

SUBMIT PROPOSAL TO:

STATE OF FLORIDA
DEPARTMENT OF CITRUS605 E. MAIN ST., BARTOW, FL 33830 -OR-
PO BOX 9010, BARTOW, FL 33831

Telephone Number: (863) 537-3984

STATE OF FLORIDA

REQUEST FOR PROPOSAL

CONTRACTUAL SERVICES
AcknowledgementPage 1 of 15
PagesPROPOSALS WILL BE OPENED **June 21, 2013, 2:00 P.M. EDT**
and may not be withdrawn within 30 days after such date and time.

PROPOSAL NO. # 12-09

AGENCY MAILING DATE:

May 10, 2013

PROPOSAL TITLE: **Beneficial impact of Orange Juice consumption on risk factors
associated with cardiovascular disease**

STATE PURCHASING SUBSYSTEM (MFMP) VENDOR NUMBER

VENDOR NAME

VENDOR MAILING ADDRESS

CITY-STATE-ZIP

AREA CODE

TELEPHONE NUMBER

TOLL-FREE NUMBER

I certify that this proposal is made without prior understanding, agreement, or connection with any corporation, firm, or person submitting a proposal for the same contractual services, and is in all respects fair and without collusion or fraud. I agree to abide by all conditions of this proposal and certify that I am authorized to sign this proposal for the proposer and that the proposer is in compliance with all requirements of the Request for Proposal, including but not limited to, certification requirements. In submitting a proposal to an agency for the State of Florida, the proposer offers and agrees that if the proposal is accepted, the proposer will convey, sell, assign, or transfer to the State of Florida all rights, title and interest in and to all causes of action it may now or hereafter acquire under the Anti-trust laws of the United States and the State of Florida for price fixing relating to the particular commodities or services purchased or acquired by the State of Florida. At the State's discretion, such assignment shall be made and become effective at the time the purchasing agency tenders final payment to the proposer.

REASON FOR NO PROPOSAL

POSTING OF PROPOSAL TABULATIONS

Proposal tabulations with recommended awards will be posted for review by interested parties at the location where proposals were opened and will remain posted for a period of 72 hours. Failure to file a Protest within the time prescribed in Section 120.57(3), Florida Statutes, shall constitute a waiver of proceedings under Chapter 120, Florida Statutes. Posting will be on or about **July 15, 2013**

AUTHORIZED SIGNATURE (MANUAL)

AUTHORIZED SIGNATURE (TYPED) TITLE

GENERAL CONDITIONS

SEALED PROPOSALS: All proposal sheets and this original acknowledgement form must be executed and submitted in a sealed envelope. The face of the envelope shall contain, in addition to the above address, the date and time of the proposal opening and the proposal number. Proposal prices not submitted on attached proposal price sheets when required shall be rejected. All proposals are subject to the conditions specified herein. Those, which do not comply with these conditions, are subject to rejection.

- EXECUTION OF PROPOSAL:** Proposal must contain a manual signature of authorized representative in the same space provided above. Proposal must be typed or printed in ink. Use of erasable ink is not permitted. All corrections made by proposer to his proposal price must be initialed. The company name and MFMP vendor number shall appear on each page of the proposal as required. Complete ordering instructions must be submitted with the proposal. If you are not a registered vendor with the Department of Management Services, contact the Division of Purchasing, 4050 Esplanade Way, Suite 360, Tallahassee, FL 32399-0950, (866) 352-3776 immediately
- NO PROPOSAL SUBMITTED:** If not submitting a proposal, respond by returning only this proposer acknowledgement form, marking it "NO PROPOSAL" and explain the reason in the space provided above. Failure to respond to a procurement solicitation without giving justifiable reason for such failure, non-conformance to contract conditions, or other pertinent factors deemed reasonable and valid shall be cause for removal of the proposer's name from the proposal mailing list. Note: To qualify as a respondent, proposer must submit a "NO PROPOSAL", and it must be received no later than the stated proposal opening date and hour.
- PROPOSAL OPENING:** Shall be public, on the date, location and the time specified on the acknowledgement form. It is the proposer's responsibility to assure that his proposal is delivered at the proper time and place of the proposal opening. Proposals, which for any reason are not so delivered, will not be considered. Offers by telegram or telephone are not acceptable. A proposal may not be altered after opening of the price proposals. NOTE: Proposal tabulations will be furnished upon written request with an enclosed, self-addressed, stamped envelope and payment of a predetermined fee. Proposal files may be examined during normal working hours by appointment. Proposal tabulations will not be provided by telephone.
- PRICES, TERMS AND PAYMENT:** Firm prices shall be proposed and include all services rendered to the purchaser.
 - TAXES:** The State of Florida does not pay Federal Excise and Sales taxes on direct purchases of services. See tax exemption number on face of purchase order. This exemption does not apply to purchases of services in the performance of contracts for the improvement of state-owned real property as defined in Chapter 192, F.S.
 - DISCOUNTS:** Cash discount for prompt payment shall not be considered in determining the lowest net cost for proposal evaluation purposes.
 - MISTAKES:** Proposers are expected to examine the conditions, scope of work, proposal prices, extensions, and all instructions pertaining to the services involved. Failure to do so will be at the proposer's risk.

