Contact: LCDR Holly Berilla, Committee Management Officer and Acting Designated Federal Official, CSAT National Advisory Council, 1 Choke Cherry Road, Rockville, Maryland 20857 (mail). Telephone: (240) 276–1252. Fax: (240) 276–2252. Email: *holly.berilla@samhsa.hhs.gov.*

Summer King,

Statistician, SAMHSA.

[FR Doc. 2015–07284 Filed 3–30–15; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0473]

Agency Information Collection Activities; Proposed Collection; Comment Request; Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on our proposed collection of certain information. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies must publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and allow 60 days for public comment. This notice invites comments on the information collection provisions of our requirements for food irradiation processors.

DATES: Submit either electronic or written comments on the collection of information by June 1, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Irradiation in the Production, Processing, and Handling of Food—21 CFR Part 179 (OMB Control Number 0910–0186)—Extension

Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation under the food additive premarket approval provisions of the FD&C Act. The regulations providing for uses of irradiation in the production, processing, and handling of food are found in part 179 (21 CFR part 179). To ensure safe use of a radiation source, § 179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation and the maximum (or minimum and maximum) energy of the emitted radiation. Section 179.21(b)(2) requires that the label or accompanying labeling bear adequate directions for installation and use and a statement supplied by us that indicates maximum dose of radiation allowed. Section 179.26(c) requires that the label or accompanying labeling bear a logo and a radiation disclosure statement. Section 179.25(e) requires that food processors who treat food with radiation make and retain, for 1 year past the expected shelf life of the products up to a maximum of 3 years, specified records relating to the irradiation process (*e.g.,* the food treated, lot identification, scheduled process, etc.). The records required by § 179.25(e) are used by our inspectors to assess compliance with the regulation that establishes limits within which radiation may be safely used to treat food. We cannot ensure safe use without a method to assess compliance with the dose limits, and there are no practicable methods for analyzing most foods to determine whether they have been treated with ionizing radiation and are within the limitations set forth in part 179. Records inspection is the only way to determine whether firms are complying with the regulations for treatment of foods with ionizing radiation.

Description of respondents: Respondents are businesses engaged in the irradiation of food.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
179.25(e), large processors	4	300	1,200	1	1,200
179.25(e), small processors	4	30	120	1	120

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR section	Number of record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Total					1,320

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

We base our estimate of burden for the recordkeeping provisions of § 179.25(e) on our experience regulating the safe use of radiation as a direct food additive. The number of firms who process food using irradiation is extremely limited. We estimate that there are four irradiation plants whose business is devoted primarily (*i.e.,* approximately 100 percent) to irradiation of food and other agricultural products. Four other firms also irradiate small quantities of food. We estimate that this irradiation accounts for no more than 10 percent of the business for each of these firms. Therefore, the average estimated burden is based on four facilities devoting 100 percent of their business to food irradiation (4 × 300 hours = 1200 hours for recordkeeping annually), and four facilities devoting 10 percent of their business to food irradiation (4 × 30 hours = 120 hours for recordkeeping annually).

No burden has been estimated for the labeling requirements in §§ 179.21(b)(1), 179.21(b)(2), and 179.26(c) because the information to be disclosed is information that has been supplied by FDA. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not subject to review by the Office of Management and Budget under the Paperwork Reduction Act.

Dated: March 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–07263 Filed 3–30–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee. This meeting was announced in the **Federal Register** of March 13, 2015. The amendment is being made to reflect a change in the April 30th *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring MD 20993–0002, *patricio.garcia@fda.hhs.gov,* 301–796–6875, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), code EN. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 13, 2015 (80 FR 13392), FDA announced that a meeting of the Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee would be held on April 30 and May 1, 2015. On page 13393, in the first and second columns, the *Agenda* portion of the document is changed to read as follows:

On April 30, 2015, the Agency is adding three Agenda items to the original five agenda items posted in the March 13, 2015, **Federal Register** document. The three additional items are: Speech Training Aids for the Hearing Impaired (Battery Powered or Non-Patient), Speech Training Aids for the Hearing Impaired (AC-powered and Patient-Contact), and Nasal Septal Button Devices. The committee will discuss and make recommendations regarding the classification of Hearing Protectors, Circumaural Hearing Protectors, Tactile Hearing Aids, Speech Training Aids for the Hearing Impaired (Battery Powered or Non-Patient), Speech Training Aids for the Hearing Impaired (AC-powered and Patient-Contact), Vestibular Analysis, Middle Ear Inflation Devices, and Nasal Septal Button Devices. These devices are considered preamendments devices since they were in commercial distribution prior to May 28, 1976, when the Medical Devices Amendments became effective. Hearing Protectors are currently regulated under the heading, ''Protector, Hearing (Insert),'' Product Code EWD, as unclassified under the 510(k) premarket notification authority. Circumaural Hearing Protectors are currently regulated under the heading, ''Protector, Hearing (Circumaural),'' Product Code EWE, as unclassified under the 510(k) premarket notification authority. Tactile Hearing Aid Devices are currently regulated under the heading, ''Hearing Aid, Tactile,'' Product Code LRA, as unclassified under the 510(k) premarket notification authority. Speech Training Aids for the Hearing Impaired (Battery Powered or Non-Patient) are currently regulated under the heading, ''Aids, Speech Training For The Hearing Impaired (Battery-Operated or Non-Patient),'' Product Code LFA, as unclassified under the 510(k) premarket notification authority. Speech Training Aids for the Hearing Impaired (AC-Powered and Patient-Contact) are currently regulated under the heading, ''Aids, Speech Training For The Hearing Impaired (AC-Powered and Patient-Contact),'' Product Code LEZ, as unclassified under the 510(k) premarket notification authority. Vestibular Analysis Apparatuses are currently regulated under the heading, ''Apparatus, Vestibular Analysis,'' Product Code LXV, as unclassified under the 510(k) premarket notification authority. Middle Ear Inflation Devices are currently regulated under the heading, ''Device, Inflation, Middle Ear,'' Product Code MJV, as unclassified under the 510(k) premarket notification authority. Nasal Septal Button Devices are currently regulated under the heading, ''Button, Nasal Septal,'' Product Code LFB, as unclassified under the 510(k) premarket notification authority. FDA is seeking committee input on the risks, safety and effectiveness, and the regulatory classification of Hearing Protectors, Circumaural Hearing Protectors, Tactile Hearing Aids, Speech Training Aids for the Hearing Impaired (Battery Powered or Non-Patient), Speech Training Aids for the Hearing Impaired (AC-Powered and Patient-Contact), Vestibular Analysis, Middle Ear Inflation Devices, and Nasal Septal Button Devices.