

*consistent with the FAA's safety and security responsibilities, including a statement as to the circumstances under which, and a summary of why, withholding such information from disclosure would not be consistent with the FAA's safety and security responsibilities, as described in 14 CFR 193.9.*

The FAA finds that withholding VDRP information provided to the FAA is consistent with the FAA's safety responsibilities. The VDRP specifically provides that appropriate corrective action must be taken by the regulated entity for all instances of regulatory noncompliance accepted under the program. To be accepted by the FAA, apparent violations disclosed under the program must be inadvertent, and, where applicable, must not indicate a lack, or reasonable question of a lack, of qualification of the regulated entity. Corrective action under the VDRP can be accomplished by the regulated entity and verified by the FAA without disclosure of the protected information. If the FAA determines that the steps taken by the entity are not those documented in the written report, the submission may be excluded from the VDRP, and appropriate legal enforcement action may be initiated.

The FAA will release information submitted under a VDRP as specified in part 193 and this proposed order. To explain the need for changes in FAA policies, procedures, and regulations, the FAA may disclose de-identified (*i.e.*, the identity of the source of the information and the names of the certificate holder, employees, and other persons, as well as any other information that could be used to ascertain the identity of the submitter, redacted) summary information that has been extracted from submissions accepted under the VDRP. The FAA may disclose de-identified, summarized VDRP information that identifies a systemic problem in the aviation system, when other persons need to be advised of the problem so that they can take corrective action. The FAA may disclose de-identified aggregate statistical information concerning VDRP submissions. The FAA may disclose independently obtained information relating to any event disclosed in a VDRP report. The FAA also may disclose any information about a disclosure initially submitted under the VDRP that is not accepted, or accepted, but later excluded because of the regulated entity's failure to comply with the criteria of the VDRP.

(6) *Summary of how the FAA will distinguish information protected under*

*part 193 from information the FAA receives from other sources.*

In accordance with AC 00-58, all VDRP submissions must be clearly identified as such by the regulated entity making the submission. Any other information received by the FAA from the regulated entity concerning the content of a VDRP submission must be clearly labeled as follows to be eligible for protection under this designation: "WARNING: The Information in this Document is Protected from Disclosure under 49 U.S.C. 40123 and 14 CFR part 193." If the information is submitted electronically, the warning notice must be appropriately embedded in the electronic submission in a fashion that assures the visibility of the warning to any viewer.

#### **Proposed Designation**

Accordingly, the Federal Aviation Administration proposes to designate the above-described information submitted under a VDRP to be protected under 49 U.S.C. 40123 and 14 CFR part 193.

Issued in Washington, DC, on May 17, 2006.

**John M. Allen,**

*Acting Director, Flight Standards Service.*

[FR Doc. E6-8078 Filed 5-24-06; 8:45 am]

**BILLING CODE 4910-13-P**

## **DEPARTMENT OF JUSTICE**

### **Drug Enforcement Administration**

#### **21 CFR Part 1300**

**[Docket No. DEA-260P]**

**RIN 1117-AA94**

#### **Definition of "Positional Isomer" as It Pertains to the Control of Schedule I Controlled Substances**

**AGENCY:** Drug Enforcement Administration (DEA), U.S. Department of Justice.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Controlled Substances Act (CSA) and its implementing regulations specify which hallucinogenic substances are considered Schedule I controlled substances. The CSA states that all salts, isomers and salts of isomers of these substances are also Schedule I controlled substances. In non-technical terms, an isomer of a substance is a different compound, but a compound which has the same number and kind of atoms. The terms "optical isomer" and "geometric isomer" are specific scientific terms and it is easy to

determine whether one substance is an optical or geometric isomer of another. The term "positional isomer," however, is subject to scientific interpretation.

This Notice of Proposed Rulemaking proposes the addition of a specific definition for the term "positional isomer" to allow for the systematic determination of which isomers of Schedule I substances would be considered to be "positional" and, therefore subject to Schedule I control.

The addition of a definition for the term "positional isomer" will assist legitimate research and industry in determining the control status of materials that are "positional isomers" of Schedule I hallucinogens. While the DEA will remain the authority for ultimately determining the control status of a given material, providing a specific definition for "positional isomer" will ensure consistent criteria are utilized in making these determinations.

This rule is relevant only to specialized forensic or research chemists. Most of these individuals are existing DEA registrants who are authorized by the DEA to handle Schedule I hallucinogenic substances.

**DATES:** Written comments must be postmarked, and electronic comments must be sent, on or before July 24, 2006.

**ADDRESSES:** To ensure proper handling of comments, please reference "Docket No. DEA-260P" on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to the DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be directly sent to the DEA electronically by sending an electronic message to [dea.diversion.policy@usdoj.gov](mailto:dea.diversion.policy@usdoj.gov). An electronic copy of this document is also available at the <http://www.regulations.gov> Web site. The DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. The DEA will not accept any file format other than those specifically listed here.

**FOR FURTHER INFORMATION CONTACT:** Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration,

Washington, DC 20537 at (202) 307-7183.

#### SUPPLEMENTARY INFORMATION:

##### Background

In many instances, the control of a substance under the CSA often includes the specific substance listed under the CSA, as well as the substance's salts, isomers and/or salts of isomers. In most instances, the term isomer includes only optical isomers. In other instances, however, the term isomer includes positional and/or geometric isomers.

In non-technical terms, isomers are different compounds that have the same molecular formula (the same number and types of atoms). The terms "optical isomer" and "geometric isomer" are specifically defined and well understood scientific terms, and it is easy to determine whether one substance is an optical or geometric isomer of another. The term "positional isomer," however, is not universally defined and, therefore, is subject to scientific interpretation. In order to ensure that consistent criteria are utilized in determining whether one substance is considered a "positional isomer" of another, the DEA is proposing that a specific definition for "positional isomer" be added to 21 CFR 1300.01(b)(21).

##### Existing CSA and CFR References to "Positional Isomers"

The CSA and its implementing regulations (21 CFR 1308.11(d)) specify which hallucinogenic substances are considered Schedule I controlled substances. Under the CSA and its implementing regulations, there are only three references to the term "positional isomer":

(1) Pursuant to 21 U.S.C. 802(14), "the term 'isomer' means the optical isomer, except as used in Schedule I(c) and Schedule II(a)(4). As used in Schedule I(c), the term "isomer" means any optical, positional, or geometric isomer. As used in Schedule II(a)(4), the term "isomer" means any optical or geometric isomer."

(2) Under 21 CFR 1300.01(b)(21), "The term "isomer" means the optical isomer, except as used in §§ 1308.11(d) and 1308.12(b)(4) of this chapter. As used in § 1308.11(d) of this chapter, the term "isomer" means the optical, positional, or geometric isomer. As used in § 1308.12(b)(4) of this chapter, the term "isomer" means the optical or geometric isomer."

(3) 21 CFR 1308.11(d) states, "Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material,

compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of 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 (for purposes of this paragraph only, the term "isomer" includes the optical, positional and geometric isomers)."

##### Why Proposed Definition Is Needed

The CSA (21 U.S.C. 802(14) and 21 U.S.C. 812(c)(I)(c)) and its implementing regulations (21 CFR 1308.11(d)) specify which hallucinogenic substances are considered Schedule I controlled substances. The CSA further states that all salts, isomers and salts of isomers of these substances are also Schedule I controlled substances.

Under the definition of "isomer" found in 21 CFR 1300.01(b)(21), "The term "isomer" means the optical isomer, except as used in §§ 1308.11(d) and 1308.12(b)(4) of this chapter. As used in § 1308.11(d) of this chapter, the term "isomer" means the optical, positional, or geometric isomer. As used in § 1308.12(b)(4) of this chapter, the term "isomer" means the optical or geometric isomer."

Therefore, according to this definition as it specifically applies to hallucinogens, the term "isomer" includes all optical, positional, or geometric isomers. As such, all salts, isomers (including optical, positional, or geometric isomers) and salts of isomers (including optical, positional, or geometric isomers) of the hallucinogenic substances listed in 21 U.S.C. 812(c)(I)(c) and 21 CFR 1308.11(d) are considered Schedule I controlled substances.

Because the determination as to whether a substance is considered a "positional isomer" can be subject to scientific interpretation, the DEA believes it is necessary to specifically define the term "positional isomer". This definition will only pertain to those substances that are "positional isomers" of Schedule I controlled substances pursuant to 21 U.S.C. 812(c)(I)(c) and 21 CFR 1308.11(d).

The DEA is not proposing the addition of definitions for either optical or geometric isomers. The DEA believes that these terms are highly specific and are not subject to differing scientific interpretation.

##### Proposed Criteria That Will Apply to Positional Isomers

Pursuant to 21 U.S.C. 802(14), 21 U.S.C. 812(c)(I)(c) and 21 CFR 1308.11(d) positional isomers of

Schedule I hallucinogens are any and all substances which:

(1) Are not already controlled in a different Schedule I category, or are listed in another Schedule, or are specifically exempted from control by law; and

(2) Have the same molecular formula and core structure as a Schedule I hallucinogen; and

(3) Have the same functional group(s) and/or substituent(s) as those found in the respective Schedule I hallucinogen, attached at any position(s) on the core structure, but in such manner that no new chemical functionalities are created and no existing chemical functionalities are destroyed relative to the respective Schedule I hallucinogen; except that

(4) Rearrangements of alkyl moieties within or between functional group(s) or substituent(s), or divisions or combinations of alkyl moieties, that do not create new chemical functionalities or destroy existing chemical functionalities, would be within the definition of positional isomer (and therefore be controlled).

As clarification, note that the "core structure" is the parent molecule that is the common basis for the class; for example, tryptamine, phenethylamine, or ergoline. The following are examples of rearrangements resulting in creation and/or destruction of chemical functionalities. These rearrangements result in compounds which are not positional isomers: ethoxy to *alpha*-hydroxyethyl, hydroxy and methyl to methoxy, or the repositioning of a phenolic or alcoholic hydroxy group to create a hydroxyamine. Examples of rearrangements resulting in compounds which would be positional isomers include, but are not limited to: *tert*-butyl to *sec*-butyl, methoxy and ethyl to isopropoxy, N,N-diethyl to N-methyl-N-propyl, or *alpha*-methylamino to N-methylamino.

##### Impact of Rule Limited to Specialized Forensic or Research Chemists

The addition of a definition for the term "positional isomer" as it applies to 21 CFR 1308.11(d) will assist legitimate research and industry in determining the control status of substances that are isomers of Schedule I hallucinogens. While the DEA will remain the authority on ultimately determining the control status of a given substance, providing a specific definition for "positional isomer" will greatly reduce any potential confusion or inconsistencies in making these determinations.

This definition will enable researchers and industry to determine definitively whether a substance is a

“positional isomer” of a Schedule I hallucinogen. As such, they will be able to know the control status of a particular substance when considering new research.

This rule is relevant only to specialized forensic or research chemists. Most of these individuals are existing DEA registrants who are authorized by the DEA to handle Schedule I hallucinogenic substances.

#### **Specific Changes and Proposed Definition**

As currently defined in 21 CFR 1300.01(b)(21), the term “isomer” means the optical isomer, except as used in § 1308.11(d) and § 1308.12(b)(4) of this chapter. As used in § 1308.11(d) of this chapter, the term “isomer” means any optical, positional, or geometric isomer. As used in § 1308.12(b)(4) of this chapter, the term “isomer” means any optical or geometric isomer.

Title 21 CFR 1300.01(b)(21) is proposed to be revised to include a specific definition for the term “positional isomer”. The proposed modification will specify that, as used in § 1308.11(d), the term “positional isomer” means any substance possessing the same molecular formula and core structure and has the same functional group(s) and/or substituent(s) as those found in the respective Schedule I hallucinogen, attached at any position(s) on the core structure, but in such manner that no new chemical functionalities are created and no existing chemical functionalities are destroyed relative to the respective Schedule I hallucinogen.

Rearrangements of alkyl moieties within or between functional group(s) or substituent(s), or divisions or combinations of alkyl moieties, that do not create new chemical functionalities or destroy existing chemical functionalities, would be within the definition of positional isomer. For purposes of this definition, the “core structure” is the parent molecule that is the common basis for the class. Some examples would include tryptamine, phenethylamine, or ergoline. Examples of non-permissible rearrangements resulting in creation and/or destruction of chemical functionalities (and therefore would not be considered positional isomers) include, but are not limited to: ethoxy to *alpha*-hydroxyethyl, hydroxy and methyl to methoxy, or the repositioning of a phenolic or alcoholic hydroxy group to create a hydroxyamine. Examples of permissible rearrangements (that are within the definition of positional isomers) include: *tert*-butyl to *sec*-butyl,

methoxy and ethyl to isopropoxy, N,N-diethyl to N-methyl-N-propyl, or *alpha*-methylamino to N-methylamino.

#### **Scientific/Technical Nature of Proposed Definition**

The DEA understands that the proposed definition is highly technical and laden with scientific terms. However, the DEA believes that such a highly technical definition is necessary to ensure that consistent criteria are utilized in determining whether one substance is a “positional isomer” of another.

#### **Request for Comments**

The proposed definition of “positional isomer” will be used in the determination of the control status of substances as Schedule I controlled substances pursuant to 21 CFR 1308.11(d). This definition is highly technical in nature and the DEA has sought to provide specific criteria for determination as to whether a substance is a “positional isomer” of Schedule I hallucinogens. The DEA welcomes input from all interested parties regarding the proposed definition of “positional isomer.” Prior to publication of a Final Rule, the DEA will consider all comments received. Comments must be submitted on or before July 24, 2006.

#### **Regulatory Certifications**

##### *Regulatory Flexibility Act*

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. The inclusion of the definition of positional isomer set forth herein is unlikely to subject any new substances to CSA control. Also, this rule does not require the obtaining of new DEA registrations. Most persons affected by this rule are already DEA registrants (or would have to become registrants even absent this rule in order to handle Schedule I hallucinogens.) Further, this rule does not impose any additional regulatory burden on the regulated community. The proposed change simply will ensure that consistent criteria are utilized in making scheduling determinations.

#### **Executive Order 12866**

The Deputy Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 section 1(b). The DEA has determined that this is not a significant regulatory

action. Therefore, this action has not been reviewed by the Office of Management and Budget.

#### **Executive Order 12988**

This regulation meets the applicable standards set forth in §§ 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

#### **Executive Order 13132**

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

#### **Unfunded Mandates Reform Act of 1995**

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$117,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

#### **Small Business Regulatory Enforcement Fairness Act of 1996**

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$114,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

#### **List of Subjects in 21 CFR Part 1300**

Controlled substances, Definitions, Drug traffic control.

For the reasons set out above, 21 CFR part 1300 is proposed to be amended as follows:

#### **PART 1300—DEFINITIONS [AMENDED]**

1. The authority citation for part 1300 continues to read as follows:

**Authority:** 21 U.S.C. 802, 871(b), 951, 958(f).

2. § 1300.01 is proposed to be amended by revising paragraph (b)(21) to read as follows:

**§ 1300.01 Definitions relating to controlled substances.**

\* \* \* \*

(b) \* \* \*

(21)(i) The term *isomer* means the optical isomer, except as used in § 1308.11(d) and § 1308.12(b)(4) of this chapter. As used in § 1308.11(d) of this chapter, the term “isomer” means any optical, positional, or geometric isomer. As used in § 1308.12(b)(4) of this chapter, the term “isomer” means any optical or geometric isomer.

