UNITED STATES OF AMERICA

+ + + + +

DEPARTMENT OF HEALTH AND HUMAN SERVICES

+ + + + +

PRE-PROPOSAL CONFERENCE

+ + + + +

ANTIGEN-SPARING PANDEMIC INFLUENZA VACCINES:
RFP ORDC V&B 05-08

+ + + + +

Tuesday,
April 18, 2006

+ + + + +

The above-entitled matter convened in Room 800 of the Hubert Humphrey Building, 200 Independence Avenue, Southwest, Washington, D.C., at 2:00 p.m.

DHHS STAFF PRESENT:

SCHUYLER ELDRIDGE
Contracting Officer
ROBIN ROBINSON
Program Director
DAVID K. BECK
Chief Contracting Officer
VITTORIA CIOCE
Project Officer
DARRICK EARLY
Contract Specialist
SHENG LI
Project Officer

P-R-O-C-E-E-D-I-N-G-S

2:12 p.m.

MR. ELDRIDGE: Good afternoon, everyone and welcome and thank you for coming to our Pre-Proposal Conference on the -- on our Request for Proposals for the Antigen-Sparing Pandemic Influenza Vaccines, and that RFP Number is ORDC V&B 05-08.

My name is Schuyler Eldridge. I'm a Contracting Officer here at the Department, and I'd like to introduce everyone else that's here representing the Department.

Dr. Robin Robinson is the Program Director. Darrick Early is the Contract Specialist. Dr. Vittoria Cioce in the back is the Project Officer, and Dr. Sheng Li in the back Project Officer.

The purpose of our conference this afternoon is to discuss the RFP. We received a lot of questions, and we're going to try to answer as many as we can during this time.

We also have handed out 3-by-5 cards that you can use to address any other questions that we might not get to or that we don't clarify for you during this session.

Please don't put any markers on those

cards just put questions.

What we will do is we'll try to get to some of those questions if we have time, but if we don't, we're going to post those questions as an amendment to the RFP and we'll get those out as quickly as possible. So, check the FedBizOpps for those questions later in the week, possibly the beginning of next week.

Want to make one note that proposals are still due May 2nd, 2006 at 3:00. There's no change as a result of this conference.

I'd like to turn it over to Dr. Robinson and again, thank you for coming.

DR. ROBINSON: Thank you, Schuyler.

Welcome one and all. Your presence here points out the interest that you have and that you are committed to the pandemic influenza preparedness plans of your own companies and associates and that you're committed to what the U.S. government is doing toward pandemic preparedness.

This is one of many measures that we are taking in order to prepare the United States, and it's specifically for pandemic vaccines as the largest way in order to make a difference for a pandemic with

vaccines will be through the use of antigen-sparing approaches in order to stretch out what we -- the capacity we have which will change from year to year as we move forward with other solicitations and contracts that will be awarded.

Again, welcome, and first let me say a little bit about what this RFP entails. Our intention and rationale for this was that there are medical devices and/or other products such as adjuvants, chemokines, immunokines that can do (a) reduce -- enhance immunogenicity, i.e., going from one or more doses down to -- to one dose; and (2) stretching the amount of antigen required for a pandemic vaccine.

Our goal is to provide vaccine within six months to every citizen in the United States. So, therefore, right now, we would need 600 million doses of vaccine because our immune systems are naive or virgin to a pandemic virus, and there are other ways in which that can be accomplished without having to overburden a capacity that is already taxed with over-building facilities that would then affect seasonal vaccine.

The intent -- well, the mandatory goals here or -- or criteria will be that (1) you have to

have a commitment to having a pandemic program with one of these products; (2) that you have the capacity built into the United States of 150 million doses of vaccine or other product within six months of a pandemic or that you can demonstrate to the Department that you could provide a capacity that can be purchased and stockpiled prior to or in the first moments of a pandemic if the product is built abroad.

The product can be part of a vaccine. It can be administered separately from a vaccine. It can be used to deliver the vaccine, and so there are a number of different models here. So, this -- and we welcome all of them because we have a commitment to leave no stone unturned in our efforts to become prepared for a pandemic.

