For the reasons set out above, DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11:
■ a. Redesignate paragraphs (b)(89) through (110) as (b)(92) through (113);
■ b. Redesignate paragraphs (b)(84) through (b)(88) as (b)(86) through (90);
■ c. Redesignate paragraphs (b)(83) as (b)(84); and
■ d. Add new paragraphs (b)(83), (b)(85), and (b)(91);

The additions to read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

* * * * * * *	
(83) *para*-bromofentanyl (*N*-(4-bromophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide)	9872
* * * * * * *	
(85) *para*-fluoroacetyl fentanyl (*N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide)	9874
* * * * * * *	
(91) *para*-methyl acetyl fentanyl (*N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide)	9875
* * * * * * *	

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Signing Authority

This document of the Drug Enforcement Administration was signed on June 2, 2025, by Acting Administrator Robert J. Murphy. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2025–10372 Filed 6–9–25; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA1146]

Schedules of Controlled Substances: Placement of 3-Methoxyphencyclidine (1-[1-(3-methoxyphenyl) cyclohexyl]piperidine) in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing 3-methoxyphencyclidine, including its salts, isomers, and salts of isomers, an arylcyclohexylamine hallucinogen, in schedule I of the Controlled Substances Act. This action is proposed to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle 3-methoxyphencyclidine.

DATES: Comments must be submitted electronically or postmarked on or before July 10, 2025. Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). The electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Requests for a hearing and waivers of an opportunity for a hearing or to participate in a hearing, together with a written statement of position on the matters of fact and law involved in the hearing, must be received on or before July 10, 2025.

ADDRESSES: Interested persons may file written comments on this rulemaking in accordance with 21 CFR 1308.43(g). To ensure proper handling of comments, please reference ''Docket No. DEA1146'' on all correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration (DEA) encourages commenters to submit all comments electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

• *Paper comments:* Paper comments that duplicate electronic submissions are not necessary. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

• *Hearing requests:* All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be filed with the DEA Administrator, who will make the determination of whether a hearing will be needed to address such matters of fact and law in the rulemaking. Such requests must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. For informational purposes, a courtesy copy of requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration,

Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249. As required by 5 U.S.C. 553(b)(4), a summary of this rule may be found in the docket for this rulemaking at *www.regulations.gov*.

SUPPLEMENTARY INFORMATION: In this proposed rule, the Drug Enforcement Administration (DEA) proposes to schedule 3-methoxyphencyclidine (1-[1-(3-methoxyphenyl)cyclohexyl] piperidine; 3-MeO-PCP) in schedule I of the Controlled Substances Act (CSA), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. DEA will make comments available for public inspection online at *https://www.regulations.gov*. Such information includes personal identifying information (such as your name, address, State or Federal identifiers, etc.) voluntarily submitted by the commenter. In general, all information voluntarily submitted by the commenter, unless clearly marked as Confidential Information in the method described below, will be publicly posted. Comments may be submitted anonymously. The Freedom of Information Act applies to all comments received.

Commenters submitting comments which include personal identifying information (PII), confidential, or proprietary business information that the commenter does not want made publicly available should submit two copies of the comment. One copy must be marked ''CONTAINS CONFIDENTIAL INFORMATION'' and should clearly identify all PII or business information the commenter does not want to be made publicly available, including any supplemental materials. DEA will review this copy, including the claimed PII and confidential business information, in its consideration of comments. The second copy should be marked ''TO BE PUBLICLY POSTED'' and must have all claimed confidential PII and business information already redacted. DEA will post only the redacted comment on *https://www.regulations.gov* for public inspection.

For easy reference, an electronic copy of this document and supplemental information to this proposed rule are available at *https://www.regulations.gov*.

Request for Hearing or Appearance; Waiver

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA).[1] Interested persons, as defined in 21 CFR 1300.01(b), may file requests for a hearing in conformity with the requirements of 21 CFR 1308.44(a) and 1316.47(a), and such requests must:

(1) state with particularity the interest of the person in the proceeding;

(2) state with particularity the objections or issues concerning which the person desires to be heard; and

(3) state briefly the position of the person with regard to the objections or issues.

Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(c), together with a written statement of position on the matters of fact and law involved in any hearing.[2]

All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to DEA using the address information provided above. The decision whether a hearing will be needed to address such matters of fact and law in the rulemaking will be made by the Administrator. If a hearing is needed, DEA will publish a notice of hearing on the proposed rulemaking in the **Federal Register**.[3] Further, once the Administrator determines a hearing is needed to address such matters of fact and law in rulemaking, he will then designate an Administrative Law Judge (ALJ) to preside over the hearing. The ALJ's functions shall commence upon designation, as provided in 21 CFR 1316.52.

In accordance with 21 U.S.C. 811 and 812, the purpose of a hearing would be to determine whether 3-MeO-PCP meets the statutory criteria for placement in schedule I.

Legal Authority

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on his own motion. 21 U.S.C. 811(a). This proposed action is supported by a recommendation from the then Assistant Secretary for Health of the Department of Health and Human Services (HHS).

In addition, the United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)–(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention indicating that a drug or other substance has been added to a schedule specified in the notification, the Secretary of HHS (Secretary),[4] after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.[5] In the event that the Secretary did not so consult with the Attorney General, and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) control. Pursuant to 21 U.S.C. 811(a)(1), the Attorney General (as delegated to the Administrator of DEA) may, by rule, add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed.

[1] 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D.

[2] 21 CFR 1316.49.

[3] 21 CFR 1308.44(b), 1316.53.

[4] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

[5] 21 U.S.C. 811(d)(3).

Background

3-Methoxyphencyclidine (1-[1-(3-methoxyphenyl)cyclohexyl]piperidine; 3-MeO-PCP) is an arylcyclohexylamine that has been identified in the United States' illicit drug market. It is a 3-methoxy derivative of phencyclidine (PCP; schedule II substance) and produces similar hallucinogenic effects as PCP. 3-MeO-PCP has no approved medical use in the United States.

On June 10, 2021, the Secretary-General of the United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs (CND), during its 64th Session in April 2021, voted to place 3-MeO-PCP in Schedule II of the 1971 Convention (CND Decision 64/4). As a signatory to this international treaty, the United States is required, by scheduling under the CSA, to place appropriate controls on 3-MeO-PCP to meet the minimum requirements of the treaty. The relevant treaty provisions and domestic statutes executing those provisions are below.

To begin, Article 2, paragraph 7(b), of the 1971 Convention sets forth the minimum requirements that the United States must meet when a substance has been added to Schedule II of the 1971 Convention. Pursuant to the 1971 Convention, the United States must require licenses for the manufacture, export and import, and distribution of 3-MeO-PCP. The CSA's registration requirement as set forth in 21 U.S.C. 822, 823, 957, and 958, as well as implementing regulations in 21 CFR parts 1301 and 1312, set forth this licensing requirement.

In addition, the United States must adhere to specific export and import provisions that are provided in the 1971 Convention. The CSA's export and import provisions established in 21 U.S.C. 952, 953, 957, and 958, and implemented in 21 CFR part 1312, execute these requirements.

Likewise, under Article 13, paragraphs 1 and 2, of the 1971 Convention, a party to the 1971 Convention may notify another party, through the UN Secretary-General, that it prohibits the importation of a substance in Schedule II, III, or IV of the 1971 Convention. If such notice is presented to the United States, the United States shall take measures to ensure that the named substance is not exported to the country of the notifying party. The CSA's above-mentioned export provisions set forth these procedures.

Further, under Article 16, paragraph 4, of the 1971 Convention, the United States is required to provide annual statistical reports to the International Narcotics Control Board (INCB). Using INCB Form P, the United States shall provide the following information: (1) In regard to each substance in Schedule I and II of the 1971 Convention, quantities manufactured, exported to and imported from each country or region as well as stocks held by manufacturers; (2) in regard to each substance in Schedule III and IV of the 1971 Convention, quantities manufactured, as well as quantities exported and imported; (3) in regard to each substance in Schedule II and III of the 1971 Convention, quantities used in the manufacture of exempt preparations; and (4) in regard to each substance in Schedule II–IV of the 1971 Convention, quantities used for the manufacture of non-psychotropic substances or products.

Lastly, under Article 2, paragraph 7(b)(vi) of the 1971 Convention, the United States must adopt measures in accordance with Article 22 to address violations of any statutes or regulations that are adopted pursuant to its obligations under the 1971 Convention. The United States complies with this provision, as persons acting outside the legal framework established by the CSA are subject to administrative, civil, and/or criminal action.

DEA notes that there are differences between the schedules of substances in the 1971 Convention and the CSA. The CSA has five schedules (schedules I–V) with specific criteria set forth for each schedule. Schedule I is the only possible schedule in which a drug or other substance may be placed if it has high potential for abuse and no currently accepted medical use in treatment in the United States. See 21 U.S.C. 812(b). In contrast, the 1971 Convention has four schedules (Schedules I–IV) but does not have specific criteria for each schedule. The 1971 Convention simply defines its four schedules, in Article 1, to mean the correspondingly numbered lists of psychotropic substances annexed to the Convention, and altered in accordance with Article 2.

