You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314 for submitting NDAs and abbreviated new drug applications, including supplemental applications and annual reports, have been approved under OMB control number 0910–0001. The collections of information in 21 CFR parts 211 and 212 (current good manufacturing practices) have been approved under OMB control numbers 0910–0139 and 0910–0667.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: August 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16984 Filed 8–7–18; 8:45 am]

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 or we) 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 September 7, 2018.

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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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 (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 the 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 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 07, 2018 (83 FR 9743), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment.

The comment supports continued use of Forms FDA 3427 and FDA 3429. Specifically, the commenter is addressing the issue of discontinuing the forms as previously referenced, wherein FDA issued a proposed rule (79 FR 16252) to eliminate the need for the forms. Because FDA is not discontinuing use of the forms at this time, and this comment relates to the proposed rule (79 FR 16252) and not to the information collection itself, we make no 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 website (*https://www.fda.gov/MedicalDevices/default.htm*).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Supporting data for reclassification petition—21 CFR 860.123	.....	6	1	6	497	2,982
Supplemental Data Sheet	3427	6	1	6	1.5	9
General Device Classification Questionnaire	3429	6	1	6	1.5	9
Total	.....	.....	.....	.....	.....	3,000

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

Based on reclassification petitions received in the past 3 years, FDA anticipates that six petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff who: (1) Are familiar with the requirements for submission of a reclassification petition, (2) have consulted and advised manufacturers on these requirements, and (3) have reviewed the documentation submitted.

The burden estimate for this information collection has not changed since the past OMB approval.

Dated: August 2, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16983 Filed 8–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the President's Council on Sports, Fitness, and Nutrition; Correction

AGENCY: Office of the Assistant Secretary for Health, President's Council on Sports, Fitness, and Nutrition, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting; correction.

SUMMARY: The Department of Health and Human Services published a document in the **Federal Register** of July 27, 2018, concerning the upcoming annual meeting of the President's Council on Sports, Fitness, and Nutrition (PCSFN). The document contained an incorrect location and time.

FOR FURTHER INFORMATION CONTACT: Ms. Holli M. Richmond, Executive Director, Office of the President's Council on Sports, Fitness, and Nutrition, Tower Building, 1101 Wootton Parkway, Suite 560, Rockville, MD 20852, (240) 276–9567.

Correction

In the **Federal Register** of July 27, 2018, in FR Vol. 83 No. 145, on page 35662, in the second column, correct the **DATES** and **ADDRESSES** captions to read:

DATES: The meeting will be held on September 21, 2018, from 9:00 a.m. to 12:30 p.m.

ADDRESSES: Hubert H. Humphrey Building, 200 Independence Avenue SW, Room 800, Washington, DC 20201.

Dated: August 1, 2018.

Holli M. Richmond,

Executive Director, Office of the President's Council on Sports, Fitness, and Nutrition, U.S. Department of Health and Human Services.

[FR Doc. 2018–16970 Filed 8–7–18; 8:45 am]

BILLING CODE 4150–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the President's Council on Sports, Fitness, and Nutrition; Correction

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, President's Council on Sports, Fitness, and Nutrition.

ACTION: Notice of meeting; correction.

SUMMARY: The Department of Health and Human Services published a document in the **Federal Register** of July 27, 2018, concerning the upcoming annual meeting of the President's Council on Sports, Fitness, and Nutrition (PCSFN). The document contained an incorrect location and time.

FOR FURTHER INFORMATION CONTACT: Ms. Holli M. Richmond, Executive Director, Office of the President's Council on Sports, Fitness, and Nutrition, Tower Building, 1101 Wootton Parkway, Suite 560, Rockville, MD 20852, (240) 276–9567.

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ADDRESSES: Hubert H. Humphrey Building, 200 Independence Avenue SW, Room 800, Washington, DC 20201.

Dated: August 1, 2018.

Holli M. Richmond,

Executive Director, Office of the President's Council on Sports, Fitness, and Nutrition, U.S. Department of Health and Human Services.

[FR Doc. 2018–16969 Filed 8–7–18; 8:45 am]

BILLING CODE 4150–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Nursing Research.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose