REQUEST FOR INFORMATION
Drug Enforcement Administration
Diversion Control Division

THIS IS A REQUEST FOR INFORMATION ANNOUNCEMENT ONLY. This is not a solicitation and is issued solely for information, planning purposes and market research only. It does not constitute a Request for Proposal (RFP) or a promise to issue an RFP. This RFI does not commit the Government to contract for any supply or service. The Drug Enforcement Administration (DEA) is not at this time seeking proposals. The purpose of this RFI is to seek industry information about existing contractors that can provide the service stated in the Statement of Work (SOW).

The DEA consistently seeks to obtain information and comments from industry that will provide the agency with insight into market conditions and/or scientific advances that will aid in the refinements of requirements and the formation of an acquisition strategy for in vivo rodent testing to determine abuse potential of new and emerging drugs. This RFI is designed to conduct market research to determine the current level of availability in the current market. The DEA is interested in obtaining information from contractors that can meet the requirements in the SOW. Small businesses are encouraged to respond to this RFI in order to assist the DEA in determining the potential level of interest, adequate competition, and technical capability of the Small Business community to fulfill this requirement. However, responses to this RFI are solicited from all interested parties.

Not responding to this RFI does not preclude participation in any future RFP, if any is issued. If a solicitation is released, it will be synopsized on the Federal Business Opportunities (FedBizOpps) website. It is the responsibility of the potential offers' to monitor these sites for additional information pertaining to this requirement.

Responses

Interested parties are requested to respond to this RFI with a white paper.

Section 1 of the white paper shall provide administrative information, and shall include the following as a minimum:

Company name; mailing address; physical address; point of contact(s); telephone number, fax number; email address; Federal Tax Identification Number, DUNS number; NAICS code; company business size (if small indicate type); and GSA schedule number (if applicable), and must be registered in Systems for Award Management (www.SAMS.gov) to be considered for this requirement.

A corporate, institution or company capability statement between one and five pages that includes relevant experience within the last three years. Relevant experience is defined as

possessing the experience described in the SOW. The capability statement should include a detailed description of similar tests/studies performed with other government agencies.

A representative sample of contracts your firm was awarded to provide the requirements as described in this notice within the past three years. For each contract listed include the type of contract; total estimated value; contract period of performance (e.g., base and number of option periods); customer (i.e. federal agency) and respective point of contact (e.g., point of contact's name, phone number, and email address).

The Government encourages creativity and innovation in responses to the RFI. The North American Industry Classification System (NAICS) code applicable to this requirement is 621511. Any questions about this RFI should be submitted in writing to Jacqueline Schottler no later than April 16, 2018, 10:00 a.m. local Eastern Daylight Time. Answers to general questions will be provided under an amendment to the RFI and posted on FBO. Answers to vendor specific questions will be provided directly to vendor. Interested parties are requested to submit the above requested information (Capabilities Statements) via email directly to Jacqueline.P.Schottler@usdoj.gov no later than May 11, 2018 10:00 a.m. local Eastern Daylight Time. Any responses received after the closing date will not be considered. No literature will be returned to responding sources and each source is solely responsible for all expenses associated with submitting their literature. All information will be kept confidential and will not be disseminated to the public. This sources sought synopsis neither constitutes a Request for Proposal (RFP), nor does it restrict the Government to an ultimate acquisition approach. This synopsis should not be construed as a commitment by the Government for any purpose. Request for a solicitation will not receive a response.

Section 2 of the white paper shall answer the requirements listed in the SOW.

Statement of Work

Evaluation of Abuse Potential Using *In Vivo* Pharmacological Studies

I. Background

The Drug Enforcement Administration's (DEA) Diversion Control Division (DC), Drug and Chemical Evaluation Section (DRE) is responsible for evaluating drugs and chemicals to determine whether these substances have abuse potential. These evaluations are used by DEA to support its domestic scheduling activities. In order for DEA to determine the abuse potential of drugs and chemicals, pharmacological, medical, epidemiological, and other scientific data for these drugs, when necessary, are needed to initiate the administrative procedure to place these substances under regulatory control according to the guidelines of the Controlled Substances Act (CSA).

Recently, numerous novel psychoactive substances (NPS) to include synthetic cannabinoids, synthetic cathinones, synthetic opioids, other stimulants, depressants or hallucinogens have emerged within the United States and poses significant risk to the public safety. Numerous NPS have been identified in samples submitted to federal, state and local forensic laboratories. There have been reports of overdoses, including fatalities, associated with the abuse of numerous NPS. In response to the associated public health threat with the abuse of NPS, the Administrator of the DEA has placed several NPS in Schedule I of the CSA under a temporary scheduling order to avoid an imminent hazard to the public safety. Preliminary studies (*in vitro*) have shown that these NPS share pharmacological similarities with other known drugs of abuse. However, detailed information on their biological and pharmacological activities is limited.

II. Brief description of work

For this project, unless otherwise specified by the DEA representative, the vendor shall purchase the reference drugs and all test substances approved by the DEA for testing. The DEA will provide the test substances otherwise not commercially available to the potential vendor for the requested testing. Most of these substances are Schedule I substances. Therefore, the vendor should already have a Schedule I researcher registration with DEA. The vendor shall conduct appropriate preclinical studies such as locomotor activity study, analgesia study, cannabinoid tetrad study, and drug discrimination evaluation on these substances in comparison to appropriate controls and reference standard substances. The reference training drugs shall include, but not be limited to, DOM (2,5-dimethoxy-4-methylamphetamine), LSD (lysergic acid diethylamide), DMT (*N*,*N*-dimethyltryptamine), methamphetamine, MDMA (3,4-methylenedioxymethamphetamine), , THC (Δ^9-tetrahydrocannabinol), morphine, fentanyl, and other drugs as directed by the DEA representative. Each substance shall be assessed for its abuse potential by using appropriate studies in rodents. The vendor will provide the DEA with investigational study results and a description of the methodology used to conduct the investigation in the form of a study report based on the timeline specified in this statement of work (SOW), if not earlier. If a report on all requested studies cannot be provided by the

specified timelines, a letter stating the anticipated date of completion of investigations and anticipated delivery of a study report will be required prior to that date. The vendor will evaluate up to a maximum of 20 new psychoactive substances (NPS) during the first year of the agreement. The number of test substances will be renegotiated yearly between DEA and the potential vendor. Final study conditions, including but not limited to the number of rodent, or the strain of rodent used, shall be subject to approval of the DEA representative.

III. Specific requirements

Task 1. Drug source, storage and recordkeeping.

Unless otherwise specified by the DEA representative (if it is determined that the test substance is not commercially available), the vendor shall purchase the reference and test drugs. The vendor shall conduct a preclinical evaluation of these test substances (as specified in tasks listed below) in comparison to appropriate controls and the appropriate reference standard. Pharmacological evaluation of each test substance shall be done using appropriate *in vivo* assays as approved by DEA.

The vendor shall maintain electronic and paper copies of a chronological log of the test substance receipt and evaluation using Microsoft Excel spreadsheet software.
When each substance is received, shall be made: (1) the test substance's name; (2) the source of the test substance (if it is a purchased or a standard substance); (3) the date testing of the test substance was authorized; (4) the date the test substance was received (If provided by the DEA); (5) the amount of test substance received (if provided by the DEA); (6) pharmacological studies authorized by DEA for the test substance (e.g. locomotor activity, analgesia, drug discrimination,); (7) the date when the study began for each authorized study; (8) the amount of test substance used for each authorized study; (9) the date when the study was completed for each authorized study; and (10) the date when the report was sent to the DEA. This cumulative Receipt and Evaluation log shall be kept up to date and forwarded to the DEA representative upon request.

All test substances are in Schedule I of the Controlled Substances Act (CSA). Therefore, it is required that the test substances be stored under Schedule I requirements as specified by the CSA and that vendor evaluating the test substances shall be registered with the DEA as a Schedule I researcher. All reference drugs are in Schedule II of the CSA. Therefore appropriate DEA license and storage requirement shall be maintained. In cases where test substances are not Schedule I, drug storage requirements shall be maintained under Good Laboratory Practices (GLP) or GLP-like conditions.

Task 2. Protocols of *in vivo* pharmacological studies (locomotor activity, analgesia, cannabinoid tetrad and drug discrimination) in laboratory rodent animals

General protocols that are used for *in vivo* locomotor activity, analgesia, tetrad, and drug discrimination studies and standard operating procedures (SOP) shall be provided by the vendor to the DEA. The protocols shall contain a description of the methodology used to conduct the investigation, a description of the apparatuses that will be used for conducting the studies,

maintenance of the animals to be used in the tests, procedures for analysis of the data including proposed statistical methods, and proposed presentations of the data and study results. Specifically, the study protocol should conform to the following standards:

I. A study protocol shall be provided for each individual *in vivo* pharmacological study. For example, one protocol should be provided for locomotor activity, one protocol for analgesia study, one protocol for cannabinoid tetrad, and one protocol for drug discrimination study.
II. The study protocols must be specifically written to meet the protocol preferences as listed in this SOW under Tasks 3, 4, 5, 6, and 7.
III. The study protocol should closely follow the format of the materials and methods section that would be submitted for a peer-reviewed journal article. Details including the animal strain, number of animal, animal care, experimental design, data analysis including statistical methods and generation of results (e.g. ED_{50} and 95% confidence limit values, repeated measures ANOVA as appropriate) shall be included.
IV. The study protocol shall include examples of how data will be presented. For example, representative dose-response curves, tables, and statistical analyses should be included. This information can be taken from previously published studies. However, this information should be included in a section as part of the study protocol and shall not be submitted as a separate file, but the data should be cited (i.e. submitting the example paper with the study protocol would not be considered acceptable).
V. Signature lines shall be included on each study protocol. Upon approval of the protocol by DEA and the vendor, the protocol will be signed by each representative. The original signed document will remain with DEA. A copy of the signed protocol will be provided to the vendor. The signed protocols will serve as an official record.

The preferred laboratory rodent animal will be the rat for the drug discrimination study and the mouse for locomotor activity and cannabinoid tetrad study. Depending on the analgesia assay, mice and/or rats may be considered based on the species that is typically used for the specific analgesia assay. If alternative rodent animal species or alternate species are selected, the vendor will provide to the DEA a comprehensive rationale for selecting a different animal species. The DEA and the vendor shall agree on the strain of rodent to be used for each of the studies. Each test substance evaluation shall entail at least two independent replications. Final pharmacological assay conditions for evaluation of all test substances shall be subject to the approval of the DEA representative.

Following receipt of the standard protocols by the DEA representative, a phone conversation may be scheduled to discuss the study protocols and SOPs. Any significant deviations or modifications from the protocol by the vendor must be authorized by DEA. The vendor must provide a modified protocol (e.g., change in time points, change in vehicle used, modification needed based on a specific test substance, etc.), the amended or modified protocol must be submitted in writing to the DEA representative for review and approval. The DEA representative must approve work with each new assay modifications.

Task 3. Evaluation of test substances in the *in vivo* locomotor activity study

Using the general protocol and SOPs agreed to by the vendor and DEA in Task 2, the vendor shall, as specified by the DEA representative, evaluate standard (reference) and/or test substances using the *in vivo* locomotor activity assay. The goal of this *in vivo* pharmacological study (locomotor activity study) is to identify parameters to include but not limited to onset of action, time to peak effect, duration of action, and dose effect response before conducting other tests for the fentanyl-related substances. Locomotor activity assays shall be conducted in mice unless otherwise agreed upon by both the DEA and vendor.

Briefly, locomotor activity study will be conducted in an automated activity monitoring device each housed within a sound-attenuating chamber that provides dim illumination. Prior to testing, mice will be injected via appropriate route with either vehicle or reference substances or test substance and immediately placed in the chamber for locomotor activity monitoring. In all studies, horizontal activity (interruption of photocell beams) will be measured for 360 min within 5-min periods. Testing shall be conducted with one mouse per activity chamber.

Experimental groups for evaluating each test substance should consist of appropriate number of doses (three experimental doses at a minimum) using a pharmacologically- effective dose range to generate a dose response curve, and a statistically appropriate number of animals per group (at least 8 animals). Appropriate controls shall be used. For each active test substance, ED50 (50% effective dose) and 95% confidence limit values shall be calculated. Data on dose-response curves shall also be presented and reported. The mean horizontal activity counts/5 min for this 30-min period shall fit to a linear function of log10 dose of the descending portion of the dose-effect curve.

In the event that any experimental issues arise (e.g. inability to dissolve test compound, unexpected results, animal lethality), the vendor shall immediately notify the DEA representative, in writing (email) with the issue and if the issue was resolved. Based on the issue noted by the vendor, the DEA representative may schedule a phone conversation or respond by email. All experimental issues that arise and the resolutions shall be documented in writing even if the issue and resolutions are discussed in a phone conversation.

The vendor shall provide monthly progress reports to the DEA representative in writing. The progress reports shall contain, but not be limited to, 1) substance evaluated, 2) brief description of results (ED_{50}), 3) substance to be evaluated, 4) doses to be evaluated and any other relevant information.

Following completion of the *in vivo* locomotor activity study for each test substance, the results in the form described in Task 1 (e.g. ED50 and 95% confidence limit values, dose response curves) shall be provided to the DEA representative for review and acceptance. The DEA representative may contact the vendor if there are any notable issues with the results.

Task 4. Evaluation of test substances in *in vivo* analgesic effects

The goal of this *in vivo* pharmacological study is to understand whether administration of test substances can result in analgesic effect. Using the general protocol and SOPs agreed to by the vendor and DEA in Task 2, the vendor shall, as specified by the DEA representative, evaluate

standard (reference) and/or test substances using the agreed upon *in vivo* analgesia assays. Analgesia assays shall be conducted in mice or rats unless otherwise agreed upon by both the DEA and vendor. The vendor shall follow the DEA-approved *in vivo* analgesia protocol for conducting these studies.

Briefly, to evaluate analgesic effects, experimental groups for evaluating each test substance shall consist of appropriate number of doses and statistically appropriate number of animals per group. Data from the proposed experiments shall be summarized in terms of ED_{50} (median effective dose; a dose producing the analgesic effect by 50%). Dose response curves from the studies shall also be included. Reference drugs shall be included in the proposed study. ED_{50} values may be presented as mean ± SEM. A 95% confidence interval or an equivalent data reporting measurement should be calculated from the dose-response curves. A statistical analysis of data collected from all tests for comparing different treatment groups with vehicle control should be performed and the resulting data should be presented. To determine the receptor mediated effect, the analgesic effect of these compounds shall be evaluated in the presence of appropriate dose(s) of standard receptor antagonist(s).

The vendor shall have the equipment available for analgesia testing procedures for the warm-water tail assay. Additionally, it is encouraged to use dosing methods, such as cumulative dosing, and having multiple and/or automated apparatus for evaluating the analgesic effects to increase efficiency of completing the experiments. All reference drugs and test drugs shall be purchased by the vendor. The vendor shall provide monthly progress reports to the DEA representative in writing. The progress reports shall contain, but not be limited to, 1) substance evaluated, 2) brief description of results (ED_{50}), 3) substance to be evaluated, 4) doses to be evaluated and any other relevant information.

In the event that any experimental issues arise (e.g. inability to dissolve test compound, unexpected results, animal lethality), the vendor shall immediately notify the DEA representative, in writing (email) with the issue and if it was resolved. Based on the issue noted by the vendor, the DEA representative may schedule a phone conversation or respond by email. All experimental issues that arise and the resolutions shall be documented in writing even if the issue and resolutions are discussed in a phone conversation.

Task 5. Evaluation of test substances in the *in vivo* cannabinoid tetrad testing battery.

The goal of this study is to evaluate the effects of test substances on antinociception, body temperature, spontaneous locomotor activity, and catalepsy. Using the general protocol and SOPs with agreement of the vendor and DEA in Task 2, the investigators shall, as specified by the DEA representative, evaluate standard (reference) and/or test substances using the agreed upon *in vivo* tetrad testing battery. The *in vivo* tetrad testing battery shall be conducted in mice unless otherwise agreed upon by both the DEA and vendor. Test substances selected for the tetrad test battery shall not be included as a test substance in Tasks 3 and 4 (*in vivo* locomotor activity test and *in vivo* analgesia test) unless otherwise specified by the DEA representative.