Proposed Determination to Schedule 3-MeO-PCP

Pursuant to 21 U.S.C. 811(b), DEA gathered the necessary data on 3-MeO-PCP and on October 25, 2021, submitted it to the then Assistant Secretary for Health of HHS with a request for a scientific and medical evaluation of available information and a scheduling recommendation for 3-MeO-PCP. On November 15, 2022, HHS provided to DEA a scientific and medical evaluation entitled ''Basis for the Recommendation to Control 1-[1-(3-Methoxyphenyl)cyclohexyl]piperidine and its Salts in Schedule I of the Controlled Substances Act'' and a scheduling recommendation. Following consideration of the eight factors and findings related to these substances' abuse potential, legitimate medical use, and dependence liability, HHS recommended that 3-MeO-PCP and its salts be controlled in schedule I of the CSA under 21 U.S.C. 812(b).

In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS and all other relevant data, and completed its own eight-factor review pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by HHS and DEA in their respective eight-factor analyses, and as considered by DEA in this proposed scheduling determination. Please note that both the DEA and HHS analyses, including the evaluation of the eight factors determinative of control along with their supporting data and citations, are available in their entirety under ''Supporting Documents'' of the public docket for this proposed rule at *https://www.regulations.gov* under docket number ''DEA–1146.''

1. The Drug's Actual or Relative Potential for Abuse

In addition to considering the information HHS provided in its scientific and medical evaluation document for 3-MeO-PCP, DEA also considered all other relevant data regarding actual or relative potential for abuse of 3-MeO-PCP. The term ''abuse'' is not defined in the CSA; however, the legislative history of the CSA suggests the consideration of the following four criteria in determining whether a particular drug or substance has a potential for abuse: [6]

a. Individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or

b. There is a significant diversion of the drug or other substance from legitimate drug channels; or

c. Individuals are taking the drug or other substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such substance; or

d. The drug or substance is so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that it will have

[6] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., 2nd Sess. (1970) reprinted in 1970 U.S.C.C.A.N. 4566, 4603.

the same potential for abuse as such substance, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

DEA reviewed the scientific and medical evaluation provided by HHS and all other data relevant to the abuse potential of 3-MeO-PCP. These data as presented below demonstrate that 3-MeO-PCP has a high potential for abuse.

a. There is evidence that individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.

Data show that 3-MeO-PCP has been encountered by law enforcement in the United States (see Factor 5 below, discussing evidence of abuse in the United States), indicating 3-MeO-PCP is available for abuse. Non-fatal and fatal intoxications have been reported in the United States and Europe. The 2020 European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) [7] report on 3-MeO-PCP mentioned 19 cases of severe intoxication that resulted in hospitalization and 21 confirmed deaths (by analysis of postmortem biological samples). 3-MeO-PCP was determined to be the cause of death in at least seven of those cases (WHO, 2020). According to HHS, individuals are using 3-MeO-PCP for its hallucinogenic effects and taking it in amounts sufficient to create a hazard to their health.

b. There is significant diversion of the drug or substance from legitimate drug channels.

HHS states that 3-MeO-PCP is not a Food and Drug Administration (FDA)-approved drug for treatment in the United States and is unaware of any country in which its use is legal. 3-MeO-PCP is available for purchase from legitimate chemical synthesis companies because it is used in scientific research.

EMCDDA reported drug seizures of 3-MeO-PCP from 12 countries, including several European countries (Lithuania, Romania, Italy, Spain, Latvia, Austria, Slovenia, and France) and noted that 24 countries had the capability to detect 3-MeO-PCP in drug samples (WHO, 2020).

NFLIS-Drug [8] data reflects that 3-MeO-PCP is present in the U.S. drug market. DEA interprets this to mean that 3-MeO-PCP is being abused domestically as a recreational drug. From January 2011 to August 2024, NFLIS-Drug registered 399 reports from several states pertaining to the trafficking, distribution, and abuse of 3-MeO-PCP. These encounters of 3-MeO-PCP by law enforcement indicate that this substance is being trafficked in the United States.

c. Individuals are taking the substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such substance.

3-MeO-PCP is not an FDA-approved drug product and practitioners may neither legally prescribe nor dispense these substances. Therefore, it is inferred that individuals are taking 3-MeO-PCP on their own initiative, rather than based on medical advice from practitioners licensed by law to administer drugs. This is consistent with the data from law enforcement seizures and case reports, discussed in greater detail in Factor 5.

d. The drug or substance is so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that the drug or substance will have the same potential for abuse as such drugs, thus making it reasonable to assume that there may be significant diversion from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

3-MeO-PCP is a synthetic arylcyclohexylamine and is a 3-methoxy analogue of the abused drug phencyclidine (PCP; schedule II) and has pharmacological properties similar to other arylcyclohexylamines such as PCP and ketamine (schedule III). Both the DEA and the HHS analyses concluded that 3-MeO-PCP is being abused for its hallucinogenic effects.

PCP is a hallucinogen with a long history of abuse with clinical effects that include dissociation and euphoria. 3-MeO-PCP has a similar pharmacological profile to PCP, where the primary mechanism of action is thought to be on glutamatergic neurotransmission. Glutamate is the major excitatory neurotransmitter system in the brain. *In vitro* binding studies show that 3-MeO-PCP binds to the glutamatergic N-methyl-D-aspartate (NMDA) receptor and acts as an antagonist with higher potency compared to PCP (schedule II) and ketamine (schedule III). As a result, 3-MeO-PCP is expected to have a high abuse potential and pose a high risk to public health (HHS, 2022).

Due to the psychological and cognitive disturbances associated with 3-MeO-PCP, as with other similar schedule II and III hallucinogens noted above, it is reasonable to conclude that 3-MeO-PCP has substantial capability to be a hazard to the health of the user and to the safety of the community.

2. Scientific Evidence of the Drug's Pharmacological Effects, If Known

3-MeO-PCP is a novel psychoactive substance with a mechanism of action similar to PCP that produces psychopharmacological effects similar to other dissociative amnestic drugs such as PCP and ketamine. Based on non-clinical *in vitro* studies, 3-MeO-PCP has higher affinity for the NMDA receptor and acts as an antagonist, suggesting it may have greater potency than PCP or ketamine. 3-MeO-PCP also interacts with monoamine transmission through binding at the serotonin transporter and increasing serotonin transmission. Non-clinical *in vivo* studies show 3-MeO-PCP acts as a NMDA receptor antagonist through the Maximal Electroshock Seizure (MES) test and substitutes for PCP in drug discrimination. Although no clinical studies have been performed for 3-MeO-PCP, case reports show that the effects of 3-MeO-PCP are similar to abuse of or intoxication with PCP.

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

3-MeO-PCP is a centrally-acting hallucinogen that is part of the arylcyclohexylamine hallucinogen family and shares structural similarities with schedule II and III phenethylamine hallucinogens such as PCP and ketamine. 3-MeO-PCP (Chemical Abstracts Service Registry Number 72242–03–6) has a molecular formula of $C_{18}H_{27}NO$ and a molecular weight of 273.41 g/mol. The half-life of 3-MeO-PCP is estimated to be 10–11 hours. 3-MeO-PCP undergoes extensive metabolism, such that at least 30 phase I and II metabolites can be generated. Globally, there have been at least 19 cases of severe intoxication that required hospitalization and 21 deaths, where 3-MeO-PCP was identified in the blood of the decedent. In at least seven

[7] The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) is an agency of the European Union tasked with gathering and analyzing data of drug trends.

[8] NFLIS-Drug represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle more than 96% of an estimated 1 million distinct annual state and local drug analysis cases. NFLIS includes drug chemistry results only from completed analyses. Although NFLIS-Drug data are not direct evidence of abuse, they can lead to an inference that a drug has been diverted and abused. See 76 FR 77330, 77332 (Dec. 12, 2011). NFLIS-Drug data was queried on September 6, 2024.

of those deaths, 3-MeO-PCP was listed as the cause of death. HHS notes that in many of the cases reported by the WHO, other drugs of abuse were also identified clouding the direct toxicity of 3-MeO-PCP, and there is not sufficient information otherwise available to provide specific toxicity information regarding 3-MeO-PCP since its usage was primarily with other substances or lacking poly substance use information.

4. Its History and Current Pattern of Abuse

3-MeO-PCP is a relatively new drug in the drug abuse and drug trafficking setting, and thus, there is relatively little information related to its history and pattern of abuse. The World Health Organization (WHO) reports that 3-MeO-PCP has been available in Europe since 2010. Distribution and trafficking of 3-MeO-PCP began increasing in 2011 (WHO, 2020). The history and current pattern of abuse of 3-MeO-PCP is described in law enforcement reports and anecdotal reports by drug abusers. In the United States, law enforcement entities initially encountered 3-MeO-PCP in 2011, according to the National Forensic Laboratory Information System (NFLIS)-Drug [9] database. See Factor 5 for additional information.

HHS noted that since 3-MeO-PCP is an analogue of PCP with similar mechanisms of action, the extensive history and pattern of PCP abuse may be appropriate to inform on the potential pattern of abuse of 3-MeO-PCP. The 2011 Substance Abuse and Mental Health Services Administration reported 75,538 emergency department visits related to PCP use. The 2011 National Survey on Drug Use and Health data showed that 6.1 million Americans, 12 years or older, reported using PCP in their lifetime. A case series study conducted at a tertiary care center reported patients with PCP intoxication tended to be young males who presented with signs and symptoms of retrograde amnesia, nystagmus, hypertension, and agitation. Coadministration with other substances was common (*e.g.,* benzodiazepines, alcohol, marijuana, cocaine).

5. The Scope, Duration, and Significance of Abuse

3-MeO-PCP has pharmacological effects similar to the schedule II hallucinogen PCP (with higher potency) and has no currently accepted medical use in the United States or anywhere in the world. HHS states (2022) it is not associated with an investigational new drug application or an approved new drug application.

In the United States, evidence of abuse of 3-MeO-PCP initially appeared in 2011, one year later than was reported by the EMCDDA. Since then, reports of worldwide abuse have increased substantially. According to the WHO Critical Review Report published in 2020, 15 countries reported that 3-MeO-PCP was being used by individuals for its psychoactive properties. The WHO document also reported a total of 314 drug seizures from 2018–2020. Within the United States, from January 2011 to August 2024, there were 399 exhibits reported to the NFLIS-Drug database, which show evidence of trafficking, distribution, and abuse of 3-MeO-PCP in 33 states.

Case reports and case series of abuse and deaths associated with 3-MeO-PCP have been published globally. 3-MeO-PCP is typically abused orally and by insufflation (sniffing or snorting), but has also been reported to be smoked, inhaled, or vaporized. It is often used with other substances (*e.g.,* benzodiazepines, cannabinoids). Clinical effects from 3-MeO-PCP are similar to other abused arylcyclohexylamines hallucinogens (*e.g.,* PCP) and include confusion, dissociation, hallucinations, sedation through agitation, disinhibition, euphoria, cognitive changes, sensory changes, motor changes, and cardiovascular effects (*e.g.,* hypertension and tachycardia).

Abuse of 3-MeO-PCP has been characterized as causing acute public health and safety issues worldwide. The WHO reported that 3-MeO-PCP has been available in Europe since 2010. Based on available abuse data, public health risk, and drug trafficking data, the WHO recommended to the United Nations (UN) that 3-MeO-PCP be controlled internationally. In April 2021, the UN Commission on Narcotic Drugs voted to place 3-MeO-PCP into Schedule II of the 1971 Convention.

6. What, if Any, Risk There Is to the Public Health

3-MeO-PCP shares similar mechanisms of action with and produces similar physiological and subjective effects (see Factor 2 for more information) as other schedule II and III hallucinogens, such as PCP and ketamine. Thus, 3-MeO-PCP poses the same risks to public health as similar hallucinogens. Predominantly, the risks to public health are borne by users (*i.e.,* hallucinogenic effects, sensory distortion, impaired judgement, strange or dangerous behaviors), but they can affect the general public, as with driving under the influence. There have been reports of distressing responses and death associated with 3-MeO-PCP in medical literature, many of which, but not all, report poly-substance use. Adverse events associated with 3-MeO-PCP have been reported and include, but not limited to, hypertension, confusion, dissociation, hallucinations, tachycardia, nystagmus, respiratory acidosis, hypothermia, coma, and death. The 2020 review published by the WHO noted at least 19 cases of severe intoxications occurred after use of 3-MeO-PCP that required hospitalization and 21 deaths were reported where 3-MeO-PCP was confirmed in blood samples. At least seven of those deaths were attributed to 3-MeO-PCP as the cause of death. Thus, based on the review of both HHS and DEA, serious adverse events that may include death represent a risk to the individual drug users and to public health.

7. Its Psychic or Physiological Dependence Liability

HHS noted that a study with 4-MeO-PCP (a structural isomer) does produce rewarding (conditioned place preference) and reinforcing effects (self-administration) through activation of the mesolimbic dopamine reward pathway in rats. Therefore, HHS concluded that it is likely that 3-MeO-PCP produces similar effects in rats. The only literature available on human exposure to 3-MeO-PCP is based on case study reports, two of which indicate long-term use of 3-MeO-PCP.

[9] NFLIS-Drug is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States. NFLIS-Drug data were queried on September 6, 2024.

HHS noted that no studies have evaluated the dependence potential of 3-MeO-PCP. However, 3-MeO-PCP has similar pharmacological properties of PCP (schedule II) and ketamine (schedule III), which do have well-demonstrated dependence potential. Thus, the HHS and DEA reviews both concluded that it is probable that 3-MeO-PCP has a dependence profile similar to these known substances.

8. Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA

3-MeO-PCP is not an immediate precursor of any controlled substance of the CSA as defined by 21 U.S.C. 802(23).

Conclusion

Based on consideration of the scientific and medical evaluation and accompanying recommendation of HHS, and on DEA's own eight-factor analysis, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of 3-MeO-PCP. As such, DEA proposes to schedule 3-MeO-PCP as a controlled substance under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule, per 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all other available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 812(b)(1), finds that:

(1) *3-MeO-PCP has a high potential for abuse.*

3-MeO-PCP is a synthetic arylcyclohexylamine, chemically related and pharmacologically similar to the ethylamine analog of phencyclidine (PCE; schedule I), the thiophene analog of phencyclidine (TCP; schedule I), phencyclidine (PCP, schedule II), and ketamine (schedule III). 3-MeO-PCP, similar to PCP and ketamine, produces dissociative anesthetic and hallucinogenic effects.

3-MeO-PCP has a pharmacological profile similar to other arylcyclohexylamines, such as PCP (schedule II) and ketamine (schedule III). Binding studies demonstrate a similar mechanism of action (*i.e.,* NMDA receptor antagonism) and case reports indicate that 3-MeO-PCP clinically resembles PCP intoxication (*i.e.,* hallucinogenic effects). Little evidence exists regarding 3-MeO-PCP direct psychic or physiologic dependence liability; 3-MeO-PCP fully substituted for PCP in drug discrimination studies. However, it can be assumed from the above evidence (Factor 7) that 3-MeO-PCP has a physical dependence liability similar to these controlled substances, with evidence of dependence potential.

(2) 3-MeO-PCP has no currently accepted medical use in treatment in the United States.

3-MeO-PCP is not legally marketed in the United States, as the FDA has not approved a marketing application for a drug product containing 3-MeO-PCP for any indication. As noted in the HHS review, 3-MeO-PCP lacks current marketing approval under a new drug application or an abbreviated new drug application, and is not subject to an investigational new drug application. There is no evidence that 3-MeO-PCP has a currently accepted medical use in treatment in the United States.[10]

[10] To place a drug or other substance in schedule I under the CSA, DEA must consider whether the substance has a currently accepted medical use in treatment in the United States. 21 U.S.C. 812(b)(1)(B). There is no evidence suggesting that 3-MeO-PCP has a currently accepted medical use in treatment in the United States. To determine whether a drug or other substance has a currently accepted medical use, DEA has traditionally applied a five-part test to a drug that has not been approved by FDA: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. Marijuana Scheduling Petition; Denial of Petition; Remand, 57 FR 10499 (Mar. 26, 1992), pet. for rev. denied, Alliance for Cannabis Therapeutics v. Drug Enforcement Admin., 15 F.3d 1131, 1135 (D.C. Cir. 1994). DEA and HHS applied the traditional five-part test for currently accepted medical use in this matter. In a recent published letter in a different context, HHS applied an additional two-part test to determine currently accepted medical use for substances that do not satisfy the five-part test: (1) whether there exists widespread, current experience with medical use of the substance by licensed health care practitioners operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which the part 1 is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that HHS's two-part test would be sufficient to establish that a drug has a currently accepted medical use. Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana at 3 (April 11, 2024). For purposes of this proposed rule, there is no evidence that health care providers have widespread experience with medical use of 3-MeO-PCP, or that the use of 3-MeO-PCP is recognized by entities that regulate the practice of medicine under either the traditional five-part test or the two-part test.

(3) *There is a lack of accepted safety for use of 3-MeO-PCP under medical supervision.*

Because 3-MeO-PCP has no approved medical use and has not been thoroughly investigated as a new drug, its safety for use under medical supervision is not determined. Thus, there is a lack of accepted safety for use of this substance under medical supervision.

Based on these findings, the Acting Administrator of DEA concludes that 3-MeO-PCP warrants control in schedule I of the CSA. More precisely, because of its hallucinogenic effects, and because it may produce hallucinogenic-like dependence in humans, DEA proposes to place 3-MeO-PCP, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical description, in 21 CFR 1308.11(d) (the hallucinogenic substances category of schedule I).

Requirements for Handling 3-MeO-PCP

If this rule is finalized as proposed, 3-MeO-PCP would be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. Registration. Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) 3-MeO-PCP would need to be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. Security. 3-MeO-PCP would be subject to schedule I security requirements, and handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling this substance also would need to comply with the screening requirements of 21 CFR 1301.90–1301.93.