(d) INVOICING AND PAYMENT: The contractor shall be paid upon submission of properly certified invoices to the purchaser at the prices stipulated on the contract at the time the order is placed, after delivery and acceptance of goods, less deductions if any, as provided. Invoices shall contain the contract number or purchase order number and the contractor's MFMP vendor number. An original and one (1) copy of the invoice shall be submitted. The final payment shall not be made until after the contract is complete unless the State has agreed otherwise. Invoices for fees or other compensation for services or expenses submitted in accordance with the rates at or below those specified in Sections 112.061 and 287.058, F.S.

Interest Penalties: Payment shall be made in accordance with Section 215.422, F.S., which states the contractors' rights and the State agency's responsibilities concerning interest penalties and time limits for payment of invoices. **VENDOR OMBUDSMAN:** Vendors providing goods and services to an agency should be aware of the following time frames. Upon receipt, an agency has five (5) working days to inspect and approve the goods and services, unless bid specifications, purchase order or contract specifies otherwise. An agency has 20 days to deliver a request for payment (voucher) to the Department of Financial Services. The 20 days are measured from the latter of the date the invoice is received or the goods or services are received, inspected and approved. If a payment is not available within 40 days, a separate interest penalty set by the Chief Financial Officer pursuant to Section 55.03, F.S., will be due and payable, in addition to the invoice amount, to the vendor. To obtain the applicable interest rate, contact the agency purchasing office. The interest penalty provision applies after a 35 day time period to health care providers, as defined by rule. Interest penalties of less than one (1) dollar will not be enforced unless the vendor requests payment. Invoices which have to be returned to a vendor because of vendor preparation errors will result in a delay in payment. The invoice payment requirements do not start until a properly completed invoice is provided to the agency. A Vendor Ombudsman has been established within the Department of Financial Services. The duties of this individual include acting as an advocate for vendors who may be experiencing problems in obtaining timely payment(s) from a State agency. The Vendor Ombudsman may be contacted at (850)413-5516 or by calling the State Comptroller's Hotline, 1-800-342-2762. The Division of Purchasing shall review the conditions and circumstances surrounding non-payment, and unless there is a bona fide dispute, the Division may, in writing, authorize the contract supplier to reject and return purchase orders from said agency until such time as the agency complies with the provisions of Section 215.422, F.S.

(e) ANNUAL APPROPRIATIONS: The State of Florida's performance and obligation to pay under this contract is contingent upon an annual appropriation by the Legislature.

- CONFLICT OF INTEREST:** The award hereunder is subject to the provisions of Chapter 112, F.S. Proposers must disclose with their proposal the name of any officer, director, or agent who is also an employee of the State of Florida, or any of its agencies. Further, all proposers must disclose the name of any State employee who owns, directly or indirectly, an interest of five percent (5%) or more in the proposer's firm or any of its branches. In accordance with chapter 287, F.S., no person or firm receiving a contract that has not been procured pursuant to Section 287.057(1) or (3), F.S., to perform a feasibility study of the potential implementation of a subsequent contract, participating in the drafting of a request for proposals, or developing a program for future implementation shall be eligible to contract with the agency for any contracts dealing with that specific subject matter; and proposers must disclose with their proposal any such conflict of interest.

- 6. **AWARDS:** As the best interest of the State may require, the right is reserved to reject any and all proposals or waive any minor irregularity or technicality in proposals received. Proposers are cautioned to make no assumptions unless their proposal has been evaluated as being responsive. All awards made as a result of this proposal shall conform to applicable Florida Statutes.
- 7. **INTERPRETATIONS/DISPUTES:** Any questions concerning conditions and specifications shall be directed in writing to this office for receipt no later than ten (10) days prior to the proposal opening. Inquiries must reference the date of proposal opening and proposal number. No interpretation shall be considered binding unless provided in writing by the State of Florida in response to requests in full compliance with this provision. Any person who is adversely affected by the Agency's decision or intended decision concerning a procurement solicitation or contract award and who wants to protest such decision or intended decision shall file a protest in compliance with Rule 28-110, Florida Administrative Code. Failure to file a protest within the time prescribed in Section 120.57(3), F.S., shall constitute a waiver of proceedings under Chapter 120, F.S.
- 8. **NOTICE OF BID PROTEST BONDING REQUIREMENT:** Any person who files an action protesting a decision or intended decision pertaining to contracts administered by the Division or a State agency pursuant to Section 120.57(3)(b), F.S., shall post with the Division or the State agency at the time of filing the formal written protest, a bond payable to the Division or State agency in an amount equal to 1 percent of the Division's or state agency's estimate of the total volume of the contract, which bond shall be conditioned upon the payment of all costs which may be adjudged against him in the administrative hearing in which the action is brought and in any subsequent appellate court proceeding. For protest of decisions or intended decisions of the Division pertaining to agencies' requests for approval of exceptional purchases, the bond shall be in the amount equal to 1 percent of the requesting agency's estimate of the contract amount for the exceptional purchase requested. In lieu of a bond, the Division or State agency may, in either case, accept a cashier's check or money order in the amount of the bond. **FAILURE TO FILE THE PROPER BOND AT THE TIME OF FILING THE FORMAL PROTEST, WILL RESULT IN A DENIAL OF THE PROTEST.**
- 9. **GOVERNMENTAL RESTRICTIONS:** In the event any governmental restrictions may be imposed which would necessitate alteration of the material quality of the services offered on this proposal to their completion, it shall be the responsibility of the successful proposer to notify the purchaser at once, indicating in his letter the specific regulation which required an alteration, including any price adjustments occasioned thereby, or to cancel the contract at no further expense to the State.
- 10. **DEFAULT:** Failure to perform according to this proposal and/or resulting contract shall be cause for your firm to be found in default in which event any and all reprourement costs may be charged against your firm. Any violations of these stipulations may also result in:
 - (a) Contractor's name being removed from the Division of Purchasing vendor mailing list.
 - (b) All State agencies being advised not to do business with the contractors without written approval of the Division of Purchasing
- 11. **LEGAL REQUIREMENTS:** Applicable provision of all Federal, State, county and local laws, and of all ordinances, rules, and regulations shall govern development, submittal and evaluation of all proposals received in response hereto and shall govern any and all claims and disputes which may arise between person(s) submitting a proposal response hereto and the State of Florida, by and through its officers, employees, authorized representatives, or any other person, natural or otherwise; and lack of knowledge by any bidder shall not constitute a cognizable defense against the legal effect thereof.
- 12. **ADVERTISING:** In submitting a proposal, proposer agrees not to use the results therefrom as a part of any commercial advertising.
- 13. **ASSIGNMENT:** Any Purchase Order issued pursuant to this request for proposal and the monies which may become due hereunder are not assignable except with the prior written approval of purchaser.
- 14. **LIABILITY:** On any contract resulting from this proposal the proposer shall hold and save the State of Florida, its officers, agents, and employees harmless against claims by third parties resulting from the contractor's breach of this contract or the contractor's negligence. This requirement does not apply to contracts between governmental agencies.
- 15. **FACILITIES:** The State reserves the right to inspect the proposer's facilities at any time with prior notice.
- 16. **CANCELLATION:** The State shall have the right of unilateral cancellation for refusal by the contractor to allow public access to all documents, papers, letters, or other material subject to the provisions of chapter 119, F.S., and made or received by the contractor in conjunction with the contract.
- 17. **PUBLIC RECORDS:** Any material submitted in response to this Request for Proposal will become a public document pursuant to Section 119.07, F.S. This includes material, which the responding proposer might consider to be confidential, or a trade secret. Any claim of confidentiality is waived upon submission, effective after opening pursuant to Section 119.07, F.S.

Right to Audit. The DEPARTMENT shall have the right to audit or inspect any and all records, reports, documents and such other supporting evidence as it deems necessary to verify compliance with the terms of this contract. The VENDOR shall provide such records in hard copy, machine-readable form, or both, as requested. VENDOR shall maintain such records and allow DEPARTMENT to exercise such right to audit for a period of five years after final payment on this contract, or longer if required by law. The VENDOR shall include the 'right to audit provisions' of this contract in all agreements with subcontractors and any other business entities providing goods or services in direct or indirect support of this contract. Should DEPARTMENT exercise this right to audit, VENDOR shall provide adequate and appropriate workspace as well as access to photocopy machines and the right to interview current VENDOR employees and contact information for former employees.

UNAUTHORIZED ALIENS. The DEPARTMENT shall consider the employment by any contractor of unauthorized aliens a violation of section 274A(e) of the Immigration and Nationalization Act. Such violation shall be cause for unilateral cancellation of this contract.

NOTE:

ANY AND ALL SPECIAL CONDITIONS AND SPECIFICATIONS ATTACHED HERETO WHICH VARY FROM THE GENERAL CONDITIONS SHALL HAVE PRECEDENCE. THIS SHEET AND THE ACCOMPANYING BID CONSTITUTE AN OFFER FROM THE BIDDER. IF ANY OR ALL PARTS OF THE BID ARE ACCEPTED BY THE STATE OF FLORIDA, AN AUTHORIZED REPRESENTATIVE OF THE AGENCY SHALL AFFIX HIS SIGNATURE HERETO, AND SHALL THEN CONSTITUTE THE WRITTEN AGREEMENT BETWEEN PARTIES. THE CONDITIONS OF THIS FORM BECOME A PART OF THE WRITTEN AGREEMENT BETWEEN THE PARTIES.

STATE OF FLORIDA, DEPARTMENT OF: _____

BY: _____

AUTHORIZED AGENCY SIGNATURE

CONTRACT NUMBER _____

EFFECTIVE _____

(Date)

**SWORN STATEMENT PURSUANT TO SECTION 287.133(3)(A),
FLORIDA STATUTES, ON PUBLIC ENTITY CRIMES**

THIS FORM MUST BE SIGNED AND SWORN TO IN THE PRESENCE OF A NOTARY PUBLIC OR OTHER OFFICIAL AUTHORIZED TO ADMINISTER OATHS.

1. This sworn statement is submitted to _____
[Print name of the public entity]

by _____
[Print individual's name and title]

for _____
[Print name of entity submitting sworn statement]

Whose business address is

and (if applicable) its Federal Employer Identification Number (FEIN) is _____

(If the entity has no FEIN, include the Social Security Number of the individual signing this sworn statement:

_____)

2. I understand that a "public entity crime" as defined in Paragraph 287.133(1)(g), **Florida Statutes**, means a violation of any state or federal law by a person with respect to and directly related to the transaction of business with any public entity or with an agency or political subdivision of any other state of the United States, including, but not limited to, any bid or contract for goods or services to be provided to any public entity or an agency or political subdivision of any other state or of the United States and involving antitrust, fraud, theft, bribery, collusion, racketeering, conspiracy, or material misrepresentation.
3. I understand that "convicted" or "conviction" as defined in Paragraph 287.133(1)(b), **Florida Statutes**, means a finding of guilt or a conviction of a public entity crime, with or without an adjudication of guilt, in any federal or state trial court of record relating to charges brought by indictment or information after July 1, 1989, as a result of a jury verdict, nonjury trial, or entry of a plea of guilty or nolo contendere.
4. I understand that an "affiliate" as defined in Paragraph 287.133(1)(a), **Florida Statutes**, means:
1. A predecessor or successor of a person convicted of a public entity crime; or
 2. An entity under the control of any natural person who is active in the management of the entity and who has been convicted of a public entity crime.

The term "affiliate" includes those officers, directors, executives, partners, shareholders, employees, members, and agents who are active in the management of an affiliate. The ownership by one person of shares constituting a controlling interest in another person, or a pooling of equipment or income among persons when not for fair market value under an arm's length agreement, shall be a prima facie case that one person controls another person. A person who knowingly enters into a joint venture with a person who has been convicted of a public entity crime in Florida during the preceding 36 months shall be considered an affiliate.

5. I understand that a "person" as defined in Paragraph 287.133(1)(e), **Florida Statutes**, means any natural person or entity organized under the laws of any state or of the United States with the legal power to enter into a binding contract and which bids or applies to bid on contracts for the provision of goods or services let by a public entity, or which otherwise transacts or applies to transact business with a public entity. The term "person" includes those officers, directors, executives, partners, shareholders, employees, members, and agents who are active in management of an entity.

6. Based on information and belief, the statement, which I have marked below, is true in relation to the entity submitting this sworn statement. **[Indicate which statement applies.]**

_____ Neither the entity submitting this sworn statement, nor any of its officers, directors, executives, partners, shareholders, employees, members, or agents who are active in the management of the entity, nor any affiliate of the entity has been charged with and convicted of a public entity crime subsequent to July 1, 1989.

_____ The entity submitting this sworn statement, or one or more of its officers, directors, executives, partners, shareholders, employees, members, or agents who are active in the management of the entity, or an affiliate of the entity has been charged with and convicted of a public entity crime subsequent to July 1, 1989.

_____ The entity submitting this sworn statement, or one of its officers, directors, executives, partners, shareholders, employees, members, or agents who are active in the management of the entity, or an affiliate of the entity has been charged with and convicted of a public entity crime subsequent to July 1, 1989. However, there has been a subsequent proceeding before a Hearing Officer of the State of Florida, Division of Administrative Hearings and the Final Order entered by the Hearing Officer determined that it was not in the public interest to place the entity submitting this sworn statement on the convicted vendor list. **[Attach a copy of the final order.]**

I UNDERSTAND THAT THE SUBMISSION OF THIS FORM TO THE CONTRACTING OFFICER FOR THE PUBLIC ENTITY IDENTIFIED IN PARAGRAPH 1 (ONE) ABOVE IS FOR THAT PUBLIC ENTITY ONLY AND, THAT THIS FORM IS VALID THROUGH DECEMBER 31 OF THE CALENDAR YEAR IN WHICH IT IS FILED. I ALSO UNDERSTAND THAT I AM REQUIRED TO INFORM THE PUBLIC ENTITY PRIOR TO ENTERING INTO A CONTRACT IN EXCESS OF THE THRESHOLD AMOUNT PROVIDED IN SECTION 287.017, **FLORIDA STATUTES**, FOR CATEGORY TWO OF ANY CHANGE IN THE INFORMATION CONTAINED IN THIS FORM.

[SIGNATURE]

Sworn to and subscribed before me this _____ day of _____, 20 ____ .

Personally known _____

OR Produced identification _____ Notary Public – State of _____

(Type of identification) My commission expires _____

(Printed, typed, or stamped commissioned name of notary public)

REQUEST FOR PROPOSAL

The Beneficial Impact of Orange Juice Consumption on Risk Factors Associated with Cardiovascular Disease

I. BACKGROUND

The Department of Citrus (Department) is an executive agency of the Florida State Government whose purpose is to maximize consumer demand for Florida citrus products to ensure the sustainability and economic well-being of the Florida citrus grower, the citrus industry and the State of Florida. Department is responsible for conducting a wide variety of programs in both domestic and foreign markets involving industry regulation, scientific, market and economic research, advertising, marketing, public and industry relations, and consumer promotions.

II. STATEMENT OF PURPOSE

1. **NEED** – An international consortium of orange growers and juice suppliers has joined in an effort to fund human clinical research investigating the health benefits associated with the consumption of orange juice (OJ). This consortium is known as the Citrus Health Claim Initiative (CHCI) and is composed of representatives of the U.S./Florida, Brazil, and the European Union (EU via the European Fruit Juice Association— AIJN).

Recent clinical and other research has provided a significant and growing ‘body of evidence’ supporting the health benefits associated with the consumption of citrus products. Further strengthening of this body of evidence is still required if formal ‘health claims’ are to be approved by appropriate authorities and agencies (FDA, EFSA). These entities publish specific guidelines for pursuing approval of health claims.

The present request is aimed at obtaining scientifically validated evidence supporting the health benefits provided by orange juice consumption. Proposals are sought to provide FDOC/CHCI available options for clinical studies seeking such evidence, and identification of clinical research groups capable of/interested in performing such research. Each proposal submitted should document the basic outline of a clinical study proposal for funding with detailed budget outline.

Results of these specific clinical studies funded by the FDOC/CHCI are expected to be used in conjunction with other data/results from prior and ongoing clinical studies and other research as the basis for developing health claim dossiers. FDOC/CHCI is seeking evidence developed in compliance with guidelines and requirements of regulatory agencies in Europe and the U.S.¹ and the proposed study should be designed accordingly.

¹USA – Food & Drug Administration (FDA) – <http://www.fda.gov/Food/default.htm>

EU – European Food Safety Authority (EFSA) – : <http://www.efsa.europa.eu/en/efsajournal/doc/2474.pdf>

2. OBJECTIVE – On behalf of the FDOC/CHCI, Department is seeking proposals from clinical research entities/groups describing human clinical studies defining and evaluating the beneficial effects of orange juice consumption on the risk of development of cardiovascular diseases. Study parameters should also provide for the evaluation of potentially detrimental effects associated with such consumption as well as design elements that provide further insight into the mechanism(s) of action associated with benefits due to consumption of 100% orange juice (and its natural components as found in commercially available juices).

3. REQUIREMENTS –

A. Required elements of clinical study

- 1) A human clinical intervention study utilizing preferably a parallel design.
- 2) Comparative evaluation including appropriate statistics of the effects over a 12 week period.
- 3) The study should be a ‘dose-response’ design using 3 arms:
 - a) an orange juice;
 - b) that same orange juice with an additional amount of natural citrus hesperidin; and
 - c) control drink.
- 4) Tested quantities should be compatible with a balanced diet.
- 5) Evaluations should include effects on recognized risk factors for cardiovascular disease development, e.g.,
 - a) Blood pressure
 - b) LDL cholesterol
 - c) Oxidized LDL
 - d) Flow-mediated vasodilatation (FMD)
 - e) Other
 - f) Relevant secondary parameters or markers

B. Study must involve well-characterized participants who are otherwise healthy individuals, but considered to be at greater risk for the development of cardiovascular diseases or related conditions.

C. The proposal research program should include but is not limited to:

- 1) Evaluation of long-term (‘chronic’) effects of daily orange juice consumption on risks of development of cardiovascular disease(s) showing beneficial changes in related vascular function(s).
- 2) Evaluation of similar or related effects on some short-term (post-prandial, ‘acute’) effects as part of the chronic study.
- 3) Measurements of the appropriate markers to assess the above-mentioned outcomes.
- 4) Design allowing completion of clinical studies within two years from initiation of contract.

Important remark: The focus of the proposed research is upon 100% OJ consumption and **not** isolated/extracted component(s).

III. SCOPE OF SERVICES

1. SERVICES AND RESPONSIBILITIES

A. State Requirements

Bidding agency acknowledges that Department is a governmental state Agency and that Department is bound by state laws, rules and policies, which must be followed by Vendor when providing such services. These laws, rules and policies include Chapter 601, F.S. (Florida Citrus Code), Chapter 287, F.S. (Procurement), Chapter 119, F.S. (Public Records) and Chapter 20, F.A.C. (Department Rules and Regulations) and FDOC Purchasing, Fiscal and Travel Policies.

The State of Florida, through the Department of Management Services, has instituted MyFloridaMarketPlace, a statewide eProcurement system. Pursuant to Section 287.057(23), F.S., (2002), all payments shall be assessed a Transaction Fee of one percent (1.0%), which the Vendor shall pay to the State; refer to section III.2.H. of RFP.

B. Scope of Work

Required elements of clinical study

- 1) A human clinical intervention study utilizing preferably a parallel design;
- 2) Comparative evaluation including appropriate statistics of the effects over a 12 week period;
- 3) The study should be a 'dose-response' design using 3 arms:
 - a) an orange juice;
 - b) that same orange juice with an additional amount of natural citrus hesperidin; and
 - c) control drink;
- 4) Tested quantities should be compatible with a balanced diet.
- 5) Evaluations should include effects on recognized risk factors for cardiovascular disease development, e.g.,
 - a) Blood pressure
 - b) LDL cholesterol
 - c) Oxidized LDL
 - d) Flow-mediated vasodilatation (FMD)
 - e) Other
 - f) Relevant secondary parameters or markers

Study must involve well-characterized participants who are otherwise healthy individuals, but considered to be at greater risk for the development of cardiovascular diseases or related conditions

The proposal research program should include but is not limited to:

- a) Evaluation of long-term ('chronic') effects of daily orange juice consumption on risks of development of cardiovascular disease(s) showing beneficial changes in related vascular function(s)
- b) Evaluation of similar or related effects on some short-term (post-prandial, 'acute') effects as part of the chronic study
- c) Measurements of the appropriate markers to assess the above-mentioned outcomes
- d) Design allowing completion of clinical studies within two years from initiation of contract.

Important remark: The focus of the proposed research is upon 100% OJ consumption and **not** isolated/extracted component(s).

C. Services and Deliverables

1) Services - Human clinical studies defining and evaluating the beneficial effects of orange juice consumption on the risk of development of cardiovascular diseases. Study parameters should also provide for the evaluation of potentially detrimental effects associated with such consumption as well as design elements that provide further insight into the mechanism(s) of action associated with benefits due to consumption of 100% orange juice (and its natural components as found in commercially available juices).

2) Deliverables

- a) Evaluation of long-term ('chronic') effects of daily orange juice consumption on risks of development of cardiovascular disease(s) showing beneficial changes in related vascular function(s)
- b) Evaluation of similar or related effects on some short-term (post-prandial, 'acute') effects as part of the chronic study
- c) Measurements of the appropriate markers to assess the above-mentioned outcomes
- d) Design allowing completion of clinical studies within two years from initiation of contract
- e) Quarterly Status Reports providing a narrative of progress/status of study, or other status reports at such times as are reasonable to disseminate preliminary information
- f) A Final Report relating all findings relative to the purposes, requirements, objectives, services and deliverables outlined above.

D. Purchasing

As stated in section III.A., the Department is an executive agency of the State of Florida and must abide by all purchasing rules as mandated by the section 287, Florida Statutes and Rule 60A, Florida Administrative Code.

E. Staffing

Not Applicable – at Vendor’s discretion within contracted services.

F. Publications

Vendor shall have the right to use data generated in the course of conducting the Study for research, education, patient care purposes and publishing results of the Study consistent with the terms of Department CONTRACTED SERVICES and without payment of royalties or other fees. Vendor will further agree to provide DEPARTMENT with results of the research contracted hereunder, and any reports or articles published by Vendor reporting such results. Vendor also shall invite DEPARTMENT to participate in any media conferences based upon results of the research contracted hereunder.

Department will not use the name of Vendor, nor of any member of Vendor’s project staff, in any publicity, advertising, or news release without the prior written approval of an authorized representative of Vendor and such approval will not be unreasonably withheld

G. Performance Measurement

Proof of performance will be provided to the Department prior to an invoice payment and will be demonstrated by, but not limited to:

- 1) For interim invoices and with respect to contracted payment terms, quarterly reports providing narrative of status of the study, as defined in contracted services
- 2) For final invoices and with respect to contracted payment terms, a “Final Report” as defined in contracted services
- 3) Department and Vendor will jointly agree to appropriate ad hoc verbal reports and discussion of Project
- 4) Department and Vendor will jointly agree to appropriate public presentations and journal publications with respect to study findings

H. Use of Name

Neither Department nor Vendor will use the name of Department/Vendor, nor of any member of Department/Vendor’s project staff, in any publicity, advertising, or news release without the prior written approval of an authorized representative of Department/Vendor and such approval will not be unreasonably withheld. Vendor will not, under any circumstances, advertise or otherwise state or imply that Department has tested and/or approved any product or process, without prior written approval of Department.

I. Ownership

Department shall maintain all rights, title and interest in data generated in the course of conducting the Study, except that notwithstanding the foregoing, Vendor shall have the right to use data generated in the course of conducting the Study for research, education, patient care purposes and publishing results of the Study consistent with the terms of contracted services and without payment of royalties or other fees.

J. Conflict of Interest

Department and Vendor shall provide each other appropriate information with respect to identification of Conflict of Interest.

K. Intellectual Property

- 1) It is recognized and understood that certain existing inventions and technologies are the separate property of Department or Vendor are not affected by contracted services, and neither party shall have any claims to or rights in such separate inventions and technologies of the other party.
- 2) Inventorship shall be determined in accordance with U.S. patent law or by mutual agreement if the Invention is not patentable.
- 3) Except as expressly provided herein, nothing in CONTRACTED SERVICES shall be construed as granting or implying any rights to either party pertaining to background intellectual property rights of the other party, under any patents or intellectual property rights associated therewith.
- 4) Notwithstanding anything to the contrary contained herein, Vendor shall retain ownership of all raw clinical data as contained in its participant and medical records or other original source documentation and may use such data together with any research or study data as Vendor deems reasonable and appropriate for publication, research, education and patient care without payment of royalties or other fees.

2. CONSIDERATIONS

A. Amount

Please provide the total cost to complete the services outlined in this request, along with your terms for payment. If any payments are required upon execution of contract, or prior to any services being rendered, a full justification for the advance payment is required.

B. Program Summary -- Costs

- 1) At a minimum, proposals must include a program summary of estimated costs describing the services to be performed, period of activity and expected performance measures for the approved activity. All contracted services will be defined in contracted services documentation defining considerations in terms of Department's fiscal year (July 1 through June 30).

2) Should additional funds be required for any reason, Vendor shall, prior to incurring the additional costs, prepare a Revised Cost of Program Summary and submit it with an appropriate explanation to Department for approval.

3) Except for the employment of agents at its own expense, Vendor shall not engage third parties to perform any services or otherwise obligate or commit Department for expenses or payments of any kind without specific prior written approval of Department.

C. Travel

There shall be no payment for travel. All travel and related costs will be the responsibility of Vendor as part of the estimated project costs.

D. Method of Payment

Department shall require an invoice referencing the Cost Estimate/ Program Summary (if required) and outlining the services provided forty (40) days prior to each scheduled payment as specified in 215.422, F.S.

E. Financial Consequences

Vendor fees and reimbursement for costs incurred are paid after services are rendered, subsequent to receipt of invoice, proof of adequate performance (section III.1.G), and pre-audit of supporting documentation (section III.2.D). Additional financial consequences may be specified in contract, if applicable.

F. Right to Audit

The Department shall have the right to audit or inspect any and all records, reports, documents and such other supporting evidence as it deems necessary to verify compliance with the terms of this contract. The Vendor shall provide such records in hard copy, machine-readable form, or both, as requested. Vendor shall maintain such records and allow Department to exercise such right to audit for a period of five years after final payment on this contract, or longer if required by law. The Vendor shall include the 'right to audit provisions' of this contract in all agreements with subcontractors and any other business entities providing goods or services in direct or indirect support of this contract. Should Department exercise this right to audit, Vendor shall provide adequate and appropriate workspace as well as access to photocopy machines and the right to interview current Vendor employees and contact information for former employees.

G. Financial Control/Risk Assessment

Do you publish financial statements on a regular basis? If so, how frequently? Are these statements available upon client request?

Do you engage an outside accounting firm to audit annual financial statements and/or to review internal control systems? If so, can you provide copies

of these reports upon client request? If not, please provide a description of the internal controls in place to support your operation.

The FDOC is prohibited from making payment to other than the primary contractor. To what extent can you pay 3rd party vendors, with reimbursement by FDOC to you to follow in 30 days?

H. MyFloridaMarketPlace Transaction Fee

The State of Florida through the Department of Management Services has instituted MyFloridaMarketPlace, a statewide eProcurement system. Pursuant to section 287.057(23), Florida Statutes (2002), all payments shall be assessed a Transaction Fee of one percent (1.0%), which the Vendor shall pay.

For payments within the State accounting system (FLAIR or its successor), the Transaction Fee shall, when possible, be automatically deducted from payments to the Vendor. If automatic deduction is not possible, the Vendor shall pay the Transaction Fee pursuant to Rule 60A-1.031(2), F.A.C. By submission of these reports and corresponding payments, Vendor certifies their correctness. All such reports and payments shall be subject to audit by the State or its designee.

The Vendor shall receive a credit for any Transaction Fee paid by the Vendor for the purchase of any item(s) if such item(s) are returned to the Vendor through no fault, act, or omission of the Vendor. Notwithstanding the foregoing, a Transaction Fee is non-refundable when an item is rejected or returned, or declined, due to the vendor's failure to perform or comply with specifications or requirements of the agreement.

Failure to comply with these requirements shall constitute grounds for declaring the Vendor in default and recovering procurement cost from the Vendor in addition to all outstanding fees. VENDORS DELINQUENT IN PAYING TRANSACTION FEES MAY BE EXCLUDED FROM CONDUCTING FUTURE BUSINESS WITH THE STATE.