The amount of money that we have here has been reported in various venues including testimony of Assistant Secretary Igwnobie and the -- to Congress, and we are looking at this as an advance development contract. It is not an acquisition contract. Okay.

For approximately contract -- multiple contracts of 150 million, that number is flexible, it could be less, it could be a little bit more, but that's what we're budgeted at right now, and that is

within the framework of FY 'O6 emergency funding that was provided in the DOD bill last December. FY '07 monies may be reprogrammed to accommodate if there's some outstanding proposals that need further funding in an incremental way.

The technical evaluation criteria that we'll use we wanted a standard methodology and approach in which we would -- a technical panel comprised of industry, academia, and government scientists that are in influenza and in vaccines will convene, and they will look at the merits of a particular approach and how well that can be carried out as opposed -- by that particular company or consortium.

One of the things that we have -- and that will consist of about 30 points. One of the things that we have -- that's a little different from other RFPs that we've had in the past is comparable advantages and potential limitations. Usually, that's folded into the methodology and approach, but we want you to spell out what you see are your advantages and what you see as your limitations. It's as important to say what your limitations are as what your advantages are because we need to know that you

realize how far you can take that technology and what are your solutions for overcoming these limitations.

I would suggest that in that portion that you put together decision trees also as to go and no go on certain approaches and alternatives or contingencies that certain things do work or if they don't work.

Basically, what your facilities for manufacturing the product, where you're doing the clinical trials, and what your proposed commercial scale facilities would be like if they're not already in place.

Important also is the organizational experience. Not only have the people that will be the key personnel in the proposal, but -- that will lead the project, but also your company or consortium's experience with government contracts, with bringing products to market, and to licensure should be pointed out there. And then the personnel -- your key personnel being your principal investigators and those that are going to be important in the clinical evaluation, in the clinical manufacturing, in the movement of the product from IND toward licensure and finally, your time line to licensure in the form of

milestones and in what you see or your big obstacles in obtaining licensure here in the United States. If it's licensed in the other country, you might want to include that as your experiences with that licensure.

So, there are a different number of questions. We've received quite a number of questions, and we'll try to entertain a number of ones that you have here, but the first ones that we will present are those that were repeats that we had a number of duplicates of these and so, based on that, the -- there needs to be some clarification about those issues. And after those questions have been presented and answered, we will then entertain your questions that you have here. Certainly, over the next two and three days, any other questions that have been presented previously or during this meeting or afterwards, we will do our best to provide the answers over the next -- at least by next Tuesday or Wednesday have the answers and -- in the amendment.

Okay. The RFP for manufacturing of a foreign site, if the product -- I'm sorry, if the product has long-term stability data such that the product is suitable for stockpiling at an FDA licensed facility of the U.S., can HHS provide guidance on what

type of long-term stability data that will be suitable to permit product produced outside of the U.S. to be stockpiled within the U.S.? For example, for what time period must stability be demonstrated?

As you can imagine, that -- there's no set answer to that. As a person that deals with stockpiles for other issues and other countermeasures, I can tell you that we would love to see five years, but I know that in many cases you're not going to see that. So, it is whatever your best effort's going to be. If it's two years for some of the vaccines that's really all you can do because those are perishable items, but some of your adjuvants can last almost to as long as one can actually measure it and other medical devices.

So, I would advise you to look at your products, see what data there already exists for stability and what your projected master plan for stability programs entail and present that as your best effort towards that.

What -- what we're doing here is very -- is a little different because we did not want to be too inclusive on this. We in our other RFPs have maintained the vaccines must be manufactured in the

U.S. The reason we did not for this particular RFP is because there are certain products that can be manufactured overseas that will be able to be purchased and are in large enough quantity that we could buy them and they could be used with the vaccine, in the delivery device, or at the bedside with a vaccine and, therefore, could have stockpiling capability, and so we wanted to be -- provide a little bit broader scope of offers to the table at this -- with this RFP.

We also understand that many of these products will not be as far in development as others we've seen in the past, but that's why the -- the requirement that an IND be submitted within six months of a contact award is there so that we have to -- we have to put a line in the sand at some point and we feel that that is reasonable and fair as this is an advanced development contract. If you're too far -- to early in the process to meet that, then I would recommend that there are NIH programs in DMID that could support these types of activities.

The second question is can -- Phase III calls for a novel adjuvant containing cell culture pandemic vaccine originally developed for RFP 05-04 be

reimbursed under this antigen-sparing RFP particularly if the vaccine is sufficiently different from the vaccine such that a separate license is required?

And the answer to that is you certainly are welcome to submit a proposal if you so choose. However, if it's -- if it's deemed to be very close to the vaccine that one saw -- that one is awarded for the cell-based vaccine contract, then we will not double fund, or you can choose. You can choose the cell-based one or you can choose later in the summer if you are so chosen to be awarded the antigen-sparing that, but at this point, that -- that will be your own down selection.

Another question is what will the criteria -- what will be the criteria to define what is a potent dose of H5N1 vaccine? Will it be CHMP criteria or some other criteria?

I want to address this in twofold. One is that you will need to if it is an inactivated vaccine, demonstrate the potency of the product in terms of what is now used by the FDA which is an SRID assay and for clinical results, there are -- we will be using those criteria set forth in the FDA guidelines that came out in late March. So, I suggest if you haven't

seen those that you do so, and we will be providing those on our -- our ORDC website again for you to see that, but they already are on the FDA website for guidance for pandemic influenza vaccine manufacturing and I think that will address the two and three criteria that are necessary to meet a clinical endpoint.

Okay. This is always a good one. What type of firm commitment is HHS anticipating regarding the establishment of facilities capable of producing 180 million doses for stockpile within six months of U.S. licensure?

And the technical proposal certainly needs a written statement by the offerer and the subcontractors to establish a facility or -- in the U.S. -- or can demonstrate that they have the ability to -- to provide a product that can be stockpiled. The commitment that we have there is internal in the -- in the actual contract award and -- and the feasibility of production plan that one has there. So that you have to actually be able to provide where it's going to be based, what's the time lines it will be based on and it's capacity and then other details there.

So, if the Board -- usually, if the Board of Directors haven't signed on for it, that's a bad sign. Okay.

The next question is the manufacturing capacity will obviously be greatly affected by the yield and effectiveness of antigen-sparing technologies which are uncertain at this time. In light of that, how should bidders assess the likelihood of satisfying the 150 million dose commitment? Should this be calculated on certain assumed antigen content? Can we presume a dose of 3.8 micrograms?

The easiest way to answer that is the 150 million would be based without -- without an adjuvant or without a delivery system which I mean is antigen alone at 15 micrograms because that's what seasonal monovalent vaccines are, and that is consistent with what we've shown in the past.

What your approach is going to do is going to be able to take some number of that and give us a multiplier such that you can get -- you can reach that 150 million. So, per chance, if you had a -- an adjuvant and it -- you had multiplied say instead of 15 micrograms you could use 7 and a half, well, then

you would -- want to use that as your multipliers to -- to get the 150 million.

Again, the other part of that is the ability to have that in six months. Now, what does six months mean? That means that from the time the Secretary is able to make a declaration that you are able to aggressively have the vaccine or your product available such that you can meet the 150 million dose level in six months.

That's very aggressive. We understand that, and so what we ask is for your best effort.

If you come back and say, here are the numbers, and it's going to cost us a jillion dollars to do it and you say that and say this is our best effort to do it, but that's what our -- that's what we're asking you to do because and is that -- if we wait to say over a year, we will have had two waves of pandemic, and the losses could be, if they're like 1918, up to 1.9 million deaths.

So, we want to be able to what we say flatten the curve as soon as possible, and so we're putting out there a goal of 150 million in six months knowing that in many instances it's not going to be accomplished, but we do want your very best efforts.

Okay. If a bidder has a preexisting supply agreement with another national government -- commitment to supply 150 million doses within six months of licensure be subject to that preexisting commitment, and would HHS be willing to consider a proposal that provide a firm commitment of less than 150 million doses if a bidder had a preexisting contractual commitment to another government?

Again, how you're able to meet your own company's obligations is really up to you, but what we're asking for is to meet these particular obligations to us in the form of a proposal of 150 million doses in six months, and so it's up to your own priorities as to how you're able to accomplish that.

The next one is will HHS be committed to purchasing 150 million doses for stockpiling from a successful bidder? If not, what are the limitations on a bidder engaging in discussions or commitments to stockpile for other governments?

And again, this is an advance development contract solicitation and not an acquisition contract solicitation. When we buy H5N1 vaccine, that's an acquisition contract. When we're supplying funding

for you to do clinical trials, clinical manufacturing to scale up your development processes and so forth, that's advanced development, and so we want you to be very clear about distinguishing those two.

Do we have a commitment at some point in the future? Well, it is our intent, but we do not know at what time we would plan to acquire these. Of course, they would have to be shown that they were -- had efficacy and safety and that they -- and hopefully have moved to a licensed product status.

As you can imagine, we will be looking at -- at all different types of countermeasures and ways to stretch our vaccine supplies and we hope that this will facilitate our efforts down the road with -- when these bear fruit.

Okay. This one is -- I've kind of entered before. As it assumes that a company submits a bid to this RFP was also awarded a contract to 05 RFP 05-04 – cell culture vaccines which also have a similar requirement and assumes that the cell culture vaccine candidate was an antigen-sparing adjuvant cell culture vaccine. Assuming that -- such facts, does this antigen-sparing adjuvantated cell culture capacity under the cell culture contract also satisfy the

capacity under this RFP?

The capacities are very similar. Okay. So, that's not -- there's not a difference there. Again, we're not going to award a contract and give you money for the same work done twice. It's not in our best interest and really not in yours either.

Okay. On page five of the RFP states that the purpose of this RFP is to support advanced stage development of enhanced immunity and/or antigen-sparing strategies for pandemic influenza vaccination and please define advanced stage. And what we find in advanced stage are those activities that would support the clinical development of a product toward licensure -- basically post-IED toward licensure.

Certainly, we do understand that there may be some preclinical studies that need to be accompanied such as toxicology studies, and those certainly would be within the realm of this RFP, but we will not fund if there -- if you haven't done the first animal studies. We're not going to -- that's just not what we're about.

The NIH has a very good program to fund that, and we want to fund this toward licensure and that we -- the agency within the Department has

indicated that they will move this as fast as humanly possible, but they refuse as part of their overall pandemic influenza preparedness efforts as well.

The next question is does this RFP only support development activities designed to lead toward licensure of a pandemic vaccine or does the Department also anticipant that their inter-pandemic licensure should result from activities funded through this RFP?

Because this -- these efforts are seen as pivotal in having a pandemic influenza vaccine capacity meet our goals, it is for pandemic vaccine or what we would call pre-pandemic vaccine such as H5N1. That -- it is in concert with a seasonal vaccine that your company or consortium is entertaining or actively is pursuing is reasonable, but that's not what our funding mechanism is for this. This is strictly for a pandemic. So, it is a little different from some of our other RFPs which will -- are funding concurrently both seasonal and pandemic.

Certainly comparability studies with seasonal vaccine primarily in the elderly and the children would be appropriate, but that's not the scope of this RFP.

On page 52 of the RFP under the technical

evaluation criteria for facilities, yes, someone caught -- there was a -- one of them -- one of the old ones slipped through. It is -- the set of 300 is 150 to be consistent throughout this. So, it's -- someone should get a little star next to their name because they did catch it, and we appreciate all those. So, that will be an amendment to change the RFP to reflect that in the technical evaluation section.

