. However, the order of the questions follows the template in Figure 2. Thus, item 4 in the present form becomes item 1. The present items 1, 2, and 3 become items 3, 4 and 5. The "collector" question from earlier versions of Form 3429 is restored as item 6.

Petitioner submits that the proposed revision of Form 3429 is easier to follow than the current version, it conforms to the definitions of the three device classes, and it tells the user what would be the appropriate class for the device under consideration.

In addition, the petition suggests that subsequent versions of Form 3429 be explicitly identified by a version number or other designation. A space for this has been placed at the bottom of the Form with the label "Rev. No."

C. Environmental Impact

There would be no environmental impact if this petition is granted.

D. Economic Impact

There would be no appreciable economic impact if this petition is granted; it seems likely to produce some savings by introducing clarity and simplicity by using a rational approach to classification.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which this petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Leroy L. Hamilton, Ph.D.
13002 Autumn Drive
Silver Spring, MD 20904
301-384-8949

EXHIBIT A. PROPOSED REVISION FOR FORM FDA 3429

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: Month Day, Year (See PRA Statement on Page 2)
PANEL MEMBER/PETITIONER			DATE
GENERIC TYPE OF DEVICE	PRODUCT CODE	CLASSIFICATION RECOMMENDATION	

1. 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 and Go to item 12. If "No," go to item 2.
2. 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," go to item 3.
3. IS THE DEVICE LIFE-SUSTAINING OR LIFE-SUPPORTING?	□ YES □ NO	Go to item 4.
4. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE ON PREVENTING IMPAIRMENT OF HUMAN HEALTH?	□ YES □ NO	Go to item 5.
5. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY?	□ YES □ NO	Go to item 6.
6. DID YOU ANSWER "YES" TO ANY OF THE ABOVE 3 QUESTIONS (Items 3, 4, and 5)?	□ YES □ NO	If "Yes," Classify in Class III and go to Item 10. If "No," Classify in Class I and go to item 12.
7. SINCE THERE IS SUFFICIENT INFORMATION TO ESTABLISH SPECIAL CONTROLS TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS IDENTIFY BELOW THE SPECIAL CONTROLS NEEDED TO PROVIDE SUCH REASONABLE ASSURANCE FOR CLASS II. □ Guidance Document □ Performance Standard(s) □ Device Tracking □ Testing Guidelines □ Other (Specify) _____ [LINES AS NEEDED]		Go to item 8.
8. IF A REGULATORY PERFORMANCE STANDARD IS NEEDED TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF A CLASS II OR CLASS III DEVICE, IDENTIFY THE PRIORITY FOR ESTABLISHING SUCH A STANDARD. □ Low Priority _____ □ Medium Priority _____ □ High Priority _____ □ Not Applicable _____		Go to item 9.
9. FOR A DEVICE RECOMMENDED FOR RECLASSIFICATION INTO CLASS II, SHOULD THE RECOMMENDED REGULATORY PERFORMANCE STANDARD BE IN PLACE BEFORE THE RECLASSIFICATION TAKES EFFECT?	□ YES □ NO □ NOT Applicable	Go to item 11.
10. FOR A DEVICE RECOMMENDED FOR CLASSIFICATION/RECLASSIFICATION INTO CLASS III, IDENTIFY THE PRIORITY FOR REQUIRING PREMARKET APPROVAL APPLICATION (PMA) SUBMISSIONS. □ Low Priority _____ □ Medium Priority _____ □ High Priority _____ □ Not Applicable _____		Go to item 11.

11. IDENTIFY THE NEEDED RESTRICTION(S)
□ Only upon the written or oral authorization of a practitioner licensed by law to administer or use the device
□ Use only by persons with specific training or experience in its use
□ Use only in certain facilities
□ Other (Specify) _____
_____[lines as needed]_____

12. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO
Food and Drug Administration
Center for Devices and Radiological Health
Office of the Center Director
Regulations Staff, WO66-4436
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FORM FDA 3429 (mm/yy)	Rev. No.	Page x

Copies of the cited petition and FDA's denial letter are attached. (These were assigned Docket Numbers FDA-2014-P-0283-0001 and FDA-2014-P-0283-0003, respectively.)

Leroy Leslie Hamilton, Ph.D.
Regulatory Specialist

Attachments

2014Mar3_Form3429Revision

Citizen_Petition_Denial_Response_from_FDA_CDRH_to_Leroy_Leslie_Hamilton

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

May 16, 2014

Leroy Leslie Hamilton, Ph.D.
13002 Autumn Drive
Silver Spring, MD 20904

Re: Citizen Petition Docket No. FDA-2014-P-0283

Dear Dr. Hamilton:

This letter responds to the above referenced petition filed on March 5, 2014, requesting that the Food and Drug Administration (FDA) revise Form FDA 3429 to indicate the appropriate classification of a medical device by reinstating a corrected third column.

You assert that due to the removal of the third column in a previous revision, respondents completing the questionnaire are left without useful guidance, including the appropriate classification for the device in question. For the reasons stated below, your request is denied.

I. Background

FDA considers the information supplied on Form FDA 3429 in proposing a classification. Typically, 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 for 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.

II. Discussion

After careful consideration, FDA previously determined that unnecessary information had been included in Form FDA 3429 that could confuse readers. The extraneous information in the last column and in row four described merely one approach of understanding device classifications, albeit not the only approach. The information in the third column was therefore removed in 2012 to improve clarity. FDA retained the information in the previous two columns regarding opinion-based determinations of potential risks and regulatory controls to take into consideration when contemplating a classification change, while the extraneous information that was not necessary to readers including the legal significance of those opinion-based determinations was removed.

Furthermore, as stated in FDA's March 25, 2014 proposed rule regarding reclassification procedures, FDA intends to no longer require use of FDA Form 3429 when considering a classification change. (79 FR 16260). The proposed rule provides, in relevant part:

> "FDA...proposes removing the requirement to answer the classification questionnaire.... The classification questionnaire provides recommendations and information for FDA to consider during the classification process... As FDA has gained experience with the classification processes, questions concerning the utility of the classification questionnaire...have arisen. FDA believes that a more efficient use of FDA and petitioner resources would be to focus on the information the petitioner provides concerning review of available valid scientific evidence, appropriate regulatory controls given the risks presented by the device, and regulatory standards to understand whether general controls are sufficient to provide [reasonable assurance of safety and effectiveness] or whether general controls and special controls are sufficient to provide [reasonable assurance of safety and effectiveness]."

If you have comments on the proposal to no longer require Form FDA 3429, you can submit comments to the docket for the proposed rule (see proposed rule for instructions for submitting comments). For your reference, this is the internet address of the proposed rule: https://www.federalregister.gov/articles/2014/03/25/2014-06364/medical-device-classification-procedures.

For the foregoing reasons your petition is denied. If you have any questions regarding this response, please contact Paul Gadiock of our Regulations Staff at (301) 796-5736.

Sincerely,

Nancy Stade, J.D.
Deputy Director for Policy
Center for Devices and
Radiological Health