| | | |
|---|---|---|
| (79) | 1-(4-methoxyphenyl)-*N*-methylpropan-2-amine (other names: *para*-methoxymethamphetamine, PMMA), ..... | (1245) |

* * * * *

**Uttam Dhillon,**

*Acting Administrator.*

[FR Doc. 2020–09599 Filed 5–14–20; 8:45 am]

**BILLING CODE 4410–09–P**

## EXECUTIVE OFFICE OF THE PRESIDENT

### Office of National Drug Control Policy

### 21 CFR Part 1401

**RIN 3201–AA02**

### Criteria for Designation of Emerging Drug Threats in the United States

**AGENCY:** Office of National Drug Control Policy.

**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** The Office of National Drug Control Policy is announcing this Advance Notice of Proposed Rulemaking (ANPRM) and requests information relevant to criteria for designating and terminating the designation of emerging drug threats in the United States pursuant to the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). This ANPRM briefly summarizes the White House Office of National Drug Control Policy's (ONDCP) ongoing work in this area and describes the criteria that ONDCP is considering to monitor and identify emerging drug threats. The ANPRM invites interested parties to submit comments, data, and other pertinent information concerning ONDCP's development of proposed criteria for designating emerging drug threats and terminating such designations.

**DATES:** Send comments on or before June 30, 2020.

**ADDRESSES:** You may send comments, identified by RIN number 3201–AA02 and/or docket number ONDCP–2020–0001, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. See **SUPPLEMENTARY INFORMATION** for file formats and other information about electronic filing.
- *Email: OGC@ondcp.eop.gov,* Include docket number ONDCP–2020–0001 and/or RIN number 3201–AA02 in the subject line of the message.
- *Mail:* Executive Office of the President, Office of National Drug Control Policy, 1800 G Street NW, 9th Floor, Washington, DC 20006, Attn: Office of General Counsel.

*Instructions:* All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Questions concerning this ANPRM should be directed to Michael J. Passante, Acting General Counsel, Office of General Counsel, Office of National Drug Control Policy, Executive Office of the President, at *OGC@ondcp.eop.gov* (email) or (202) 395–6622 (voice).

**SUPPLEMENTARY INFORMATION:**

## I. Public Participation

ONDCP strongly recommends using electronic means for submitting comments. Due to COVID–19, comments submitted through conventional mail delivery services may not be received in a timely manner. To ensure proper handling, please reference RIN 3201–AA02 on your correspondence. The mailing address may be used for paper, disk, or CD–ROM submissions.

Interested persons are invited to submit written data, views, or arguments on all aspects of this ANPRM. All comments must be submitted in English, or accompanied by an English translation. Please note that all comments received are considered part of the public record and made available for public inspection at *www.regulations.gov.* Such information includes personally identifiable information (such as a person's name, address, or any other data that might personally identify that individual) that the commenter voluntarily submits.

If you want to submit personally identifiable information as part of your comment, but do not want it to be posted online, you must include the phrase ''PERSONALLY IDENTIFIABLE INFORMATION'' in the first paragraph of your comment and precisely and prominently identify the information for which you seek redaction.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment and precisely and prominently identify the confidential business information for which you seek redaction. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on *www.regulations.gov.* Personally identifiable information and confidential business information provided as set forth above will be placed in the agency's public docket file, but not posted online. To inspect the agency's public docket file in person, you must make an appointment with agency counsel. Please see the **FOR FURTHER INFORMATION CONTACT** paragraph above for the agency counsel's contact information specific to this rulemaking.