The next question is please clarify the objective C listed on page six of the RFP. It is our understanding that if a product has extended long-term stability, i.e., two years or more and subsequently is suitable for stockpiling in the U.S. at an FDA licensed facility that the product can be produced outside the U.S. This facility must have the capacity to support and stockpile purchases commensurate with U.S. pandemic influenza vaccine needs, but we understand objective C to mean that the facility need not be located in the U.S. as long as the product is suitable.

To make it short, yes, that is correct. The manufacturing facility may be located abroad provided it is demonstrated and has shown to be acceptable by the Department. That it -- a product

can be stockpiled in a capacity meeting our needs.

The next question, regarding mandatory criteria 2A found on page 50 of the RFP shown below. Our interpretation is that in the case of an adjuvantated -- in fact, C, the reference to product refers to the final formulated adjuvantated vaccine. Please confirm.

And I -- when I saw this, I wanted -- I wanted to break it down into several things. There will be some products we realize that you will pre-formulate with an antigen to make the vaccine and so, what this refers to is the final container product there.

In other cases, the product can be used along side the antigen vaccine such as the bedside. Such that the final container product is the immunokine or adjuvant or such or even a syringe or other delivery devices that would be separate from that. So, the final product there would be the syringe or the -- the adjuvant product or what have you that then can be used at the bedside.

And, of course, finally, if it is a syringe, it would be one that could be used with the final vaccine product that could actually have

adjuvant in it.

Will pre-award costs be eligible for reimbursement, and certainly, I -- I would defer to the chief contracting officer on this, but it has been our belief that on a case-by-case basis that there will be -- that we will consider reimbursable items depending on the scope of the work and the time line relative to the overall project.

I -- I wouldn't put things four or five years ago that you did in this, but certainly if it's within -- directly related to this and is during the proposal and evaluation time, it could be considered.

The next question is can renovation costs to an existing building or manufacturing facility such as enhanced air handling, et cetera, et cetera and then I'll answer that very briefly. No.

There's a separate pot of money so to speak and then -- which RFI 06-02 addresses this in which we will have an RFP coming out that will be for facility renovation or retro-fitting of facilities. It would not -- is not within the scope of this RFP. It'll be a separate one.

Next question is will the Department make vaccines developed under contract to the U.S.

government available to companies selected as a result of the solicitation for animal and clinical testing of the antigen-sparing products? Should potential offerer's plans for animal clinical testing of their antigen-sparing products anticipate testing with vaccines funded by the -- funded by the government?

In your proposal, it is -- the offerer's responsibility to provide your own antigen source because we can't choose what is best for you and nor should we. What we are doing is -- some of you have noted is that we ask really two things from you. A commitment to do this and the other is to allow the U.S. government and -- and most likelihood the NIH to be able to evaluate the products that you're developing such that at some point in the future when we want to acquire these vaccines or adjuvants or syringes or patches or whatever you have are available, then we can have some scientific basis for choosing them in an acquisition process and that -- so that is one of the requirements of the RFP.

It is similar to some of the other RFPs that have come from the Department over the past year or so, and that information as you might expect will be -- will be proprietary and confidential, and we

will work within each individual company to allow you to know what -- get the results with your individual product, and we'll be very careful about how to handle this, and so we understand this is somewhat very delicate, but at -- at the -- with the country needing as much information it can on pandemic preparedness and many companies are already sharing information publicly about their products. We see it -- we see it as a reasonable thing provided that we maintain certain guidelines when we do evaluate them.

I think that's -- is there anything? I think probably at this time before we get to the -- the last key dates, contact information, there are some questions that you might have from here.

MR. ELDRIDGE: If there are questions that weren't addressed in the last presentation, please take a moment to write them down on those cards. I ask you again not to put any markers on your cards. I'll collect them and if -- and we have a little bit of time. We'll address them right here.

Those that we don't get to, we will put in an amendment to the solicitation. That should be out by end of the week, early next week.

Primary point of contact, prior to this,

it had been Darrick Early. As of today, it's Schuyler Eldridge. That's me. Schuyler. My e-mail at the bottom schuyler.eldridge@hhs.gov.

And forgive me, earlier, I failed to introduce -- my boss is in the back of the room, Mr. David Beck. He's the Chief Contracting Officer for RDC.

