

**“Production, Analysis, and Distribution of Cannabis,
Marijuana Cigarettes, and Related Materials”**

AMENDMENT OF SOLICITATION NO.: RFP- N01DA-10-7773

AMENDMENT NO.: 01

EFFECTIVE DATE: September 17, 2009

ISSUED BY:

National Institute on Drug Abuse, NIH
NIDA R&D Contracts Management Branch
Neuroscience Office of Acquisitions
6101 Executive Boulevard
Room 260 MSC 8402
Bethesda, Maryland 20892-8402

Point of Contact: [Amy Sheib](#), Contract Specialist
[Kenneth E. Goodling](#), Contracting Officer

NAME AND ADDRESS OF CONTRACTOR: To All Offerors

The above numbered solicitation is amended as set forth below. The hour and date specified for receipt of Offers is NOT extended. Offerors must acknowledge receipt of this amendment on each copy of the offer submitted. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

All other terms and conditions of the RFP remain unchanged.

DESCRIPTION OF AMENDMENT (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

PURPOSE: To modify/clarify the RFP requirements and respond to questions submitted under the RFP. Unless specifically noted, all specifications remain unchanged.

The RFP is modified as follows:

1. Delete SECTION H.10. PRIVACY ACT, HHSAR 352.270-11 (January 2006) in its entirety.

2. Delete SECTION I.3.7. FAR Clause 52.244-1, Privacy Act Notification (April 1984) in its entirety.
3. Delete SECTION I.3.8. FAR Clause 52.244-2, Privacy Act (April 1984) in its entirety.
4. Delete SECTION J Attachment 13 “Privacy Act System of Records” in its entirety.

The responses to questions are as follows:

Question 1. *Can I ask you for any information past 9/11/09 about this application?*

Answer 1. No technical questions will be addressed.

Question 1.a. *I am just worried that I will not send in the appropriate paper work and get a fine of some sort. Will I get a fine?*

Answer 1.a. No.

Question 2. *Can I have a lawyer look over the application?*

Answer 2. There is no requirement that you have a lawyer. This is a business decision you must make independently.

Question 3. *Where do the seeds come from or do I have to get them myself?*

Answer 3. If someone other than the incumbent contractor gets the contract award, cannabis seeds will be provided as necessary to start with.

Question 4. *Do I have to send in the cannabis at the end of a full grow season?*

Answer 4. The storage requirement is described in the RFP.

Question 5. *What is the circumference of the cannabis cigarettes?*

Answer 5. About 25 mm.

Question 5.a. *And how do they have to packaged?*

Answer 5.a. Individual cannabis cigarettes are packaged in metallic cylindrical cans so that they can be stored frozen at the optimum temperature. The labeling is to be done as recommended by Food and Drug Administration for Investigational New Drug products.

Question 5.b. *Do they have to be in a package like regular cigarettes?*

Answer 5.b. No, they need to be packaged to meet all the regulatory requirements.

Question 5.c. *Do they have a symbol on the cigarette or a seal or something?*

Answer 5.c. No. There is no symbol on the cigarettes, but all regulatory requirements must be met.

Question 5.d. *What are the package specifications on them?*

Answer 5.d. Please refer to appropriate Code for Federal Regulations or contact Food and Drug Administration for this information. All regulatory requirements are to be complied with.

Question 6. *Will I be train how to **check** the THC levels and how to run the lab.*

Answer 6. The offerors are required to have all requisite qualifications, skills, and abilities to deliver all deliverables as required under the RFP.

Question 7. *Can I put the lab in my proposal?*

Answer 7. The offerors are required to have all facilities in place prior to the award of the contract.

Question 8. *Will my taxes go up on my farm?*

Answer 8. You should consult your tax advisor.

Question 9. *Will my insurance go up and will I have to have a different policy for this adventure.*

Answer 9. You should consult your technical advisors and insurance agent.

Question 10. *How much insurance coverage will I have to have?*

Answer 10. You should consult your tax advisor.

Question 11. *Will I get a tax break. And if so how much?*

Answer 11. You should consult your tax advisor.

Question 12. *Will the local authorities be notified?*

Answer 12. You must contact your state drug enforcement authorities and federal Drug Enforcement Administration.

Question 13. *Does my plantation have to be inclosed or can I grow in my field?*

Answer 13. This requirement is described in the RFP.

Question 14. *Can I grow more then aces that is said?*

Answer 14. No.

Question 14.a. *Approximately twenty aces maybe more?*

Answer 14.a. Please see the previous answer.

Question 15. *What are the limitations on growing on federal land and how do I go about it?*

Answer 15. The offerors are required to have all facilities in place prior to the award of the contract.

Question 15.a. *How do I find it, where I live?*

Answer 15.a. The offerors are required to have all facilities in place prior to the award of the contract.

Question 15.b. *I live in U.P. Michigan and there is a county hear that I feel would be the best for growing. I was wondering if there was any federal land there?*

Answer 15.b. The offerors are required to have all facilities in place prior to the award of the contract.

Question 16. *Can I produce more then the amount need for manufacturing option 2a,2b,2c,2d and 2e?*

Answer 16. No, you are required to do and deliver as stated in the RFP under the Statement of Work.

Question 17. *What would I do with over stock of growing?*

Answer 17. You may consult your local drug enforcement authorities and technical advisors.

Question 17.a. *Can I manufacture more with option 2a through 2e?*

Answer 17.a. Please see question number 16.

Question 17.b. *Can I distribute to medical patience in Michigan and/or put up a distribution store.*

Answer 17.b. No, you will do as required in the RFP.

Question 18. *Do I have contract with other from hear and other countries to meet up with the quantity and qualities?*

Answer 18. Please review RFP, and consult your technical advisors. Business decisions must be made independently.

Question 18.a. *Or do I have to find my own to distribute to?*

Answer 18.a. The NIDA Contracting Officer's Technical Representative will provide distribution instructions.

Question 18.b. *Or will I have contact from you?*

Answer 18.b. The NIDA Contracting Officer's Technical Representative will provide distribution instructions.

Question 19. *If I purchase land will I own the property when contract is up?*

Answer 19. The offerors are required to have all facilities in place prior to the award of the contract.

Question 20. *Do I have to factor in packaging prices, label and shipping etc. in my proposal?*

Answer 20. Yes, all estimated costs should be included in the contract proposal.

Question 21. *Can I grow in part of the lab section?*

Answer 21. No.

Question 22. *Can I also be growing outside and in at the same time?*

Answer 22. Please review the RFP.

Question 23. *Can I have less than 15 people and still get a full contract?*

Answer 23. Yes, if you meet all of the qualification and skills of a potential offeror.

Question 24. *Can I go over the amount of 500,000?*

Answer 24. Yes, if you meet all of the qualification and skills of a potential offeror.

Question 25. *Will not every having a contract with the federal government effect my proposal?*

Answer 25. No, please see Past Performance evaluation criteria in Section M.

Question 26. *If I am awarded the contract will I get the funds before March of 2010 to start in march?*

Answer 26. The period of performance is specified in the RFP. Funding will be available at the start of the period of performance. Under a cost reimbursement type contract, the contractor will be paid as costs are incurred and invoiced.

Question 27. *Do my employers have to be union or do I just have the posted in my establishment?*

Answer 27. Please consult with your legal advisor/s.

Question 28. *What is the percentages of the product of cannabis?*

Answer 28. Please refer to the requirements of the Statement of Work.

Question 28.a. *Is it more by the potency of the product or is there a base price?*

Answer 28.a. Please review the RFP.

Question 28.b. *And is there any way to negotiate the pricing?*

Answer 28.b. All proposals will be evaluated by a peer review committee, after which NIDA will establish a competitive range. If your proposal is in the competitive range, you will be contacted concerning negotiation procedures.

Question 29. *How would I go about the negotiating the price?*

Answer 29. Please see the previous response.

Question 30. *Is it considered a sale or is it considered manufacturing?*

Answer 30. It is a Research and Development contract.

Question 31. *Will there be additional people to contact through the time period on the contract?*

Answer 31. Upon contract award, you will be provided the name of a NIDA Contracting Officer's Technical Representative.

Question 32. *Will there be any one from now till the due date for the proposal to contact?*

Answer 32. Amy Sheib, NIDA Contract Specialist

Question 33. *I also have a question on travel existences. Does that include overseas for consultation?*

Answer 33. All estimated costs should be included in the contract proposal.

Question 34. *And also can I have them come hear on consulting?*

Answer 34. This is a business decision you must make independently.

Question 35. *Does that have to be in the proposal contract or do I do that as a quarterly?*

Answer 35. All estimated costs should be included in the contract proposal.

Question 36. *I also was wondering about if I hired someone from overseas like Amsterdam, would they have to become a U.S. before the contract?*

Answer 36. Please consult your business and legal advisors.

Question 37. *Would that also be away that they could get citizenship, you would it be for the time period of the contract or no?*

Answer 37. Please consult with your local Immigration and Naturalization authorities.

Question 38. *I was wondering if there is any grants that I could get maybe for schooling or if I could add that in my proposal?*

Answer 38. There is no schooling grant in the RFP. The offerors are required to have all requisite qualifications, skills, and abilities to deliver all deliverables as required under the RFP.

Question 39. *If an entity's or person's awareness of this project have no prior convictions, however are currently involved in what is deemed as "federally illegal", is there a way they can be involved in this project without subjecting themselves or what they do, or have been doing, to any sorts of punishable offenses. (I.E. If a current grower is contacted can we secure his or her safety, prior to contract, and after contact, regardless of involvement in THIS contract or not?)*

The reason for this is:

A. There are many "farmer's" of the multiple strains (read THC levels) already in action, operating illegally. If they were (sub)contracted, it would serve to save on production costs.

B. If the NIH decides in a few years to continue to go forward and market these, it would be better to have larger stock supply ready. This will also help serve in the production and resource availability.

C. If the DEA is using this as a sort of "fronts" to uncover illegal operations the contract wordings would oversee the protections of person's whom were willfully involved in a protected project, and thus not allow for federal persecutions (or so we'd hope.)

D. The scope of available use of what is readily available now, may allow for the project time to begin at a sooner date, thus allowing greater access to information.

Answer 39. Please contact your local and state drug enforcement authorities and federal drug enforcement administration.

Question 40. *Is it an absolute requirement of the winning proposal to have had 3 prior contracts?*

Answer 40. No, please see Past Performance evaluation criteria in Section M.

Question 41. *What if the proposing organization has had none, but is willing to subcontract those (3) who have? Is this okay?*

Answer 41. Subcontracting is a business decision. Business decisions must be made independently.

Question 42. *Will the Contract Specialist assist in networking person's or other organizations whom may work well together for the best intent of this project?*

Answer 42. No, a Contract Specialist at a federal agency is a government employee and performs his/her job as required by the Agency. It is not the job of the Contract Specialist to provide networking assistance.

Question 43. *If no property is owned or in use currently now by the a proposing organization, and none can be secured via involvement of person'(s) or organization(s) as mentioned in question 39, then (this) particular organization would have to include the request for property and land for this specific use in their proposal, correct?*

Answer 43. The offerors are required to have all facilities in place prior to the award of the contract.

Question 44. *Or is prior land/property with specifications as requested an absolute pre-requirement of the contract?*

Answer 44. The offerors are required to have all facilities in place prior to the award of the contract.

Question 45. *If property is known about that is sought to be bought for this specific use, is there away to purchase it with funding now as to prepare it for the specified use(s) by the award date (2010)?*

Answer 45. The offerors are required to have all facilities in place prior to the award of the contract.

Question 46. *Is this research project being geared toward developing a market for the taxation and creation of marijuana cigarettes specifically for the recreational use of such, (such as tobacco or clove cigarettes now), or is it being done for the medical informational side, that being documented, calculates accuracy?*

Answer 46. This project is for scientific research.

Question 47. *If it is being done for the first reason, (taxation/recreational) then the need may not be as great but is still important to provide alternative use ways (such as with tobacco, you can also buy it to "chew"). Here we find need to possible allowing for the study to expand its areas of calculations and information (research) into vaporization, and/or consumption(?)*

Answer 47. Please review the RFP.

Question 48. *Can the projected project costs include cost of training or funding to return to school/or apprenticeship of contractor or subcontractors whom may be interested in specific field of study, lack the education now, and see utilizing this project not only as a scope for new ideas and research, but also for developing their own career? (I.e. Can we get paid to learn and paid to teach at the same time?)*

Answer 48. The offerors are required to have all requisite qualifications, skills, and abilities to deliver all deliverables as required under the RFP.

Question 49. *Is the RFP intended to find a replacement or find a supplement to the University of Mississippi's similar effort?*

Answer 49. It is an open competitive solicitation for a contract proposal.

Question 50. *Is the University of Mississippi no longer going to provide NIDA with marijuana?*

Answer 50. It is an open solicitation for contract proposals for consideration to award a contract. Anyone capable and qualified can apply.

Question 51. *How long does the Representations and Certification process take? I just want to make sure that time still remains for others to go through the RFP process and meet the Oct. 13 deadline.*

Answer 51. The Online Representations and Certifications Application (ORCA) process should take less than a day.

Question 52. *Has anyone besides the University of Mississippi supplied marijuana for NIDA?*

Answer 52. No.

Question 53. *When will the RFP winner be announced?*

Answer 53. Please see the cover letter.

Question 53.a. *How?*

Answer 53.a. An award notice will be published on fbo.gov after the award is made.

On page 7, Section II.B.1.A) mentions that a minimum quantity of approximately 30 Kg of cannabis shall be required during the contract duration. Option 2 is mentioned if additional quantity is required, but Option 2 references the manufacture of additional cigarettes. On page 8, Section II.B.1.F).2 requires a minimum stock of 250 Kg of bulk plant materials to be maintained.

Question 54. *Are “cannabis” and “bulk plant materials” the same?*

Answer 54. Yes.

Question 55. *Is “contract duration” the base period of 1 year, or is it the base period plus the option years?*

Answer 55. 1 year, with the potential of 4 option years as determined by the Government.

Question 56. *How much of the required minimum stock will be delivered, and how much is the offeror responsible for producing in the first year?*

Answer 56. Once a new contractor wins the award, the incumbent contractor will transfer current stock of marijuana (an estimated quantity of 250 Kg) to the new contractor. The contractor will produce the amount required to maintain the minimum stock requirements of the RFP.

Question 57. *Should Option 1 be the correct reference as opposed to Option 2 in the reference above?*

Answer 57. Yes.

Page 8, Section II.B.3 requires 2000 placebo, and 8000 of each low, medium, and high delta-9-THC containing marijuana cigarettes be manufactured once in 5 years, but the minimum stock requirements are significantly higher. Option 3 is mentioned if additional cigarettes are needed, but Option 3 addresses Training and Translational Support

Question 58. *How much of the required minimum cigarette stock will be delivered, and how much is the offeror responsible for producing in the first year?*

Answer 58. Once a new contractor wins the award, the incumbent contractor will transfer current stock of marijuana cigarettes (an estimated quantity of 125,000 total) to the new contractor. The contractor will produce the amount required to maintain the minimum stock requirements of the RFP.

Question 59. *Should Option 2 be the correct reference as opposed to Option 3 in the reference above?*

Answer 59. Yes.

B.1.E. (Page 8) second paragraph. It says, “An average of between 100 and 150 samples from DEA is to be analyzed each month for both cannabinoids and herbicide (Paraquat), respectively.

Question 60. *What does “respectively” refer to?*

Answer 60. An average of 100 and 150 samples, each of cannabinoids and herbicide (Paraquat) is required to be analyzed. Please ignore the word, “respectively”.

Question 60.a. *Would you please clarify the number of samples to be tested for cannabinoids and the number of samples to be tested for paraquat?*

Answer 60.a. The answer is given under Question #60.

Question 60.b. *Or clarify if the same samples should be tested for both cannabinoids and paraquat?*

Answer 60.b. The answer is given under Question #60.

B.5. (Page 8) The contractor shall manufacture the following per year:

- | | |
|----------------------|----------|
| a). delta-9-THC | -500.00g |
| b). CBD | - 20.00g |
| c). CBN | -10.00g |
| d). CBG, CBC, & THCV | - 1.00g |

Question 61. *The amounts of cannabinoids to be manufactured are shown to be per year. Are these the correct amounts for the base year and for each of the option years?*

Answer 61. Yes.

B.7. (Page 9) Provide adequate DEA approved storage facility and store marijuana cigarettes and other cannabinoids at -20°F or below as appropriate.

Question 62. *The storage temperature was indicated as -20° F. Should it be -20°C?*

Answer 62. It should be -20°C.

Question 63. *Does the government intend for this contract to be a level of effort term form type contract or a completion type contract?*

Answer 63. Level of Effort