For additional information and insight you should visit the **MyFloridaMarketPlace** web site. <http://dms.myflorida.com/mfmp>

I. Crimes Entity

A person or affiliate who has been placed on the convicted vendor list following a conviction for a public entity crime may not submit a bid on a contract to provide any goods or services to a public entity, may not submit a bid on a contract with a public entity for the construction or repair of a public building or public work, may not submit bids on lease of real property to a public entity, may not be awarded or perform work as a contractor, supplier, subcontractor, or consultant under a contract with any public entity, and may not transact business with any public entity in excess of the threshold amount provided in Section 287.017, for CATEGORY TWO for a period of 36 months from the date of being placed on the convicted vendor list.

J. Discrimination

In accordance with section 287.134, Florida Statutes, an entity or affiliate who has been placed on the discriminatory vendor list may not submit a bid on a contract to provide goods or services to a public entity, may not submit a bid on a contract with a public entity for the construction or repair of a public building or public work, may not submit bids on leases of real property to a public entity, may not award or perform work as contractor, supplier, sub-contractor, or consultant under contract with any public entity, and may not transact business with any public entity.

K. Nondiscrimination and Compliance

No person, on the grounds of race, creed, color, national origin, age, sex or disability, shall be excluded from participation in; be denied proceeds or benefits of; or be otherwise subjected to discrimination in performance of this Agreement as prescribed by all applicable state and federal laws and regulations. COUNSEL shall, upon request, show proof of such nondiscrimination. Failure to comply with such state and federal laws will result in the termination of this Agreement.

L. Other Special Requirements

Not applicable.

IV. TERMS OF AGREEMENT

Length of service to be provided shall be for a two year period with possible no cost extension due to the nature of research. This contract shall be effective upon execution by both parties.

The State of Florida’s performance and obligation to pay under this agreement is contingent upon an annual appropriation by the Legislature as specified in 60A-1.016(2)(c), F.A.C.

All Department contracts require a termination clause upon written notice to Vendor, submitted a specified number of days prior to termination. Department will be responsible for all services rendered within the scope of the contract.

V. EVALUATION CRITERIA

Each proposal will be evaluated and ranked by a committee of staff members familiar with the business. Points will be awarded as follows from a possible total of 100:

Scope of Work	30
Compliance/knowledge of regulatory requirements for health claims	15
Scope of Relevant Experience relative to the clinical research proposal	15
Outline of Proposed Technical Research Program and Deliverables	30
Cost -- categories of clinical study elements, along with estimated costs	10
Total	<u>100</u>

All proposals will be evaluated within this scoring system.

VI. Schedule of Events

Request for Proposals posted on the Internet	May 10, 2013
Questions Due (If applicable)	May 31, 2013, 5:00 PM EDT
Posting of Answers to Questions	June 14, 2013
Proposals Opened *	June 21, 2013, 2:00PM EDT
*Proposals received after this time, are not eligible for award.	
Review and Evaluation	June 24 thru July 12, 2013
Posting of the Award Selection	July 15, 2013
Submitted to the Citrus Commission	September 18, 2013
Award Date (or sooner if applicable)	October 1, 2013

***Opening dates are firm and cannot be changed. All other dates are subject to change.**

Emails and Faxed Proposals are not acceptable – Must be received no later than June 21, 2013, 2:00 PM EDT.

VII. Submittal Information

Five (5) copies of your proposal MUST be submitted with one of those copies suitable for automated copying or electronic media to:

Florida Dept of Citrus
Dianne Screws, Director of Purchasing & Support Services
605 E Main Street, Bartow Florida 33830

Please reference the RFP # on the outside of all mailings

Questions about the content of this proposal should be directed to:

Dan King, Ph.D., Director of Scientific Research
E-mail: dking@citrus.state.fl.us
Telephone: (863) 956-2023, Fax: (863) 956-2039

Only direct questions about submitting proposals (not content) to:

Dianne Screws, Director of Purchasing & Support Services
E-Mail: dscrews@citrus.state.fl.us
Telephone : (863)537-3984 or Fax: (877) 352-2487

REQUIRED DOCUMENTS - CHECK LIST

Form PUR 7033, PUR 1000 and PUR 1001*

Crimes Entity, Notarized and Signed

Company History

Resumes of all persons responsible for the Florida Department of Citrus Account

Reference list, Name, phone number, name of project, e-mail if avail. _____

E-Mail for future notification _____

The Department reserves the right to reject any or all proposals and to waive minor irregularities.

ADDITIONAL PURCHASING INSTRUCTIONS

*Form PUR 1000 and PUR 1001 are located at the following website:

<http://dms.myflorida.com/purchasing>. Print these forms to be included with your proposal as required documents.

Inapplicable provisions of PUR 1001 – General Instructions to Respondents

The following are not applicable:

Section 3. Electronic Submission of Responses

Responses will be submitted as explained above.