Selection of the positive and/or negative control, if required, for each test substance selected for the tetrad testing battery shall be specified by DEA to vendor. Experimental groups for evaluating each test substance should consist of appropriate number of doses (three experimental doses at a minimum), using a pharmacologically-effective dose range to generate a dose response curve, and a statistically appropriate number of animals per group (at least 8 animals). Appropriate controls shall be used. For each active test substance, ED50 (50% effective dose) and 95% confidence limit values shall be calculated. Data on dose-response curves shall also be presented and reported. Following completion of testing each test substance, the results in the form described in Task 6(b) (e.g. ED_{50} and 95% confidence limit values, dose response curves) shall be provided to the DEA representative for review and acceptance. The DEA representative may contact the vendor if there are any notable issues with the results.

The vendor shall provide monthly progress reports to the DEA representative in writing. The progress reports shall contain, but not be limited to, 1) substance evaluated, 2) brief description of results (ED_{50}), 3) substance to be evaluated, 4) doses to be evaluated and any other relevant information.

In the event that any experimental issues arise (e.g. inability to dissolve test compound, unexpected results, animal lethality), the vendor shall immediately notify the DEA representative, in writing (email) with the issue and if it was resolved. Based on the issue noted by the vendor, the DEA representative may schedule a phone conversation or respond by email. All experimental issues that arise and the resolutions shall be documented in writing even if the issue and resolutions are discussed in a phone conversation

Task 6. Evaluation of test substances in *in vivo* drug discrimination assay

The goal of this *in vivo* pharmacological study is to understand whether the test substances can be substituted for the discriminative-stimulus effects produced by a known drug of abuse. Using the general protocol and SOPs agreed to by the vendor and DEA in Task 2, the vendor shall, as specified by the DEA representative, evaluate standard (reference) and/or test substances using the *in vivo* drug discrimination assay. Drug discrimination studies shall be conducted in rats unless otherwise agreed upon by both the DEA and vendor. The vendor shall maintain groups of animals (rats) trained to discriminate the stimulus effects of a given reference drug from its vehicle during each year of the agreement.

Briefly, one group of rats should be trained to discriminate between saline (vehicle) and training drug. The vendor will determine the appropriate doses to administer to the trained rats using their preferred method of choice and will use this information to also determine an appropriate time point to commence discriminative stimulus testing (e.g. 10 minutes after dosing). Rats should be trained up to a fixed response rate between FR 10 to 20 and have an accurate response rate of at least 85% or greater. Dose-effect curves (DECs) for each test substance (fentanyl-related substance) shall be generated from paired lever response data (e.g., a pharmacologically-effective dose range from a minimal effect (less than 20%) to an optimal effect (maximal effect greater than 80 %) to generate a dose response curve) and analyzed using standard regression techniques to derive ED50 values (50% effective dose in the DEC) with 95% confidence limits

(95% CL). Each fentanyl-related substance shall be evaluated using an appropriate number of doses (at least 3 doses), an appropriate dose range to generate a DEC, and a statistically appropriate number of animals per group (N≥8 animals per dose group).

It is expected that drug discrimination training for the animals commence within a week after the protocol is approved. The vendor shall have the equipment available for drug discrimination testing procedures such that the experiments can be conducted in a relatively expedient manner for this assay. Additionally, it is encouraged to have multiple and/or automated apparatus for evaluating the discriminative stimulus effects in order to increase efficiency of completing the experiments. Reference substance and test substance shall be purchased by the vendor. The DEA will provide a test substance that is not commercially available.

In the event that any experimental issues arise (e.g. inability to dissolve test compound, unexpected results, animal lethality), the vendor shall immediately notify the DEA representative, in writing (email) with the issue and if the issue was resolved. Based on the issue noted by the vendor, the DEA representative may schedule a phone conversation or respond by email. All experimental issues that arise and the resolutions shall be documented in writing even if the issue and resolutions are discussed in a phone conversation.

The vendor shall provide monthly progress reports to the DEA representative in writing. The progress reports shall contain, but not be limited to, 1) substance evaluated, 2) brief description of results (ED_{50}), 3) substance to be evaluated, 4) doses to be evaluated and any other relevant information.

Task 7. Data presentation

The data organized in tables shall be provided to the DEA representative. Information should include, but not be limited to: (1) name of substance; (2) *in vivo* assay tested; (3) date(s) of study; (4) animal species used and source; (5) route(s) of administration, vehicle, and doses used; (6) number of animals per group; (7) observed effect at each selected dose level; and (8) calculated ED50 and 95 % confidence interval values. For instances where there is insufficient information to provide the specified information in the table, vendor will document the rationale in the table. This recordkeeping of the data and results is separate from the recordkeeping of the test substance as listed in Task 1 and also is separate from the reporting of study results listed in Tasks 3-5. The summarized data ("cumulative data table") shall be forwarded monthly to the DEA representative. The vendor and DEA will ensure all electronic information is accessible to individuals with disabilities in accordance with Section 508 of the Rehabilitation Act (29 U .S.C. 794d), as amended in 1998.

Task 8. Final study report for each fentanyl-related substance

Following completion of the experiments in Task 3, 4, 5 and 6, a final study report containing the complete methodology, data analysis, and study results for each test substance shall be provided in electronic format to the DEA.

1) **Technical Progress Reports:** the preparation and submission of regularly recurring Technical Progress Reports will be required for this agreement. These reports shall require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined by DEA Representative.

i) Quarterly: On or before the 5th working day following each quarter, the vendor shall submit one electronic copy in pdf format of a report on activities during the 3 months period. In the report, vendor shall include: all substances evaluation reports completed during the 3 months period; a table, or set of tables, of all substances tested in the contract, with the main results so far, and entries for the substances next in line for testing.

ii) Substance Evaluation Reports: For each substance evaluation test which is completed, the vendor shall submit an electronic copy in Microsoft word and a portable document file (PDF) format of a Substance Evaluation Report to the DEA Representative. Each report shall be due no later than thirty (30) calendar days after the study completion date specified in the Contractor's log of substance evaluation. The DEA representative will provide an example of a Final Study Report for the vendor to use in preparation of the report. Where feasible, data shall be presented in tables and figures and the results shall be described in a textual format. Raw data should also be included in an appendix to the report.

iii) Annual Progress Reports: On or before the 5th working day following the end of each year, vendor shall submit a report on activities during the year. Two copies, and one electronic copy in Microsoft Word and PDF format, shall be sent to the DEA. In the report, vendor shall include: section 1 – a summary of what the vendor regards as the most significant results generated on standard compounds during the past 12 months; section 2- a brief (maximum of 2 paragraphs) summary of any problems encountered while conducting established test and, if applicable, a description of how those problems were resolved, as well as a brief (maximum of 2 paragraphs) summary of progress in any study development work; section 3 - the log of compound receipt; and section 4 - the log of substance evaluation; section 5 - any other information required. The summary of significant findings (section 1) should not be an all-inclusive summary of data generated on standard substances but, rather a summary highlights. Vendor shall not summarize any data generated on test compounds. With regard to the log of compound evaluation (section 4), relevant pages shall be those which list current studies and/or completed studies which yielded Compound Evaluation Reports of the year under report. The Annual Progress Report for the year; a separate quarterly report will not be required.

iv) Final Report: The final report shall include: section 1 -a summary of the results generated over the entire performance period; section 2 -summary of any problems encountered while conducting established tests and, if applicable, a description of how those problems were resolved, as well as a summary of progress in assay development work during the entire performance period; section 3 -the log of test substance receipts as specified in Section III, Task 1 over the entire performance period; section 4 -the log of substance evaluation as specified in Section III, Task 2 over the entire performance period; section 5 -any other information DEA requires.

v) Laboratory Records: These include all data generated under Section III, Tasks 3-6 and all results collected as specified under Section III, Tasks l and 6. On or before the expiration of the agreement year, if so instructed by the DEA, the vendor shall ship these items to the DEA.

Task 9. Level of Effort

The vendor shall, as directed by the DEA, utilize up to 30 person hours per week (1,530 person hours per year) for: (1) research related activities (e.g., establishing dose response effect, drug-discrimination training); (2) evaluating specified test substances using such study; or (3) for preparing special reports or data summaries. The DEA representative must approve work with each new test method prior to its initiation. Only those test compounds specified by the DEA shall be evaluated in the new study under development. For the most part, standard substances (known drugs of abuse such as morphine, MDMA, methamphetamine, cocaine, LSD, DOM, THC, and others) shall be used. Special reports and data summaries shall adhere to a format determined by the DEA. The DEA Representatives reserve the right to visit the laboratory where testing is being conducted.

IV. Period of Performance

The period of performance for this agreement shall be for 12 month duration with the option to extend for four additional years and is subject to renewal by DEA and vendor after each performance year. The exact dates of the period of performance are to be determined. If the agreement at the end of one year is terminated by one or both parties, the period of performance will no longer extend to subsequent years. Prior to shortening the period of performance, a written notification shall be provided with 90-day notice.

V. Deliverables

If a report on any of the requested studies cannot be provided by the specified timelines, the vendor must notify the DEA immediately upon obtaining this knowledge. This notification shall be followed up by a letter to the DEA stating the reason for the delay, the anticipated date of completion of investigations, and the anticipated delivery of the study.

ITEM	DELIVERABLE	DELIVERY SCHEDULE
1	Project kick-off meeting to discuss overall project expectations, timelines, and deliverables.	Within 2 working days following receipt of protocol.
	Agreed protocols of the *in vivo* locomotor activity, analgesia, cannabinoid tetrad study, and drug discrimination assays (with noted modifications, if necessary)	Initial protocols to be provided to DEA within 30 calendar days after start of the agreement period.

		Modified or revised protocols to be provided to DEA for review within 7 calendar days of discussion/notification by either party that the protocol must be modified or revised.
2	Monthly Status Reports	30 days from contract award date and monthly thereafter.
3	Substance Evaluation Report	To DEA no later than 30 calendar days after study completion date.
4	Quarterly Progress Report	To DEA on or before the 5th working day following each reporting period.
5	Annual Progress Reports	To DEA on or before the 5th working day following each year.
6	Final Report	To DEA on or before the expiration of the agreement period.
7	Laboratory Records and Test Substances	To DEA on or before the expiration of the agreement period.

VI. Use of Data and Data Retention

All documents, data, materials, records, and information sources provided to the vendor, developed or maintained by the vendor in the performance of this contract under this SOW are deemed to be the property of the DEA. All data collected, generated, manipulated or otherwise processed under this agreement are confidential information unless or until DEA authorizes its release. None of these data may be used at any time for any purpose except to generate reports or other requirements specified in the Statement of Work, without prior written approval of the DEA. The DEA and the vendor will mutually agree to discuss matters of Freedom of Information Act (FOIA) policy before each agency independently discloses requested information.

On or before the agreement year expiration, the vendor shall deliver (or otherwise dispose per the DEA) all data, including raw databases (electronic or hard copies), tapes, software programs used to interpret or manipulate data, weight calculation files, data collection forms, file definitions, and various edited databases generated under this contract to the DEA (except for data necessary only to comply with other Federal data retention requirements, such as

requirements pertaining to clinical trials or the Food and Drug Administration's rules pertaining to drug applications).

During or after the agreement, no data may be released, presented or published except upon prior approval of the DEA. All requests which the vendor will receive from third parties for access to the data must be referred to the DEA.

The vendor shall retain, for 5 years beyond the duration of this agreement, all laboratory notebooks (which shall include paper copies of raw data) and electronic data files. Electronic data files shall be labeled and recorded in a manner that allows their association with corresponding laboratory notebook entries and paper copies of raw data. On or before the expiration date of this agreement, if so instructed by the DEA, the vendor shall ship these items to the DEA representative in Arlington, VA.