3. Labeling and Packaging. All labels and packaging for commercial containers of 3-MeO-PCP would need to comply with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

4. Quota. Only registered manufacturers would be permitted to manufacture 3-MeO-PCP in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. Inventory. Any person registered with DEA to handle 3-MeO-PCP would need to have an initial inventory of all

stocks of controlled substances (including this substance) on hand on the effective date of a final scheduling action pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant would need to take a new inventory of all stocks of controlled substances (including 3-MeO-PCP) on hand every two years pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. Records and Reports. Every DEA registrant would need to maintain records and submit reports with respect to 3-MeO-PCP, pursuant to 21 U.S.C. 827 and 832(a), and in accordance with 21 CFR 1301.74 and 1301.76, and parts 1304, 1312, and 1317.

7. Order Forms. Every DEA registrant who distributes 3-MeO-PCP would need to comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

8. Importation and Exportation. All importation and exportation of 3-MeO-PCP would need to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. Liability. Any activity involving 3-MeO-PCP not authorized by, or in violation of, the CSA or its implementing regulations would be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563, and 14192 (Regulatory Review)

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563. DEA scheduling actions are not subject to E.O. 14192, Unleashing Prosperity Through Deregulation.

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Paperwork Reduction Act

This proposed rule would not impose a new collection or modify an existing collection of information under the Paperwork Reduction Act of 1995. Also, this proposed rule would not impose new or modify existing recordkeeping or reporting requirements on state or local governments, individuals, businesses, or organizations. However, this proposed rule would require compliance with the following existing OMB collections: 1117–0003, 1117–0004, 1117–0006, 1117–0008, 1117–0009, 1117–0010, 1117–0012, 1117–0014, 1117–0021, 1117–0023, 1117–0029, and 1117–0056. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this proposed rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA proposes placing the substance 3-MeO-PCP (chemical name: 1-[1-(3-methoxyphenyl)cyclohexyl]piperidine), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, in schedule I of the CSA. This action is being taken, in part, to enable the United States to meet its obligations under the 1971 Convention. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle or propose to handle 3-MeO-PCP.

The entities affected by this rule include the manufacturers, distributors, importers, exporters, and researchers of 3-MeO-PCP. DEA determined the North American Industry Classification System (NAICS) industries that best represent these business activities. Table 1 lists the business activities and corresponding NAICS industries.[11]

TABLE 1—BUSINESS ACTIVITY AND CORRESPONDING NAICS INDUSTRIES

Business activity	NAICS code	NAICS industry description
Manufacturer	325412	Pharmaceutical Preparation Manufacturing.
Distributor, Importer, Exporter	424210	Drugs and Druggists' Sundries Merchant Wholesalers.
	424690	Other Chemical and Allied Products Merchant Wholesalers.
Researcher	541715	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology).
	611310	Colleges, Universities and Professional Schools.

From Statistics of U.S. Businesses (SUSB) data, DEA determined the number of firms and small firms for each of the affected industries, and by comparing the number of affected small entities to the number of small entities

[11] Executive Office of the President Office of Management and Budget, North American Industry Classification System, United States, 2022, *https://www.census.gov/naics/reference_files_tools/2022_NAICS_Manual.pdf.* (Accessed 4/2/2024).

for each industry, DEA determined whether a substantial number of small entities are affected in any of the industries. Table 2 lists the number of firms, small firms, and percent small firms in each affected industry.

TABLE 2—PERCENT SMALL ENTITIES BY INDUSTRY

NAICS industry	Firms [12]	SBA size standard [13]	Small firms [14]	Percent small entities (%)
325412—Pharmaceutical Preparation Manufacturing	1,007	1,300	931	92.4
424210—Drugs and Druggists' Sundries Merchant Wholesalers	6,958	250	6,663	95.8
424690—Other Chemical and Allied Products Merchant Wholesalers	6,069	175	5,781	95.3
541715—Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)	8,019	1,000	7,571	94.4
611310—Colleges, Universities and Professional Schools	2,433	$34.5	1,515	62.3

Based on the American Chemical Society's SciFinder database, DEA identified 13 entities supplying 3-MeO-PCP across these industries. Suppliers include 325412, 424210, and 424690 industries. Even if all affected suppliers were small entities, they would account for only 0.10 percent of the small entities in those industries, not a substantial number.[15] Additionally, DEA expects the number of researchers working with 3-MeO-PCP is small because 3-MeO-PCP lacks current marketing approval under a new drug application or an abbreviated new drug application, and is not subject to an investigational new drug application as noted in the HHS review. Also, DEA believes the researchers working with 3-MeO-PCP may also work with other controlled substances; hence, they have probably already registered with DEA and are qualified to handle controlled substances. For these reasons DEA believes the number of affected researchers that are small entities is not a substantial number of small entities in 541715 and 622310 industries.

