

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2014-N-1051]

**Modified Risk Tobacco Product Applications: Applications for 10 Products Submitted by Swedish Match North America Inc.; Reopening of Comment Period; Correction****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 31, 2015 (80 FR 45661). The document reopened the period for public comment on modified risk tobacco product applications (MRTPAs) submitted by Swedish Match North America Inc. for 10 tobacco products and announced the availability for public comment of amendments to the MRTPAs. The document was published with an incorrect paragraph in the *Comments* section. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2015-18782, appearing in the **Federal Register** of Friday, July 31, 2015, the following correction is made:

On page 45661, in the third column, the first paragraph of the *Comments* section is corrected to read:

**A. General Information About Submitting Comments**

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document.

**B. Public Availability of Comments**

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>. As a matter of Agency practice, FDA generally does not post comments submitted by individuals in their individual capacity on <http://www.regulations.gov>. This is determined by information indicating

that the submission is written by an individual, for example, the comment is identified with the category "Individual Consumer" under the field entitled "Category (Required)," on the "Your Information" page on <http://www.regulations.gov>. For this docket, however, FDA will not be following this general practice. Instead, FDA will post on <http://www.regulations.gov> comments to this docket that have been submitted by individuals in their individual capacity. If you wish to submit any information under a claim of confidentiality, please refer to 21 CFR 10.20.

**C. Information Identifying the Person Submitting the Comment**

Please note that your name, contact information, and other information identifying you will be posted on <http://www.regulations.gov> if you include that information in the body of your comments. For electronic comments submitted to <http://www.regulations.gov>, FDA will post the body of your comment on <http://www.regulations.gov> along with your state/province and country (if provided), the name of your representative (if any), and the category identifying you (e.g., individual, consumer, academic, industry). For written submissions submitted to the Division of Dockets Management, FDA will post the body of your comments on <http://www.regulations.gov>, but you can put your name and/or contact information on a separate cover sheet and not in the body of your comments.

Dated: August 3, 2015.

**Leslie Kux,***Associate Commissioner for Policy.*

[FR Doc. 2015-19418 Filed 8-6-15; 8:45 am]

**BILLING CODE 4164-01-P****DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2015-D-2537]

**Request for Quality Metrics; Notice of Draft Guidance Availability and Public Meeting; Request for Comments; Correction****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 28, 2015 (80 FR 44973). The document published with an

incorrect docket number. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Lisa Granger, Office of Policy, Planning, Legislation, and Analysis, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2015-18448, appearing on page 44973, in the **Federal Register** of Tuesday, July 28, 2015, the following correction is made:

On page 44973, in the first column, in the headings section of the document, "[Docket No. FDA-2014-D-2537]" is corrected to read "FDA-2015-D-2537".

Dated: August 3, 2015.

**Leslie Kux,***Associate Commissioner for Policy.*

[FR Doc. 2015-19487 Filed 8-6-15; 8:45 am]

**BILLING CODE 4164-01-P****DEPARTMENT OF HEALTH AND HUMAN SERVICES****Designation of a Class of Employees for Addition to the Special Exposure Cohort**

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** HHS gives notice of a decision to designate a class of employees from the Westinghouse Electric Corporation in Bloomfield, New Jersey, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000.

**FOR FURTHER INFORMATION CONTACT:** Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, 1090 Tusculum Avenue, MS C-46, Cincinnati, OH 45226-1938, Telephone 1-877-222-7570. Information requests can also be submitted by email to [DCAS@CDC.GOV](mailto:DCAS@CDC.GOV).

**SUPPLEMENTARY INFORMATION:**

**Authority:** 42 U.S.C. 7384q(b). 42 U.S.C. 7384l(14)(C).

On July 31, 2015, as provided for under 42 U.S.C. 7384l(14)(C), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All Atomic Weapons Employees who worked at the facility owned by Westinghouse Electric Corp., in Bloomfield, New Jersey, during the period from February

1, 1958, through May 31, 1958, or during the period from June 1, 1959, through June 30, 1959, for a number of work days aggregating at least 250 work days, occurring either solely under this employment, or in combination with work days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

This designation will become effective on August 27, 2015, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

**John Howard,**

*Director, National Institute for Occupational Safety and Health.*

[FR Doc. 2015-19471 Filed 8-6-15; 8:45 am]

**BILLING CODE 4163-19-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Notice of Service Delivery Area Designation for the Koi Nation of Northern California Formerly Known as the Lower Lake Rancheria**

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** This Notice advises the public that the Indian Health Service (IHS) proposes the geographic boundaries of the Service Delivery Area (SDA) for the reaffirmed Koi Nation of Northern California, formerly known as the Lower Lake Rancheria, California (Indian Entities Recognized and Eligible to Receive Services From the United States Bureau of Indian Affairs, 80 **Federal Register** 1942 Jan. 14, 2015). The Koi Nation's Federal recognition was reaffirmed by the Assistant Secretary of Indian Affairs on December 29, 2000. The Koi Nation SDA is to be comprised of Lake and Sonoma Counties in the State of California. The counties listed are designated administratively as the SDA, to function as a Purchased/ Referred Care (PRC), formerly known as contract health services, SDA, for the

purposes of operating a PRC program pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA), Pub. L. 93-638.

