## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0793]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Recall Authority

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by July 13, 2015.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0432. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Medical Device Recall Authority—21 CFR 810 (OMB Control Number 0910–0432)—Extension

This collection of information implements section 518(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360h(e)) and part 810 (21 CFR part 810), medical device recall authority provisions. Section 518(e) of the FD&C Act provides FDA with the authority to issue an order requiring an appropriate person, including manufacturers, importers, distributors, and retailers of a device, if FDA finds that there is reasonable probability that the device intended for human use would cause serious adverse health consequences or death, to: (1) Immediately cease distribution of such device; (2) immediately notify health professionals and device-user facilities of the order; and (3) instruct such professionals and facilities to cease use of such device.

Further, the provisions under section 518(e) of the FD&C Act set out the following three-step procedure for issuance of a mandatory device recall order:

- If there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA may issue a cease distribution and notification order requiring the appropriate person to immediately:
  - ○ Cease distribution of the device,
  - ○ notify health professionals and device user facilities of the order, and
  - ○ instruct those professionals and facilities to cease use of the device;
- FDA will provide the person named in the cease distribution and notification order with the opportunity for an informal hearing on whether the order should be modified, vacated, or amended to require a mandatory recall of the device; and
- After providing the opportunity for an informal hearing, FDA may issue a mandatory recall order if the Agency determines that such an order is necessary.

The information collected under the recall authority provisions will be used by FDA to do the following: (1) Ensure that all devices entering the market are safe and effective; (2) accurately and immediately detect serious problems with medical devices; and (3) remove dangerous and defective devices from the market.

In the **Federal Register** of March 11, 2015 (80 FR 13586), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Collection activity—21 CFR Section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Collections Specified in the Order—810.10(d) | 2 | 1 | 2 | 8 | 16 |
| Request for Regulatory Hearing—810.11(a) | 1 | 1 | 1 | 8 | 8 |
| Written Request for Review—810.12(a–b) | 1 | 1 | 1 | 8 | 8 |
| Mandatory Recall Strategy—810.14 | 2 | 1 | 2 | 16 | 32 |
| Periodic Status Reports—810.16(a–b) | 2 | 12 | 24 | 40 | 960 |
| Termination Request—810.17(a) | 2 | 1 | 2 | 8 | 16 |
| Total Hours | | | | | 1,040 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| Collection activity—21 CFR Section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| Documentation of Notifications to Recipients—810.15(b) | 2 | 1 | 1 | 8 | 8 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

| Collection Activity—21 CFR Section | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|---|---|---|---|---|---|
| Notification to Recipients—810.15(a)–(c) | 2 | 1 | 2 | 12 | 24 |
| Notification to Recipients; Followup—810.15(d) | 2 | 1 | 2 | 4 | 8 |
| Notification of Consignees by Recipients—810.15(e) | 10 | 1 | 10 | 1 | 10 |
| Total | | | | | 42 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 8, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0776]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reclassification Petitions for Medical Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by July 13, 2015.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0138. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Reclassification Petitions for Medical Devices (OMB Control Number 0910–0138)—Extension**

Under sections 513(e) and (f), 514(b), 515(b), and 520(*l*) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(e) and (f), 360d(b), 360e(b), and 360j(*l*)) and part 860 (21 CFR part 860), subpart C, FDA has responsibility to collect data and information contained in reclassification petitions. The reclassification provisions of the FD&C Act allow any person to petition for reclassification of a device from any of the three classes, *i.e.,* I, II, and III, to another class. The reclassification content regulation (§ 860.123) requires the submission of valid scientific evidence demonstrating that the proposed reclassification will provide a reasonable assurance of safety and effectiveness of the device type for its indications for use.

The reclassification procedure regulation requires the submission of specific data when a manufacturer is petitioning for reclassification. This includes a ''Supplemental Data Sheet,'' Form FDA 3427, and a ''General Device Classification Questionnaire,'' Form FDA 3429. Both forms contain a series of questions concerning the safety and effectiveness of the device type.

In the **Federal Register** of March 25, 2014 (79 FR 16252), FDA issued a proposed rule that would eliminate the need for Forms FDA 3427 and FDA 3429. However, because the proposed rule has not been finalized, we continue to include the forms in the burden estimate for this information collection.

The reclassification provisions of the FD&C Act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device type, or to seek reclassification from a lower to a higher class, thereby increasing the regulatory requirements applicable to that device type. If approved, petitions requesting classification from class III to class II or class I provide an alternative route to market in lieu of premarket approval for class III devices. If approved, petitions requesting reclassification from class I or II, to a different class, may increase requirements.

In the **Federal Register** of March 10, 2015 (80 FR 12642), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received.

The comment refers to changes to the form FDA 3429 as proposed by the commenter in a citizen petition (FDA–2014–P–0283–0001), which was subsequently denied by FDA in a final response letter to the petitioner (FDA–2014–P–0283–0003). Because the proposed changes have already been denied through the citizen petition process, we have not made changes to this information collection based on the comment.

The Center for Devices and Radiological Health (CDRH) has continually maintained contact with industry. Informal communications concerning the importance and effect of reclassification are provided primarily through trade organizations, and via CDRH's Web site. The consensus from the Agency's most recent contact with these trade organizations is that they are in favor of the program. The trade organizations involved are AdvaMed, the Food and Drug Law Institute (FDLI), and the National Electrical Manufacturers Association (NEMA):

AdvaMed, Tara Federici, 1030 15th Street NW., suite 1100, Washington, DC 20005, 202–452–8240;

Food and Drug Law Institute (FDLI), 1000 Vermont Ave. NW., suite 1200, Washington, DC 20005, 202–371–1420; and National Electrical Manufacturers Association (NEMA), 1300 North 17th Street, suite 1847, Rosslyn, VA 22209, 703–841–3200.

FDA estimates the burden of this collection of information as follows: