

cause psychoactive effects and adverse events, including deaths similar to heroin, fentanyl, and other opioids. As of January 2021, metonitazene has been identified in eight blood specimens associated with postmortem death investigations in the United States. There are no commercial or approved medical uses for metonitazene. On December 7, 2021, the DEA issued a temporary order (86 FR 69182) to control metonitazene as a Schedule I substance under the CSA, therefore additional permanent controls may be needed if metonitazene is placed in Schedule I of the 1961 Convention.

Eutylone (*chemical name*: 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)butan-1-one) is a designer drug of the phenethylamine class. Eutylone is a synthetic cathinone with chemical structural and pharmacological similarities to Schedule I and II amphetamines and cathinones, such as to 3,4-methylenedioxymethamphetamine, methylone, and pentylone. Eutylone emerged in the United States illicit, synthetic drug market in 2014 as evidenced by its identification in drug seizures. Other evidence indicates that eutylone, like other Schedule I synthetic cathinones, is abused for its psychoactive effects. Adverse effects associated with synthetic cathinones abuse include agitation, hypertension, tachycardia, and death. Eutylone is not approved for medical use in the United States. As a positional isomer of pentylone, eutylone is controlled in Schedule I of the CSA. As such, additional permanent controls will not be needed if eutylone is placed in Schedule II of the Convention on Psychotropic Substances.

FDA, on behalf of the Secretary of HHS, invites interested persons to submit comments on the notifications from the United Nations concerning these drug substances. FDA, in cooperation with the National Institute on Drug Abuse, will consider the comments on behalf of HHS in evaluating the WHO scheduling recommendations. Then, under section 201(d)(2)(B) of the CSA, HHS will recommend to the Secretary of State what position the United States should take when voting on the recommendations for control of substances under the 1971 Convention at the CND meeting in March 2022.

Comments regarding the WHO recommendations for control of bupropion and metonitazene under the 1961 Single Convention will also be forwarded to the relevant Agencies for consideration in developing the U.S.

position regarding narcotic substances at the CND meeting.

Dated: February 9, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2010-D-0575 and FDA-2021-N-0764]

#### **Compliance Policy Guide Sec. 510.800 Beverages—Serving Size Labeling; Compliance Policy Guide Sec. 540.420 Raw Breaded Shrimp—Microbiological Criteria for Evaluating Compliance With Current Good Manufacturing Practice Regulations; and Compliance Policy Guide Sec. 562.800 Vending Machine Food—Labeling; Withdrawal of Guidances**

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

**ACTION:** Notice; withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the withdrawal of three compliance policy guides (CPG) entitled “Compliance Policy Guide Sec. 510.800 Beverages—Serving Size Labeling,” “Compliance Policy Guide Sec. 540.420 Raw Breaded Shrimp—Microbiological Criteria for Evaluating Compliance with Current Good Manufacturing Practice Regulations,” and “Compliance Policy Guide Sec. 562.800 Vending Machine Food—Labeling.” We are withdrawing these CPGs because they have become outdated or have been superseded by subsequent FDA actions.

**DATES:** The withdrawal is applicable February 15, 2022.

**ADDRESSES:** For access to the docket, go to <https://www.regulations.gov> and insert docket number FDA-2010-D-0575 for “Compliance Policy Guide Sec. 510.800 Beverages—Serving Size Labeling” or FDA-2021-N-0764 for “Compliance Policy Guide Sec. 540.420 Raw Breaded Shrimp—Microbiological Criteria for Evaluating Compliance with Current Good Manufacturing Practice Regulations” and “Compliance Policy Guide Sec. 562.800 Vending Machine Food—Labeling” 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:** Kevin Kwon, Office of Compliance

(HFS-605), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-4597; or Alexandra Jurewitz, Office of Regulations and Policy (HFS-024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

We are announcing the withdrawal of three CPGs entitled “Compliance Policy Guide Sec. 510.800 Beverages—Serving Size Labeling,” “Compliance Policy Guide Sec. 540.420 Raw Breaded Shrimp—Microbiological Criteria for Evaluating Compliance with Current Good Manufacturing Practice Regulations,” and “Compliance Policy Guide Sec. 562.800 Vending Machine Food—Labeling.”

CPG Sec. 510.800 entitled “Beverages—Serving Size Labeling” was first issued in December 2010. This CPG provided guidance for FDA staff and industry as to when we would typically consider not taking enforcement action in connection to a “12 [fluid ounce] (360 [milliliter])” labeled serving size on specific types of beverages larger than 20 fluid ounces. On May 27, 2016, FDA issued a final rule entitled “Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments” (81 FR 34000). The final rule amended the Reference Amounts Customarily Consumed (RACCs) that are used by manufacturers to determine serving sizes for certain foods, including certain beverages. Our regulations, at 21 CFR 101.12(b), table 2, lists the categories for each type of food product and each category’s current RACC. Due to the updated RACCs for certain beverages, CPG Sec. 510.800 is now obsolete, and the enforcement discretion provided in this CPG is no longer applicable. Therefore, CPG Sec. 510.800 is being withdrawn.