DR. ROBINSON: One of the things that we always want to point out to you in the procurement process is that now that the RFP has been announced and you're providing proposals hopefully to this RFP is that all inquiries, questions, and so forth have to go through the contracting officer. We are in a procurement sensitivity and silence period and so that we don't see -- we don't want to appear to be rude because we won't answer your questions and so forth, but we want to be fair to everyone and so, therefore, we are -- people in the program are in that -- in that silence period until contractor awards later on.

So, but if you do have questions technically or about the program and so forth, we'll be happy to answer them. But, just direct them please toward the contracting officer.

MR. ELDRIDGE: One other thing I wanted to

point out, we have received very -- a lot of questions, and we plan to address all of those questions, unless they're duplicates, in the amendment. So, if we didn't present it here and you have sent it in -- you sent it in prior to today, we will address those questions with responses in the amendment.

DR. ROBINSON: Okay. I can answer a couple of these. Will the awardee be expected to use the same H5N1 virus for testing? Will HHS stipulate or provide a specific virus to be used?

Let me -- there are several things here. First of all, for the virus reference antigen that's needed for potency testing, we have an arrangement with the FDA that there has been a virus reference antigen because it has been made by a validated process. That will be available. You need to contact Jerry Weir at the FDA, and they will be able to ship not only the virus reference antigen for H5N1 that was prepared against the -- the Vietnam 2003 1203 isolate, but also the sheep antiserum that is a companion antiserum for doing the SRDS. That's the first thing.

As -- second is as we find a need to have other H5N1 virus vaccine candidates developed such as

a clade 2 isolate, similar virus reference antigen lots and antiserum will become available also. That's something the Department has been doing and will continue to do so in the future so that the manufacturers will have a common set of reagents there and that you don't have to spend your time with that because these have been already developed and already calibrated with other manufactured products.

Where are we right now? Well, certainly the -- what we would recommend is the 1203 strain and -- and that's equal to the NIBRG 14 from NIBSC for the Vietnam -- for Vietnam isolate from 2004 primarily on the merits of its production ability.

For the clade 2, there are three isolates that are -- that are available or will become available. The H5N1 Indonesian 0505 from CDC from Nancy Cox's lab has been granted -- has been instructed, tested, shown to be apathogenic and noninfectious for birds in man and ferrets also and that the -- the USDA has granted select agent exemption to that. So that virus reference antigen is available -- virus reference strain is available.

There are two virus reference strains that St. Jude is working on to make you aware of that for

clade 2. There's one from China and one from Mongolia. One of them is a -- is much further ahead than the other, and I suggest you contact Dr. Rob Webster about that.

There -- John Wood's lab in the UK at NIBSC has one that is for the Turkey isolates of the clade 2 H5N1 viruses. However, they are further behind right now, and so those won't be available for some time.

So, we're -- we're basically -- if you look at WHO, we're -- these are similar guidance that they would give you also. So, what we would do is have you contact the WHO virus reference lab. Any of those three would be more than happy.

I do point out though that the USDA has gotten -- has -- more stringent on their requirements and you would -- it would be a good idea to talk to them about importation of these virus reference strains and other materials from highly pathogenic avian influenza viruses.

Good question. Do the protection of human subject form and technical proposal cost information form count against the 40-page limit for the technical proposal? Good question. No, they do not.

The question is when a company chooses to pass on this procurement, will it be eligible to put on a future procurement contract, and the answer is it's up to you. I mean we have -- we have no exclusions. It's whoever's on the dotted line at the end when the proposal is put -- is submitted is who we're going to review. So, if you're on several proposals, then I would suggest that you do put that in there and then how you -- how you will choose if you are given -- if the contractors were given more than -- if you're on more than one award how you would choose to down select yourself. So, which should be an easy -- a decision we'd all like to have.

Since this is a cost-reimbursable contract, will the IP be given out in stockpile contract? The -- the answer's probably -- the answer's no. No, I mean your IP is your IP.

If IP is developed with government funds, then the government has then the ability to use that technology if it's -- if it needs to in -- in government contracts for emergency or such, but we're not going to go and give your information over to somebody else a priori.

Clarification, the time for those of you

that are -- are like I am, and you need to know exactly the last minute you can submit your proposal, it is, Andre, 3:00 p.m.?

MR. EARLY: 2:00 p.m.

DR. ROBINSON: It's 2:00 p.m. So, the correct --

MR. EARLY: No, I'm sorry. 3:00 p.m. is correct.

DR. ROBINSON: Three -- 3:00 p.m. Eastern Daylight Time.

MR. EARLY: Exactly.

DR. ROBINSON: Okay. That's 3:00 p.m. Okay. So, if you catch him at 2:59, you're okay. All right.

Okay. Is there an expectation that contracts to RFP 05-04 will be awarded prior to the submission date of the RFP? It could happen. I think that's probably all we can say at this point. Unless, David, you want to say anything else?

MR. BECK: No.

DR. ROBINSON: Okay. Okay. Does the Department anticipate additional funding will be available under RFP 05-04 for phase III clinical trials in licensure of pandemic vaccine as that --

okay. Well, this is not germane to this, but I will answer it, and that is that not only this, but other efforts under 05-04 and other projects and -- and other programs within our overall scope will hopefully receive funding in FY '07 and FY '08 as part of the President's initiative that he set out last November. So, we would hope that all of those things are funded in the coming year.

MR. ELDRIDGE: Will you place the names and companies of attendees on your website? No, we're not going to. No, not for this particular conference.

MR. EARLY: Schuyler.

MR. ELDRIDGE: Yes.

MR. EARLY: You may want to mention, on FedBizOpps there’s an interested vendors list, IVL, so, if you want basically the world to see that you're -- you're interested in proposing on this particular program, you can register as an interested vendor, and they can then find out that way, but you're not suppose to name attendants.

MR. ELDRIDGE: And one other business one I got out of the pile, when will budget templates be available? They're going to -- the templates are going to also be posted with the amendment when we

send out the responses to the questions.

DR. ROBINSON: And two more questions regarding the statement that offerers are responsible for procurement of antigen. Is that true also for antigen-sparing devices that operate independently of the vaccine manufacturing process, and the answer is yes. You will be responsible for that.

And which items are not included in the page count in the technical proposal? Certainly the cost proposal wouldn't count against it.

MR. EARLY: Well, any information that's not pertinent to the -- to the statement of work, please put in 250 pages, allows for the technical appendices, and that should be enough room in the appendices for -- for those peripheral documents.

DR. ROBINSON: I -- I guess a last piece of advice I'm saying is just focus on this being a solution for pandemic preparedness. It's certainly acceptable from your company and -- and it is to work toward a seasonal vaccine for elderly or children or other groups with these types of approaches, but this is specifically to address the pandemic. Because we don't have enough vaccine for -- in case of a pandemic, and we have to be able to stretch the

capacity that we have now and the capacities that we will have over the next five or six years to address this.

I mean there are other solicitations we have and hopefully, we'll be making contract awards that will be addressing this also. But, it is -- this multi-prong approach is going to be able to -- to have the effect that we want and to drive this forward, and we certainly welcome -- welcome the proposals, and we thank you for being part of the solution to this and to -- and to be part of saying yes, this is what it takes to do this and to say no, we can't do it.

Schuyler.

MR. ELDRIDGE: Are there any questions, any cards that I missed?

Again, I'd like to thank you guys for coming. Once again, I'd like to point you to my e-mail address and phone number.

Any additional questions you have please e-mail me.

We're going to have the responses from all questions and the ones posed here today posted as an amendment to the RFP at FedBizOpps no later than Tuesday of next week.

If there are no further questions, thank you for coming.

One thing I did want to mention, I'm sorry, we anticipate making the award by September 30th, 2006 based on availability of funds. Okay. So, time is of the essence. That's why we're not extending this so far.

(Whereupon, the pre-proposal conference was concluded at 3:01 p.m.)