(ii) As used in § 1308.11(d) of this chapter, the term “positional isomer” means any substance possessing the same molecular formula and core structure and having the same functional group(s) and/or substituent(s) as those found in the respective Schedule I hallucinogen, attached at any position(s) on the core structure, but in such manner that no new chemical functionalities are created and no existing chemical functionalities are destroyed relative to the respective Schedule I hallucinogen. Rearrangements of alkyl moieties within or between functional group(s) or substituent(s), or divisions or combinations of alkyl moieties, that do not create new chemical functionalities or destroy existing chemical functionalities, are allowed i.e., result in compounds which are positional isomers. For purposes of this definition, the “core structure” is the parent molecule that is the common basis for the class; for example, tryptamine, phenethylamine, or ergoline. Examples of rearrangements resulting in creation and/or destruction of chemical functionalities (and therefore resulting in compounds which are not positional isomers) include, but are not limited to: ethoxy to *alpha*-hydroxyethyl, hydroxy and methyl to methoxy, or the repositioning of a phenolic or alcoholic hydroxy group to create a hydroxylamine. Examples of rearrangements resulting in compounds which would be positional isomers include: *tert*-butyl to *sec*-butyl, methoxy and ethyl to isopropoxy, N,N-diethyl to N-methyl-N-propyl, or *alpha*-methylamino to N-methylamino.

\* \* \* \*

Dated: May 17, 2006.

**Michele M. Leonhart,**  
Deputy Administrator.

[FR Doc. E6-7979 Filed 5-24-06; 8:45 am]

BILLING CODE 4410-09-P

**DEPARTMENT OF TRANSPORTATION****Federal Highway Administration****23 CFR Parts 630, 635 and 636**

[FHWA Docket No. FHWA-2005-22477]

RIN 2125-AF12

**Design-Build Contracting**

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM); request for comments.

**SUMMARY:** The FHWA proposes to revise its regulations for design-build contracting as mandated by section 1503 of the “Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users” (SAFETEA-LU). The primary revision would involve a statutory requirement that FHWA not preclude State transportation departments or local transportation agencies from issuing request-for-proposal documents, awarding contracts, and issuing notices-to-proceed for preliminary design work prior to the conclusion of the National Environmental Policy Act (NEPA) process. The FHWA also proposes to revise certain provisions in 23 CFR part 636 to facilitate the use of public-private partnerships.

**DATES:** Comments must be received on or before July 24, 2006.

**ADDRESSES:** Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room PL-401, 400 Seventh Street, SW., Washington, DC 20590-0001, or submit electronically at <http://dmses.dot.gov/submit> or fax comments to (202) 493-2251.

Alternatively, comments may be submitted via the eRulemaking Portal at <http://www.regulations.gov>. All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically. Anyone is able to search the electronic form on all documents received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act

Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70, Pages 19477-78) or you may visit <http://dms.dot.gov>.

**FOR FURTHER INFORMATION CONTACT:** Mr. Gerald Yakowenko, Office of Program Administration, (202) 366-1562, or Mr. Michael Harkins, Office of the Chief Counsel, (202) 366-4928, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:****Electronic Access**

You may submit or retrieve comments online through the Document Management System (DMS) at: <http://dmses.dot.gov/submit>. The DMS is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the Web site. An electronic copy of this document may also be downloaded by using the internet to reach the Office of the Federal Register's home page at: <http://www.archives.gov> or the Government Printing Office's Web page at: <http://www.access.gpo.gov/nara>.

**Background**

Section 1503 of the SAFETEA-LU (Pub. L. 109-59; August 10, 2005, 119 Stat. 1144) revises the definition of a design-build “qualified project” in 23 U.S.C. 112(b)(3). Formerly, “qualified projects” included design-build projects approved by FHWA with total costs estimated to exceed \$50,000,000 or intelligent transportation system projects exceeding \$5,000,000. This statutory definition limited Federal-aid participation to design-build projects that met this monetary threshold. The revision required by Section 1503 removes the monetary threshold and defines a qualified project as “\* \* \* a project under this chapter (including intermodal projects) for which the Secretary has approved the use of design-build contracting under criteria specified in regulations issued by the Secretary.” These regulations are found in 23 CFR part 636. Thus, it is no longer necessary for the FHWA to approve design-build projects exceeding certain dollar thresholds under Special Experimental Project No. 14 (SEP-14).<sup>1</sup> When appropriate, the FHWA will continue to make SEP-14 available for

<sup>1</sup> Information concerning Special Experimental Project No. 14 (SEP-14), “Innovative Contracting Practices,” is available on FHWA's home page: <http://www.fhwa.dot.gov>. Additional information may be obtained from the FHWA Division Administrator in each State.