**DATES:** This notice is effective 30 days after date of publication in the **Federal Register** (FR).

**ADDRESSES:** Comments may be mailed to Ms. Betty Gould, Regulations Officer, Indian Health Service, 801 Thompson Avenue, Suite 450, Rockville, Maryland 20852. Comments will be made available for public inspection at this address from 8:30 a.m. to 5:00 p.m. Monday-Friday beginning approximately two weeks after publication of this notice.

**FOR FURTHER INFORMATION CONTACT:** Mr. Carl Harper, Director, Office of Resource Access and Partnerships, Indian Health Service, 801 Thompson Avenue, Suite 360, Rockville, Maryland 20852. Telephone 301/443-2694 (This is not a toll free number).

**SUPPLEMENTAL INFORMATION:** The IHS currently provides services under regulations in effect on September 15, 1987 and IHS republished at 42 CFR part 136, subparts A through C. Many of the newly recognized/restored/reaffirmed Tribes do not have reservations and either Congress has legislatively designated counties to serve as SDAs or the Director, IHS, exercised reasonable administrative discretion to designate SDAs to effectuate the intent of Congress for these Tribes. The Director, IHS, published notice of the establishment of SDAs in the June 21, 2007 FR Notice (72 FR 34262-01). The SDAs function as PRC SDAs for the purposes of operating a PRC program pursuant to the ISDEAA, Pub. L. 93-638. Thus, the PRC SDA list incorporates the SDAs that operate as PRC SDAs for newly recognized/restored/reaffirmed Tribes. At 42 CFR part 136 Subpart C, a PRC SDA is defined as the geographic area within which PRC will be made available by the IHS to members of an identified Indian community who reside in the area. Residence within a PRC SDA by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12 creates no legal entitlement to PRC but only potential eligibility for

services. Services needed but not available at an IHS/Tribal facility are provided under the PRC program depending on the availability of funds, the person's relative medical priority, and the actual availability and accessibility of alternate resources in accordance with the regulations.

As applicable to the Tribes, these regulations provide that, unless otherwise designated, a PRC SDA shall consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation (42 CFR 136.22(a)(6) (2014). On December 29, 2000 the Assistant Secretary of Indian Affairs reaffirmed the Federal recognition of the Koi Nation (Tribe), formerly known as the Lower Lake Rancheria, and the government-to-government relationship between the United States and the Tribe. The Koi Nation is located in Lake and Sonoma Counties in the State of California. After consultation with the Tribal governing body, the SDA for the Tribe was agreed upon. The purpose of this FR notice is to notify the public that the IHS now administratively designates Lake and Sonoma Counties as the Koi Nation's SDA.

Under 42 CFR 136.23 those otherwise eligible Indians who do not reside on a reservation but reside within a PRC SDA must be either members of the Tribe or maintain close economic and social ties with the Tribe. In this case, the Tribe estimated the eligible user population to be 72 enrolled Koi Nation members who are actively involved with the Tribe.

The Koi Nation's Tribal office is located in the city of Santa Rosa, Sonoma County, in the State of California. A significant number of the Koi Nation SDA eligible user population also resides in Lake County in the State of California. There are other Federally recognized Tribes in Lake and Sonoma Counties and both counties are currently part of other Tribes' PRC SDA. The Koi Nation only seeks to provide health care services to its members who reside in Lake and Sonoma Counties.

This notice does not contain reporting or recordkeeping requirements subject to prior approval by the Office of Management and Budget under the Paperwork Reduction Act of 1980.

**PURCHASED/REFERRED CARE SERVICE DELIVERY AREAS AND SERVICE DELIVERY AREAS**

Tribe/reservation	County/state
Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona.	Pinal, AZ.
Alabama-Coushatta Tribes of Texas .....	Polk, TX. <sup>1</sup>
Alaska .....	Entire State. <sup>2</sup>
Arapahoe Tribe of the Wind River Reservation, Wyoming .....	Hot Springs, WY, Fremont, WY, Sublette, WY.