## II. Introduction

Through enacting Section 8218 of the SUPPORT Act, 21 U.S.C. 1708, Congress codified its intention for the Federal government to closely monitor emerging drug threats and to take action at the outset of a trend to prevent such threats from reaching levels seen during the opioid crisis. The SUPPORT Act requires ONDCP to promulgate standards for designating an emerging drug threat and terminating such a designation. 21 U.S.C. 1708(c). The SUPPORT Act created the Emerging Threats Committee consisting of representatives from National Drug Control Program Agencies and other agencies, representatives from State, local and Tribal governments, and representatives from other entities designated by the ONDCP Director. 21 U.S.C. 1708(b). The Emerging Threats Committee is responsible for, among other matters, monitoring evolving and emerging drug threats in the United States. One of the Committee's principal responsibilities is to develop and recommend criteria that ONDCP may use to designate and terminate the designation of emerging drug threats. 21 U.S.C. 1708(b)(6).

How best to monitor and identify emerging drug threats in the United States is a question with broad public health implications. Before proceeding, ONDCP intends to benefit from a full airing of the issues through the public comment process. ONDCP's objective is to develop criteria that will enable the United States to be proactive in identifying emerging drug threats and taking action to prevent such drug threats from becoming public health emergencies.

## III. ONDCP's Emerging Threats Activities

On May 21, 2019, ONDCP Director James W. Carroll announced the formation of the Emerging Threats Committee to identify and respond to emerging drug threats in the United States. The Committee consists of 13 representatives from Federal, state, local, and Tribal governments and members of non-governmental entities.

The Emerging Threats Committee first met on May 22, 2019, and had several subsequent in-person and telephonic meetings. One of the Committee's responsibilities was to develop standards/criteria that ONDCP may use to identify and designate emerging drug threats and to terminate the designation of such drug threats. In developing proposed standards, the Committee considered various data sources, health statistics, and other indicators that may signal emerging drug threats.

After careful deliberations and discussions, the Committee developed a set of 11 proposed criteria for designating emerging drug threats. The 11 criteria consist of:

(1) The identification of a new drug, class of drugs, or other substance that creates the potential to substantially harm or adversely affect the public.

(2) An increase in morbidity or mortality due to drug overdose.

(3) A new regional or national outbreak of overdoses or other significant health harms associated with a drug, class of drugs, or other substance.

(4) Increased emergency department visits, hospitalizations, or treatment admissions related to the use of a new or evolving drug, class of drugs, or other substance.

(5) An increase in polysubstance use and substance use disorders involving multiple substances.

(6) Increased reporting by health care providers of new or novel clinical illnesses by patients with suspected or known exposure to a drug, class of drugs, or other substance.

(7) An increase in individuals or cohorts (*e.g.,* a particular population or age group) diagnosed with substance use disorder.

(8) An increase in timely surveillance of drug use measures, either regionally or nationwide, that indicates a new or evolving outbreak of illicit drug use or an increase in substance use disorders.

(9) Increased discussion through online drug user sites regarding a new or evolving drug, class of drugs, or other substances.

(10) State, local, tribal, or Federal reports of seizures involving a new or evolving drug, class of drugs, or other substances.

(11) An increase in reports by law enforcement and fire department agencies using tools such as the Overdose Detection Mapping Application Program or other near real-time suspected overdose surveillance data systems.

The Emerging Threats Committee selected these 11 proposed criteria because the Committee believes that these criteria reflect the best available standards for detecting emerging drug threats. The Committee focused on establishing standards that were fairly broad, but with the understanding that a sliding scale would be necessary to determine whether a new drug threat needed to be designated or if an ongoing designated drug threat could be safely terminated such that it no longer requires intensive efforts to prevent it from growing into a public health crisis. The notion of a sliding scale was considered to be applicable for the individual criteria as well as for all 11 evaluated holistically. As the Committee formulated the criteria, they looked at the environment from which an emerging threat would most likely be identified at the earliest possible point given the negative public health and law enforcement impacts of the drug. For example, there is evidence that increases in morbidity and mortality due to drug overdoses and increased emergency department visits, hospitalizations, or treatment admissions related to the use of a new drug or substance are good indicators of emerging drug trends.

## IV. Request for Comments

ONDCP requests public comments to assist us in determining the best criteria for designating emerging drug threats and removing such designations. ONDCP also requests that interested parties submit any pertinent public health data not discussed in this ANPRM. We request comments on the following issues relating to the public health impact, the economic impact, and provisions that should be considered for inclusion in emerging drug threats criteria. Specifically, expert analysis and opinion as well as medical, scientific, economic, and technical data are sought on the following issues:

1. *Proposed Criteria:* ONDCP requests comments on whether the 11 proposed criteria listed in Section III of this ANPRM are useful criteria for identifying emerging threats. Should any of the 11 proposed criteria be modified or eliminated? Should other criteria be considered by ONDCP in designating emerging drug threats? In both cases, if so, please explain your rationale for making the recommendation. ONDCP is particularly interested in comments on the issue of how individual criteria should be evaluated to identify emerging drug threats. Should some criteria be given more weight than others? Should a combination of some, but not all, proposed criteria be sufficient to designate an emerging drug threat? ONDCP is also interested in whether the criteria that reference increased occurrences of specific conditions should be held to certain numerical or statistical thresholds. What metrics, if any, should be used for the criteria to evaluate whether an emerging drug threat exists?

2. *Significance of Threat:* How significant should the drug threat be before ONDCP initiates the process of designating an emerging threat? How should significance be determined with respect to assessing whether a drug trend rises to a level that warrants an emerging drug threat classification? Are there any data, such as medical records or clinical research that should be included in ONDCP's decision-making process? How should the danger of the drug threat be determined?

3. *Termination of Emerging Threat Designation:* The SUPPORT Act requires ONDCP to terminate an emerging drug threat designation after the circumstances that gave rise to the designation have been abated. ONDCP is interested in comments that address the point at which an emerging drug threat designation should be terminated. Should termination of the designation be linked to decreases in numerical or statistical benchmarks associated with use of the drug? What criteria should be used to evaluate whether the threat posed by a designated drug has declined to the point that it is no longer considered an emerging drug threat?

4. *Economic impact:* Issuing an emerging drug threat designation under the SUPPORT Act triggers a series of actions that ONDCP and other National Drug Control Program Agencies must take to mitigate the impact of the designated threat. The ONDCP Director is required to publish an Emerging Threat Response Plan within 90 days of the designation and must update the plan each year until the emerging drug threat designation is terminated. That plan is required to include a comprehensive assessment of the drug threat, goals to address the threat, and performance measures related to the plan's goals, among other requirements. 21 U.S.C. 1708(d). The ONDCP Emerging Threats Coordinator is required to facilitate information

sharing and coordination with relevant agencies and entities concerning the implementation or status of emerging threats, monitor implementation of Emerging Threat Response Plans, and coordinate the development and implementation of reporting systems to support performance measurement and adherence to the plan. Agencies identified in an Emerging Threat Response Plan are required to submit a report to the Coordinator on implementation of the plan within 180 days of designation. Upon making an emerging threats designation, the ONDCP Director is required to evaluate whether a media campaign to address the threat is appropriate. If the Director determines that a media campaign is warranted and enough appropriations are available for that purpose, the Director will conduct a national anti-drug media campaign in accordance with the requirements of 21 U.S.C. 1708(f). The Director must ensure that the media campaign is evidence-based and accurate, meets accepted standards for public awareness campaigns, and uses effective strategies.

ONDCP seeks comments about the relative costs and benefits of designating emerging drug threats and implementing response plans to address such threats. What activities would federal agencies, state, local and tribal governments, health care providers and other entities be required to incur as a result of an emerging drug threat designation, and what would those activities cost? What activities would federal agencies, state, local and tribal governments, health care providers and other entities take voluntarily as result of an emerging drug threat designation, and what would those activities cost? What benefits, such as lives saved and improved public health outcomes, would result from an emerging drug threat designation? Information submitted should include any negative or positive economic effects that could result from promulgation.

