DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Recommencement in Reporting Requirements for the Federal Cigarette Labeling and Advertising Act (FCLAA) and Comprehensive Smokeless Tobacco Health Education Act (CSTHEA)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On April 27, 2020, the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), published a notice in the **Federal Register** announcing an extension of the deadline for annual reporting of data submitted for cigarettes and smokeless tobacco products, respectively, under the Federal Cigarette Labeling and Advertising Act (FCLAA) and the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA). CDC announced this extension due to the public health response to the COVID–19 pandemic. CDC has since re-evaluated this extension and determined that data submissions can recommence. Required ingredient reports and nicotine analysis reports must be submitted to CDC on or before March 31, 2024.

DATES: The deadline to submit required annual ingredient reports and nicotine analysis reports to CDC shall be March 31, 2024. Beginning March 31, 2024, ingredient reports for cigarette and/or smokeless tobacco products and specifications of the quantity of nicotine contained in smokeless tobacco products that are imported to the United States for the first time must also be submitted at the time of importation.

FOR FURTHER INFORMATION CONTACT: Kathy Gallagher, Office on Smoking and Health, the Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS S107–7, Chamblee, Georgia 30341. Email: *nccdoshfclaa@cdc.gov;* Telephone: 404–639–5349.

SUPPLEMENTARY INFORMATION:

Background

In the **Federal Register** Notice published on April 27, 2020 (85 FR 23359), CDC announced a deadline extension for submissions required under FCLAA (15 U.S.C. 1335a) and CSTHEA (15 U.S.C. 4403) for cigarettes and smokeless tobacco products, respectively, due to the public health response to the COVID–19 pandemic. CDC indicated its inability to accept data submissions or to issue Certificates of Compliance due to unforeseen circumstances created by the pandemic.

CDC has since re-evaluated its ability to accept data submissions and has determined that it can recommence receiving submissions and issuance of Certificates of Compliance. The Federal COVID–19 Public Health Emergency (PHE) Declaration ended on May 11, 2023. As established in prior notices, ingredient reports and nicotine analysis reports are due annually on March 31, and upon initial importation of a cigarette or smokeless tobacco product that is imported to the United States for sale for the first time. For all cigarette and smokeless tobacco products, the deadline to submit required annual ingredient reports and nicotine analysis reports to CDC shall be March 31, 2024. The ingredient reports and nicotine analysis reports due by this date shall fulfill the annual submission compliance for calendar year 2023. There is no requirement to retroactively submit ingredient reports or nicotine analysis reports for calendar year 2020, 2021, or 2022. Beginning March 31, 2024, ingredient reports for cigarette and/or smokeless tobacco products and specifications of the quantity of nicotine contained in smokeless tobacco products that are imported to the United States for the first time must also be submitted at the time of importation.

Information shall be submitted to CDC by mailing or faxing a written report on the letterhead of the manufacturer, packager, importer, respective counsel, or designated individual or entity. However, all faxed information should be followed up with a mailed original. CDC no longer accepts submissions transmitted on CD, 3-inch floppy disk, and/or thumb drive. Electronic mail submissions are not accepted at this time given the inability to ensure the confidentiality of information submitted.

Paperwork Reduction Act

The Paperwork Reduction Act (PRA) requires that Federal agencies obtain approval from the Office of Management and Budget (OMB) for the standardized collection of data from 10 or more entities. CDC has approval from OMB under Control Number 0920–0210, expiration January 31, 2026, to collect cigarette ingredient information. Pursuant to FCLAA, each manufacturer, packager, or importer of cigarettes must annually submit to HHS a list of ingredients added to tobacco in the manufacture of cigarettes. HHS has delegated the responsibility of implementing provisions under FCLAA to CDC. Submission of ingredient reports are due to CDC every year by March 31. With respect to cigarette products imported to the United States, the ingredient report is due upon initial importation of cigarettes into the United States.

CDC also has approval from OMB under Control Number 0920–0338, expiration January 31, 2026, to collect smokeless tobacco product ingredient and nicotine content information, through ingredient reports and nicotine analysis reports. Pursuant to the CSTHEA, each manufacturer, packager, or importer of smokeless tobacco products must annually submit to HHS a list of ingredients added to tobacco in the manufacture of smokeless tobacco products and the quantity of nicotine contained in each smokeless tobacco product. HHS has delegated the responsibility of implementing provisions under CSTHEA to CDC. Submission of ingredient reports and nicotine analysis reports are due to CDC every year by March 31. With respect to smokeless tobacco products imported to the United States, the ingredient reports and nicotine analysis reports are due upon initial importation of smokeless tobacco products into the United States.

Upon receipt of reports pursuant to FCLAA and CSTHEA, CDC issues Certificates of Compliance for all submissions that meet the following requirements: (1) the submission clearly states on whose behalf the submission is made; and (2) the list of ingredients, including chemical names and corresponding Chemical Abstract Service (CAS) registry numbers, added to tobacco in the manufacture of cigarettes and/or smokeless tobacco products is complete and without error.

This current notice published September 29, 2023 serves to provide updates to the public regarding the recommencement of annual data reporting requirements for cigarette and smokeless products manufactured, packaged, or imported in calendar year 2023, for which the next submission of data as required under FCLAA and CSTHEA must be received by CDC on or before March 31, 2024. Beginning March 31, 2024, ingredient reports and/or nicotine analysis reports for cigarette and/or smokeless tobacco products newly imported to the United States must also be submitted at the time of importation.

Tiffany Brown,

Executive Secretary,Centers for Disease Control and Prevention.

[FR Doc. 2023–21431 Filed 9–28–23; 8:45 am]

BILLING CODE 4163–18–P