CPG Sec. 540.420 entitled “Raw Breaded Shrimp—Microbiological Criteria for Evaluating Compliance with Current Good Manufacturing Practice Regulations” was first issued in August 1983. This CPG used data collected in fiscal year 1978 and listed an outdated sampling and compliance structure. The compliance criteria and the methodology used in the CPG have become outdated and are no longer useful. This CPG is superseded by the

Seafood Hazard Analysis Critical Control Point regulation in 21 CFR part 123. Seafood processors must prevent food safety hazards using critical controls and appropriate verification activities, such as end-product and in-process testing (21 CFR part 123). This CPG is also superseded by FDA's Fish and Fishery Products Hazards and Controls Guidance (Ref. 1), which describes controls for food safety hazards related to breaded shrimp. For these reasons, CPG Sec. 540.420 is now obsolete and is being withdrawn.

CPG 562.800 entitled "Vending Machine Food—Labeling" was first issued in September 1976. This CPG provided guidance for FDA staff and industry regarding certain mandatory label information for foods and beverages dispensed in vending machines after movement in interstate commerce.

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act of 2010 (ACA; Pub. L. 111–148) into law. Section 4205 of the ACA amended section 403(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(q)) and section 403A of the FD&C Act (21 U.S.C. 343–1), which governs Federal preemption of State and local food labeling requirements. Section 4205 of the ACA added section 403(q)(5)(H)(viii) to the FD&C Act to require that if an article of food is sold from a vending machine that (1) does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article or does not otherwise provide visible nutrition information at the point of purchase; and (2) is operated by a person who is engaged in the business of owning or operating 20 or more vending machines, then the vending machine operator must provide a sign in close proximity to each article of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the article of food.

In the **Federal Register** of December 1, 2014 (79 FR 71259), we issued a final rule to implement these labeling requirements; the regulations are codified at 21 CFR 101.8. With this regulatory change, CPG 562.800 is now obsolete and is being withdrawn.

## II. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>.

1. FDA, "Fish and Fishery Products Hazards and Controls Guidance, 4th Edition," June 2021.

Dated: February 9, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Public Comment Request HRSA Ryan White HIV/AIDS Program Part F AIDS Education and Training Center Program Evaluation Activities, OMB No. 0915–0281—Extension

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than April 18, 2022.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Samantha Miller, the acting HRSA Information Collection Clearance Officer at (301) 443–9094.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference, pursuant to the Paperwork Reduction Act of 1995.

*Information Collection Request Title:* HRSA AIDS Education and Training Center Evaluation Activities, OMB No. 0915–0281—Extension.

*Abstract:* The Ryan White HIV/AIDS Program's (RWHAP) AIDS Education and Training Center (AETC) Program,

authorized under Title XXVI of the Public Health Service Act, supports a network of regional and national centers that conduct targeted, multi-disciplinary education and training programs for health care providers treating people with HIV. The RWHAP AETC Program's purpose is to increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat, and medically manage people with HIV.

The RWHAP AETC Program recipients gather data on the training activities they conduct using two data collection instruments. The Event Record (ER) gathers information about each training activity including training programs, individual clinical consultations, group clinical consultations, and technical assistance events. Information on the people trained, the length of training, the content and level of the training and collaborations with other organizations is also collected. The Participant Information Form (PIF) collects information from each of the training participants, including demographics, profession, the types of HIV services they provide, and the characteristics of the patient population they serve. The RWHAP AETC Program recipients are required to report aggregated data on the training activities and trainees to HRSA once a year. HRSA is requesting an extension of the current ER and PIF with minor changes. To more accurately capture the length of a training event, RWHAP AETC trainers will be asked to report the event's end date in addition to the start date on the ER. Additionally, if an event was not supported by RWHAP AETC core funding, respondents will be able to skip three subsequent questions on the ER that are not applicable. Respondents will have the option to report multiple clinic and health professional program identification numbers to reflect multiple affiliations on the ER. Additional options were added for seven questions in the ER to allow for more complete responses (e.g., an "other" response option was added to two questions). In addition to changes on the ER, minor revisions were made to the response options for multiple questions on the PIF to improve clarity (e.g., "Substance Abuse" was changed to "Substance Use Disorder").

*Need and Proposed Use of the Information:* HRSA uses the data collected when conducting RWHAP AETC programmatic assessments to determine future program needs. These data allow HRSA to identify where gaps exist in training HIV professionals as well as to measure whether training