5. *Effectiveness of Alternative Approaches:* How can ONDCP best accomplish its goal of monitoring and identifying emerging drug threats in the United States? What other approaches to designating emerging drug threats should ONDCP consider in carrying out its responsibilities under the SUPPORT Act?

Interested parties are invited to submit comments on any or all of these and other pertinent issues related to the development of criteria for designating or terminating the designation of emerging drug threats. ONDCP appreciates any and all comments, but those most useful and likely to influence decisions on the proposed criteria will be those that are either informed by medical, public health, or law enforcement research on evidence-based methods for monitoring or identifying drug trends or involve personal experience with drug misuse and addiction.

## V. Statutory and Executive Order Review

This ANPRM has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review,'' section 1(b), The Principles of Regulation; Executive Order 13563, ''Improving Regulation and Regulatory Review,'' section 1(b), General Principles of Regulation; and Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs.'' The Office of Management and Budget (OMB) has determined that this ANPRM is a significant regulatory action under Executive Order 12866, section 3(f), and accordingly this ANPRM has been reviewed by OMB.

Pursuant to guidance issued by OMB, the requirements of E.O. 13771 do not apply to this ANPRM. This action does not propose or impose any requirements. ONDCP is merely collecting information and data on the possible economic impact that may occur as a direct or indirect result of promulgation of emerging drug threats criteria.

The requirements of the Regulatory Flexibility Act (RFA) do not apply to this action because, at this stage, it is an ANPRM and not ''rule'' as defined in 5 U.S.C. 601. Following review of the comments received in response to this ANPRM, when ONDCP decides to proceed with a notice of proposed rulemaking regarding this matter, ONDCP will conduct all relevant analyses as required by statute or Executive Order.

This ANPRM was prepared under the direction of James W. Carroll, Jr., Director, Office of National Drug Control Policy, 1800 G Street NW, 9th Floor, Washington, DC 20006. It is issued pursuant to section 8218(c) of the SUPPORT for Patients and Communities Act, 21 U.S.C. 1708(c).

**Michael J. Passante,**

*Acting General Counsel.*

[FR Doc. 2020–09469 Filed 5–14–20; 8:45 am]

**BILLING CODE 3280–F5–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Parts 1 and 301

**[REG–105495–19]**

**RIN 1545–BP21**

## Guidance Related to the Allocation and Apportionment of Deductions and Foreign Taxes, Financial Services Income, Foreign Tax Redeterminations, Foreign Tax Credit Disallowance Under Section 965(g), and Consolidated Groups; Correction

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking; correction.

**SUMMARY:** This document contains a correction to a notice of proposed rulemaking (REG–105495–19) that was published in the **Federal Register** on December 17, 2019. The proposed regulations provide guidance relating to the allocation and apportionment of deductions and creditable foreign taxes, the definition of financial services income, foreign tax redeterminations, availability of foreign tax credits under the transition tax, and the application of the foreign tax credit limitation to consolidated groups.

**DATES:** Written or electronic comments and requests for a public hearing were being accepted and must have been received by February 18, 2020. A telephonic public hearing has been scheduled for May 20, 2020.

**FOR FURTHER INFORMATION CONTACT:** Concerning the proposed regulations, Jeffrey P. Cowan, (202) 317–4924. Regarding the public hearing Regina Johnson at 202–317–5177 or email *publichearings@irs.gov.*

**SUPPLEMENTARY INFORMATION:**

### Background

The proposed regulations that are the subject of this correction are under section 861, 904, and 960 of the Internal Revenue Code.

### Need for Correction

As published, the notice of proposed rulemaking (REG–105495–19) contains errors which may prove to be misleading and need to be clarified.

### Correction of Publication

Accordingly, the notice of proposed rulemaking (REG–105495–19) that was the subject of FR Doc. 2019–24847, published at 84 FR 69124 (December 17, 2019), is corrected as follows:

1. On page 69130, third column, the last line of the first partial paragraph,