The primary costs associated with this proposed rule would be the annual registration fee for Schedule I controlled substances ($3,699 for manufacturers, $1,850 for distributors, and $296 for researchers). As mentioned above, DEA has identified 13 domestic suppliers of 3-MeO-PCP from the SciFinder database and none of these suppliers has registered with DEA to handle Schedule I controlled substances. However, it is common for suppliers to have items in their catalog while not actually having any material level of sales because FDA has not approved a marketing application for a drug product containing 3-MeO-PCP. Therefore, some suppliers may simply remove 3-MeO-PCP from their catalog without any impact. Additionally, as discussed above, the researchers who work with 3-MeO-PCP are likely to work with other controlled substances and hence, must already register with DEA.

In summary, the small entities impacted by this rule are those in 325412-Pharmaceutical Preparation Manufacturing, 424210-Drugs and Druggists' Sundries Merchant Wholesalers, and 424690-Other Chemical and Allied Products Merchant Wholesalers. The affected small entities account for only 0.1 percent of the small businesses and are not likely to manufacture or carry 3-MeO-PCP inventory. As such, the proposed rule will not, if promulgated, result in a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the ''Regulatory Flexibility Act'' section above, DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*) that this proposed action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year''. Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is proposed to be amended to read as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraph (d)(105) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

*	*	*	*	*	*	*
(105) 3-methoxyphencyclidine (Other names: 1-[1-(3-methoxyphenyl)cyclohexyl] piperidine; 3-MeO-PCP)						7457
*	*	*	*	*	*	*

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on June 3, 2025, by Acting Administrator Robert J. Murphy. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in

[12] Statistics of U.S. Businesses, 2021 SUSB Annual Data Tables by Establishment Industry, *https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html* (Accessed 4/2/2024).

[13] U.S. Small Business Administration, Table of size standards, Version March 2023, Effective: March 17, 2023, *https://www.sba.gov/sites/sbagov/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023_.xlsx*. (Accessed 4/2/2024).

[14] Note 12.

[15] 13/(931 + 6,664 + 5,781) = 0.10%.

compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2025–10503 Filed 6–9–25; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[FXES1111090FEDR–256–FF09E21000]

Endangered and Threatened Wildlife and Plants; Two Species Not Warranted for Listing as Endangered or Threatened Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notification of findings.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce findings that two species are not warranted for listing as endangered or threatened species under the Endangered Species Act of 1973, as amended (Act). After a thorough review of the best available scientific and commercial information, we find that it is not warranted at this time to list the cannulate cave isopod (*Pseudobaicalasellus cannula*) and Dry Fork Valley cave beetle (*Pseudanophthalmus montanus*). However, we ask the public to submit to us at any time any new information relevant to the status of any of the species mentioned above or their habitats.

DATES: The findings in this document were made on June 10, 2025.

ADDRESSES: Detailed descriptions of the bases for these findings are available on the internet at *https://www.regulations.gov* under the following docket numbers:

Species	Docket No.
Cannulate cave isopod	FWS–R5–ES–2025–0035.
Dry Fork Valley cave beetle	FWS–R5–ES–2025–0036.

Those descriptions are also available by contacting the appropriate person, as specified under **FOR FURTHER INFORMATION CONTACT**. Please submit any new information, materials, comments, or questions concerning these findings to the appropriate person, as specified under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Jennifer Norris, Field Supervisor, West Virginia Field Office, 304–866–3858, *Jennifer_L_Norris@fws.gov*. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Background

Under section 4(b)(3)(B) of the Act (16 U.S.C. 1533(b)(3)(B)), we are required to make a finding on whether or not a petitioned action is warranted within 12 months after receiving any petition that we have determined contains substantial scientific or commercial information indicating that the petitioned action may be warranted (''12-month finding''). We must make a finding that the petitioned action is: (1) not warranted; (2) warranted; or (3) warranted, but precluded by other listing activity. We must publish a notification of these 12-month findings in the **Federal Register**.

Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations at part 424 of title 50 of the Code of Federal Regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Lists of Endangered and Threatened Wildlife and Plants (Lists). The Act defines ''species'' as including any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature. The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range (16 U.S.C. 1532(6)) and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(20)). Under section 4(a)(1) of the Act, the Secretary of the Interior (Secretary) may determine whether any species is an endangered species or a threatened species because of any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself. However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the species' expected response and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an