

marked “Galderma Restylane Injectable Lyft Lidocaine 1 ML, The Perlane Collection, Injectable Gel with Lidocaine;” and, seven boxes marked “Galderma Restylane Injectable Lidocaine 1 ML, Injectable Gel with Lidocaine.”

Following this seizure, and others, on September 2, 2021, a Special Agent from FDA’s Office of Criminal Investigations acting in an undercover capacity purchased items through the website *www.focusisbeauty.com*. The agent ordered, (1) Intense Repair Serum, which bore the image of Botox, and was found in the section of the website titled: “Botox, Anesthetics, & Diluents;” and, (2) Intense Repair Serum, which bore the image of a product titled Daewoong Boulinum Toxin Type A Nabota and was found in the section of the website titled: “Botox, Anesthetics, & Diluents.”

On or about September 17, 2021, agents retrieved the box shipped by Ms. Kiehl. The box contained five products marked as “Botox” with writing in the Turkish language. The products were determined to be counterfeit versions of the Botox product manufactured for and only distributed in Turkey. Botox is the brand name, owned by AbbVie Inc. (AbbVie), of a drug derived from botulinum toxin type A. Botulinum toxin type A is a highly potent toxin which can cause the disease botulism when present in human beings in a sufficient amount. The FDA has approved a biological products license for Botox and a supplement to the license application for the treatment of what is commonly referred to as wrinkles. Both FDA approved licenses for Botox products limits them to use pursuant to a prescription from a licensed practitioner. While Botox products may be purchased through intermediary sources, all purchases are shipped from an AbbVie warehouse facility in Houston, Texas. This occurs to meet the strict temperature controls required for botulinum toxin-containing products.

On October 14, 2021, a search warrant was executed at Ms. Kiehl’s residence. During the execution of the warrant, agents discovered hundreds of counterfeit products violative of the FD&C Act that were imported into the United States from foreign countries. These products were discovered throughout the residence, including in a freezer among frozen food items, in a pantry among dry goods, and hidden behind a false wall. Ms. Kiehl was present during the execution of the search warrant and agreed to speak with agents. Ms. Kiehl acknowledged ordering and receiving drugs and other

products from foreign countries. She admitted to using fake recipient names on packages shipped to her from China, in an effort to avoid the seizure of the products, which were violative products. When using fake names did not stop the packages from being seized, Ms. Kiehl began using her son’s address to receive the products, which were violative products. Ms. Kiehl acknowledged selling unapproved and counterfeit drugs and other products on the website, *www.focusisbeauty.com*, and shipping those products in interstate commerce to customers.

Shipping records obtained by DHS/HSI revealed approximately 176 foreign based packages were imported by Ms. Kiehl and shipped to her residence between January 9, 2019, and September 19, 2021. Additionally, between approximately July 2017, and October 2021, Ms. Kiehl received approximately \$341,218 for the sale of misbranded and counterfeit drugs and other products that lacked the required FDA approval.

FDA sent Ms. Kiehl, by certified mail, on February 3, 2026, a notice proposing to debar her for a 10-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Ms. Kiehl’s felony conviction under Federal law for mail fraud in violation of 18 U.S.C. 1341 and causing counterfeit drugs to be made, sold, or held for sale in violation of 21 U.S.C. 331(i)(3) and 333(a)(2) was for conduct relating to the importation of any drug or controlled substance into the United States because she illegally imported and introduced misbranded prescription drug products into interstate commerce.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that the Agency considered applicable to Ms. Kiehl’s offense and concluded that the offense warranted the imposition of a 10-year period of debarment.

The proposal informed Ms. Kiehl of the proposed debarment and offered her an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Kiehl received the proposal and notice of opportunity for a hearing on February 7, 2026. Ms. Kiehl failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

## II. Findings and Order

Therefore, the Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that Ms. Kimberly Schaff Kiehl has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 10 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Ms. Kiehl is debarred for a period of 10 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Ms. Kiehl is a prohibited act.

Grace R. Graham,  
*Deputy Commissioner for Policy, Legislation,  
and International Affairs.*

[FR Doc. 2026-07864 Filed 4-22-26; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2026-N-2642]

### Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke; Established List Additions and Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; established list additions and request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is adding constituents to the list of harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke (the established HPHC list) as required by the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

**DATES:** Either electronic or written comments on the notice must be submitted by May 26, 2026.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until

11:59 p.m. Eastern Time at the end of May 26, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2026-N-2642 for "Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke; Established List Additions and Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

#### FOR FURTHER INFORMATION CONTACT:

Anna Julia Adams or Matthew Brenner, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002; 1-877-287-1373, [CTPRegulations@fda.hhs.gov](mailto:CTPRegulations@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31), enacted on June 22, 2009, amended the FD&C Act by, among other things, adding a new chapter (chapter IX) granting FDA the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health. Cigarettes, cigarette tobacco, roll-your-own (RYO)

tobacco, and smokeless tobacco were immediately subject to chapter IX.

For other types of tobacco products, the statute authorizes FDA to issue regulations "deeming" them to be subject to chapter IX. FDA published a final rule on May 10, 2016, deeming all products that meet the statutory definition of "tobacco product" set forth in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), including components and parts, but excluding accessories of deemed products, to be subject to chapter IX of the FD&C Act.<sup>1</sup>

Section 904(e) of the FD&C Act (21 U.S.C. 387d(e)) requires FDA to establish, and periodically revise as appropriate, "a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand."

In 2011, FDA provided guidance that discussed the meaning of "harmful and potentially harmful constituent" in the context of the HPHC list requirement (76 FR 5387, January 31, 2011).<sup>2</sup> In 2012, after considering comments solicited from the public, as well as scientific and other information, FDA developed a list of 93 constituents in tobacco products and tobacco smoke that are believed to be harmful or potentially harmful to health (the HPHC established list).<sup>3</sup>

In August 2016, FDA extended its authority under the Deeming Rule to all products, including components and parts (but excluding accessories of deemed products) that met the statutory definition of tobacco product, including electronic nicotine delivery systems (ENDS). Therefore, consistent with section 904(e) of the FD&C Act, the Agency considered revising the HPHC established list to reflect the current range of tobacco products now subject to the Agency's tobacco product

<sup>1</sup> See "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act," 81 FR 28974 (May 10, 2016), codified at 21 CFR part 1100. On August 9, 2023, the U.S. District Court for the District of Columbia issued an order vacating FDA's rule deeming tobacco products to be subject to FDA's tobacco product authorities "insofar as it applies to premium cigars." *Cigar Ass'n of Am. v. FDA*, No. 16-cv-01460, 2023 WL 5094869, at \*6 (D.D.C. Aug. 9, 2023), affirmed in part, reversed in part, and remanded, 132 F.4th 535 (D.C. Cir. 2025).

<sup>2</sup> FDA revised the 2011 Guidance that discusses the meaning of HPHC in the context of the HPHC list requirement in August 2016. "Harmful and Potentially Harmful Constituents" in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act available at <https://www.fda.gov/media/80109/download>.

<sup>3</sup> "Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke; Established List," 77 FR 20034 (April 3, 2012).

authorities as well as the Agency’s growing scientific expertise with respect to all tobacco products. In 2019, the Agency requested comments on whether 19 additional constituents should be added to the HPHC established list. The Agency has considered comments solicited from the public, as well as scientific and other information, and has added tobacco product constituents to the established HPHC list that FDA currently believes are harmful or potentially harmful to health based on scientific evidence. FDA is adding 18 new constituents to the established list consistent with the requirement in section 904(e) of the FD&C Act to periodically revise, as appropriate, the established HPHC list (Table 1). In this document, we are also finalizing the addition of a new criterion for whether a constituent should be added to the list and seeking comments on the proposed addition of three new constituents to the list.

**II. Background**

FDA first established the HPHC list on April 3, 2012 (77 FR 20034) (the April 2012 notice).<sup>4</sup> The list currently contains 93 HPHCs. The April 2012 notice describes the history of the HPHC established list, and for additional background, we refer readers to that notice and the notice FDA published in the **Federal Register** on August 12, 2011 (76 FR 50226) (the August 2011 notice), in which we solicited public comment, including scientific and other information, concerning the HPHCs in tobacco products and tobacco smoke, such as constituents that should be included on the HPHC established list, and the criteria used in determining whether a constituent is harmful or potentially harmful such that it should be included on the HPHC list.<sup>5</sup>

Further, on August 5, 2019 (84 FR 38032) (the August 2019 notice), FDA published a request for comments on 19 additional constituents proposed to be

added to the established list to reflect the current range of tobacco products subject to the Agency’s tobacco product authorities as well as the Agency’s growing scientific expertise with respect to all tobacco products. The August 2019 notice mentions FDA’s application of existing criteria to deemed tobacco products to propose the addition of glycidol and ethylene glycol. Glycidol is a thermal byproduct of glycerol and a common component in e-liquids. Ethylene glycol, which has also been identified in e-liquids, adversely affects reproduction and development. The notice also stated that FDA would tentatively apply one additional criterion regarding whether a constituent should be included on the HPHC list: constituents identified by the National Institute for Occupational Safety and Health (NIOSH) as having adverse respiratory effects. The notice also proposed diethylene glycol (DEG) be added to the list due to it being a potential contaminant in either glycerol or propylene glycol. If ingested, DEG can cause kidney failure, neurological damage, and death.

When determining whether a constituent should be included on the established HPHC list, FDA considers whether there is evidence that the constituent meets established criteria, such as determinations from third-party scientific and public health organizations like NIOSH, the Environmental Protection Agency (EPA) or the Agency for Toxic Substances and Disease Registry (ATSDR). As part of the Centers for Disease Control and Prevention, NIOSH is the Federal agency responsible for conducting research and making science-based recommendations to prevent work-related illness and injuries, including those related to human health hazards and respiratory disease from inhalation exposures to toxicants. FDA has now finalized its previously tentative conclusion that constituents identified

by NIOSH as respiratory toxicants will be an additional criterion that will be applied for determining whether a constituent should be included on the HPHC established list. The previously established criteria for determining whether a constituent should be included on the established HPHC list includes constituents identified by the EPA or ATSDR as having adverse respiratory or cardiac effects. Considering information from NIOSH in this regard is consistent with FDA’s current practice of looking to other recognized, government experts such as EPA or ATSDR for their ability to identify constituents as having adverse respiratory or cardiac effects. As indicated by the original criteria (the April 2012 notice), FDA has previously considered this information from NIOSH when determining whether a constituent is harmful or potentially harmful by including constituents identified by NIOSH as a potential occupational carcinogen as a current criterion.

After review and consideration of the relevant comments received from the August 2019 notice, FDA is adding 18 of the 19 proposed constituents to the HPHC list. Although FDA proposed that ethyl acetoacetate be added to the list, based on it having been tentatively identified as a respiratory toxicant, FDA has determined that there is insufficient information to warrant its inclusion on the list at this time. FDA’s determination is based on the fact that ethyl acetoacetate does not meet any of the criteria for adding constituents to the HPHC list, including that NIOSH has not identified it as having adverse respiratory effects. This determination may be revised, consistent with the directive in section 904(e) of the FD&C Act that FDA periodically revise the established list as appropriate. The list of the constituents added to the established HPHC list is in Table 1.<sup>6</sup>

**TABLE 1—LIST OF THE ADDITIONAL CHEMICALS AND CHEMICAL COMPOUNDS IDENTIFIED BY FDA AS HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS IN TOBACCO PRODUCTS AND TOBACCO SMOKE**

Constituent	Carcinogen (CA), respiratory toxicant (RT), reproductive or developmental toxicant (RDT), poisonous chemical (PC)
Acetic Acid .....	RT
Acetoin (also known as 3-hydroxy-2-butanone) .....	RT
Acetyl Propionyl (also known as 2,3-pentanedione) .....	RT
Benzyl Acetate .....	RT
Butyraldehyde .....	RT
Diacetyl .....	RT
Diethylene Glycol .....	PC

<sup>4</sup> “Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke; Established List,” 77 FR 20034 (April 3, 2012).

<sup>5</sup> “Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke; Request for Comments,” 76 FR 50226 (August 12, 2011).

<sup>6</sup> See Appendix A for complete HPHC established list.

TABLE 1—LIST OF THE ADDITIONAL CHEMICALS AND CHEMICAL COMPOUNDS IDENTIFIED BY FDA AS HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS IN TOBACCO PRODUCTS AND TOBACCO SMOKE—Continued

Constituent	Carcinogen (CA), respiratory toxicant (RT), reproductive or developmental toxicant (RDT), poisonous chemical (PC)
Ethyl Acetate	RT
Ethylene Glycol	RT, RDT
Furfural	RT
Glycerol	RT
Glycidol	CA
Isoamyl Acetate	RT
Isobutyl Acetate	RT
Methyl Acetate	RT
n-Butanol	RT
Propionic Acid	RT
Propylene Glycol	RT

**III. Request for Comments and Information**

Based on the August 2019 notice, FDA received several comments that suggested adding constituents to the established HPHC list beyond those proposed in the notice. FDA has statutory authority under section 904(e) of the FD&C Act and intends to continue to revise the established HPHC list as additional criteria are defined and additional scientific information becomes available. As a result of comments to the August 2019 notice, FDA is proposing to add three additional constituents to the established list and requests comments on the three proposed additions: pulegone, furfuryl alcohol, and methyl eugenol. These constituents are often added to e-liquid formulations as flavors, but may also be present in other tobacco products, such as cigarettes and smokeless tobacco. FDA has tentatively

concluded that these three constituents meet the criteria used in determining whether a constituent is harmful or potentially harmful and should be included on the HPHC established list, unless other scientific information obtained by or submitted to the Agency shows that the constituent is not, in fact, harmful or potentially harmful.

**IV. Identification of HPHCs Is an Ongoing Effort**

FDA continues to review relevant science to determine whether to add additional constituents to the list. That a constituent has not been so identified by FDA or other entities could be because it does not currently meet established criteria, it has not been adequately studied, or it has not yet been systematically reviewed. Consistent with the obligations under section 904(e) of the FD&C Act, FDA intends to continue: (1) our efforts to

review other disease outcomes to assess whether additional chemicals or chemical compounds in tobacco products or tobacco smoke, including chemicals or chemical compounds in the emissions from the range of tobacco products now deemed to be subject to chapter IX of the FD&C Act, are harmful or potentially harmful constituents that contribute to the risk of other diseases; (2) our consideration of whether additional or different criteria should be selected to help identify other classes of harmful or potentially harmful chemicals and chemical compounds for inclusion on the HPHC established list and whether individual constituents should be added; and (3) our efforts to review new information to determine if it would be appropriate to remove one or more of the constituents that appear on the HPHC established list, or to add additional constituents to the list.

APPENDIX A—ESTABLISHED LIST OF THE CHEMICALS AND CHEMICAL COMPOUNDS IDENTIFIED BY FDA AS HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS IN TOBACCO PRODUCTS AND TOBACCO SMOKE

Constituent	Carcinogen (CA), respiratory toxicant (RT), cardiovascular toxicant (CT), reproductive or developmental toxicant (RDT), addictive (AD), poisonous chemical (PC), banned in food (in smokeless tobacco products)
Acetaldehyde	CA, RT, AD
Acetamide	CA
Acetic Acid	RT
Acetoin (also known as 3-hydroxy-2-butanone)	RT
Acetone	RT
Acetyl Propionyl (also known as 2,3-pentanedione)	RT
Acrolein	RT, CT
Acrylamide	CA
Acrylonitrile	CA, RT
Aflatoxin B1	CA
4-Aminobiphenyl	CA
1-Aminonaphthalene	CA
2-Aminonaphthalene	CA
Ammonia	RT
Anabasine	AD
o-Anisidine	CA
Arsenic	CA, CT, RDT

## APPENDIX A—ESTABLISHED LIST OF THE CHEMICALS AND CHEMICAL COMPOUNDS IDENTIFIED BY FDA AS HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS IN TOBACCO PRODUCTS AND TOBACCO SMOKE—Continued

Constituent	Carcinogen (CA), respiratory toxicant (RT), cardiovascular toxicant (CT), reproductive or developmental toxicant (RDT), addictive (AD), poisonous chemical (PC), banned in food (in smokeless tobacco products)
A- $\alpha$ -C (2-Amino-9 <i>H</i> -pyrido[2,3- <i>b</i> ]indole)	CA
Benz[ <i>a</i> ]anthracene	CA, CT
Benz[ <i>j</i> ]aceanthrylene	CA
Benzene	CA, CT, RDT
Benzo[ <i>b</i> ]fluoranthene	CA, CT
Benzo[ <i>k</i> ]fluoranthene	CA, CT
Benzo[ <i>b</i> ]furan	CA
Benzo[ <i>a</i> ]pyrene	CA
Benzo[ <i>c</i> ]phenanthrene	CA
Benzyl Acetate	RT
Beryllium	CA
1,3-Butadiene	CA, RT, RDT
Butyraldehyde	RT
Cadmium	CA, RT, RDT
Caffeic acid	CA
Carbon monoxide	RDT
Catechol	CA
Chlorinated dioxins/furans	CA, RDT
Chromium	CA, RT, RDT
Chrysene	CA, CT
Cobalt	CA, CT
Coumarin	Banned in food
Cresols (o-, m-, and p-cresol)	CA, RT
Crotonaldehyde	CA
Cyclopenta[ <i>c,d</i> ]pyrene	CA
Diacetyl	RT
Dibenz[ <i>a,h</i> ]anthracene	CA
Dibenzo[ <i>a,e</i> ]pyrene	CA
Dibenzo[ <i>a,h</i> ]pyrene	CA
Dibenzo[ <i>a,i</i> ]pyrene	CA
Dibenzo[ <i>a,l</i> ]pyrene	CA
Diethylene Glycol	PC
2,6-Dimethylaniline	CA
Ethyl Acetate	RT
Ethyl carbamate (urethane)	CA, RDT
Ethylbenzene	CA
Ethylene Glycol	RT, RDT
Ethylene oxide	CA, RT, RDT
Formaldehyde	CA, RT
Furan	CA
Furfural	RT
Glu-P-1 (2-Amino-6-methyldipyrdo[1,2- <i>a</i> :3',2'- <i>d</i> ]imidazole)	CA
Glu-P-2 (2-Aminodipyrdo[1,2- <i>a</i> :3',2'- <i>d</i> ]imidazole)	CA
Glycerol	RT
Glycidol	CA
Hydrazine	CA, RT
Hydrogen cyanide	RT, CT
Indeno[1,2,3- <i>cd</i> ]pyrene	CA
IQ (2-Amino-3-methylimidazo[4,5- <i>f</i> ]quinoline)	CA
Isoamyl Acetate	RT
Isobutyl Acetate	RT
Isoprene	CA
Lead	CA, CT, RDT
MeA- $\alpha$ -C (2-Amino-3-methyl)-9 <i>H</i> -pyrido[2,3- <i>b</i> ]indole)	CA
Mercury	CA, RDT
Methyl Acetate	RT
Methyl Ethyl Ketone	RT
5-Methylchrysene	CA
4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK)	CA
Naphthalene	CA, RT
n-Butanol	RT
Nickel	CA, RT
Nicotine	RDT, AD
Nitrobenzene	CA, RT, RDT
Nitromethane	CA
2-Nitropropane	CA

APPENDIX A—ESTABLISHED LIST OF THE CHEMICALS AND CHEMICAL COMPOUNDS IDENTIFIED BY FDA AS HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS IN TOBACCO PRODUCTS AND TOBACCO SMOKE—Continued

Constituent	Carcinogen (CA), respiratory toxicant (RT), cardiovascular toxicant (CT), reproductive or developmental toxicant (RDT), addictive (AD), poisonous chemical (PC), banned in food (in smokeless tobacco products)
N-Nitrosodiethanolamine (NDELA)	CA
N-Nitrosodiethylamine	CA
N-Nitrosodimethylamine (NDMA)	CA
N-Nitrosomethylethylamine	CA
N-Nitrosomorpholine (NMOR)	CA
N-Nitrosonorricotine (NNN)	CA
N-Nitrosopiperidine (NPIP)	CA
N-Nitrosopyrrolidine (NPYR)	CA
N-Nitrososarcosine (NSAR)	CA
Normicotine	AD
Phenol	RT, CT
PhIP (2-Amino-1-methyl-6-phenylimidazo[4,5-b]pyridine)	CA
Polonium-210	CA
Propionic Acid	RT
Propionaldehyde	RT, CT
Propylene Glycol	RT
Propylene oxide	CA, RT
Quinoline	CA
Selenium	RT
Styrene	CA
o-Toluidine	CA
Toluene	RT, RDT
Trp-P-1 (3-Amino-1,4-dimethyl-5H-pyrido[4,3-b]indole)	CA
Trp-P-2 (1-Methyl-3-amino-5H-pyrido[4,3-b]indole)	CA
Uranium-235	CA, RT
Uranium-238	CA, RT
Vinyl acetate	CA, RT
Vinyl chloride	CA

**Grace R. Graham,**  
*Deputy Commissioner for Policy, Legislation, and International Affairs.*  
 [FR Doc. 2026-07910 Filed 4-22-26; 8:45 am]  
**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Notice of Funding Extension for the Rural Communities Opioid Response Program—Behavioral Health Care Technical Assistance**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice of funding extension.

**SUMMARY:** The Rural Communities Opioid Response Program—Behavioral Health Care Technical Assistance (RCORP-TA) strengthens, through technical assistance, rural organizations’ capacity to develop multi-sector consortia that can plan, implement, and sustain programs that improve access to and quality of behavioral health care services, including substance use disorder/opioid use disorder services. This funded extension extends RCORP-TA’s one cooperative agreement award recipient from cohort fiscal year 2022, HRSA-22-064, for a one-time 1-year period (September 1, 2026, through August 31, 2027). The current recipient, JBS International, Inc (U6BRH32364) was funded for a 4-year period of performance (September 1, 2022, through August 31, 2026).

**FOR FURTHER INFORMATION CONTACT:** Jillian Causey, Deputy Director, Rural Strategic Initiatives Division, Federal Office of Rural Health Policy, HRSA, at [jcausey@hrsa.gov](mailto:jcausey@hrsa.gov) and (301) 443-1493.

**SUPPLEMENTARY INFORMATION:**

*Intended Recipient(s) of the Award:* 1 Rural Communities Opioid Response Program—Behavioral Health Care Technical Assistance award.

*Amount of Non-Competitive Award:* \$10,000,000.

*Project Period:* September 1, 2026, to August 31, 2027.

*Assistance Listing Number:* 93.912.

*Award Instrument:* Cooperative Agreement.

*Authority:* Section 711(b)(5) of the Social Security Act (42 U.S.C. 912(b)(5)).

TABLE 1—RECIPIENT(S) AND AWARD AMOUNT(S)

Grant No.	Award recipient name	City, state	Award amount
U6BRH32364 ....	JBS International, Inc .....	North Bethesda, MD .....	\$10,000,000

*Justification:* This funding provides a one-time 1-year extension of funding to

Rural Communities Opioid Response Program—Behavioral Health Care

Technical Assistance award recipient with a budget period of September 1,