TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity | No. of respondents | No. of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Full SE 905(j)(1)(A)(i) and 910(a) | 75 | 1 | 75 | 300 | 22,500 |
| Product Quantity Change SE Report | 125 | 1 | 125 | 87 | 10,875 |
| Same Characteristics SE Report | 100 | 1 | 100 | 47 | 4,700 |
| Totals | | | | | 38,075 |

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

FDA has based these estimates on information it now has available from interactions with the industry, information related to other regulated products, and FDA's expectations regarding the tobacco industry's use of the section 905(j) pathway to market their products. Table 1 describes the annual reporting burden as a result of the implementation of the SE requirements of sections 905(j) and 910(a) of the FDC Act (*21 U.S.C. 387j(a)*). Based on current information, FDA now estimates that it will receive 300 section 905(j) reports each year. Of these 300 reports, FDA estimates that 75 of these reports will be ''full'' SE reports that take a manufacturer approximately 300 hours to prepare. Under the newly issued guidance entitled, ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions,'' FDA is recommending that certain modifications might be addressed in either a ''Same Characteristics SE Report'' or ''Product Quantity Change Report.'' FDA estimates that it will receive 100 Same Characteristics SE Reports and that it will take a manufacturer approximately 47 hours to prepare this report. FDA estimates that it will receive 125 Product Quantity Change SE Reports and that it will take a manufacturer approximately 87 hours to prepare this report. Therefore, FDA estimates the burden for submission of SE information will be 38,075 hours.

Dated: July 7, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–16952 Filed 7–10–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Extension of Comment Period for the Office of the Assistant Secretary for Preparedness and Response Public Access Plan to Federally Funded Research: Publications and Data

**AGENCY:** Department of Health and Human Services.

**ACTION:** Notice of extension of public comment period until July 13.

**SUMMARY:** The Department of Health and Human Services (HHS) is extending the comment period on the Assistant Secretary for Preparedness and Response (ASPR) Public Access Plan for Federally Funded Research: Publications and Data. The document is available to the public via *http://www.phe.gov/Preparedness/planning/science/Pages/AccessPlan.aspx.* The comment period was previously scheduled to end June 25, 2015. The public comment period is extended until July 13, 2015.

**FOR FURTHER INFORMATION CONTACT:** Please submit comments via email to *Harvey.ball@hhs.gov*

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 103 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358), the Executive Office of the President, Office of Science and Technology Policy (OSTP) issued a memorandum on February 22, 2013 to the heads of federal agencies directing them to develop plans to enhance access to the results of federally-funded scientific research. ASPR is voluntarily developing a public access plan in order to maximize availability of digitally-formatted scientific data resulting from research supported wholly or in part by federal funding that will improve the public's ability to locate and access this data.

*Background:* This plan considers the interests and needs of various stakeholders, including, but not limited to, federally funded researchers, universities, libraries, publishers, data users and civil society groups.

*Availability of Materials:* The draft copy of the ASPR Public Access Plan will be posted on the phe.gov Web site: *http://www.phe.gov/Preparedness/planning/science/Documents/AccessPlan.pdf.*

*Procedures for Providing Public Input:* All comments must be received by July 13, 2015. Please submit comments to Harvey Ball via email *harvey.ball@hhs.gov*.

Dated: July 2, 2015.

**Nicole Lurie,**

*Assistant Secretary for Preparedness and Response.*

[FR Doc. 2015–16969 Filed 7–10–15; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

### Office of Direct Service and Contracting Tribes; National Indian Health Outreach and Education—Health Reform Cooperative Agreement; Correction

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

**ACTION:** Notice; correction.

**SUMMARY:** The Indian Health Service published a document in the **Federal Register** on June 19, 2015, for the FY 2015 National Indian Health Outreach and Education, Health Reform Cooperative Agreement Program. The notice contained two incorrect dates.

**FOR FURTHER INFORMATION CONTACT:** Mr. Paul Gettys, Grant Systems Coordinator, Division of Grants Management (DGM), Indian Health Service, 801 Thompson Avenue, Suite TMP 360, Rockville, MD 20852, Telephone direct (301) 443–2114, or the DGM main number (301) 443–5204. (This is not a toll-free number.)

**Corrections**

In the **Federal Register** of June 19, 2015, in FR Doc. 2015–15157, on page 35373, in the third column, under the heading Key Dates, the correct Application Deadline Date and Proof of Non-Profit Status Due Date should read as follows: