Additional Questions and Answers to RFP NIH-NIAID-DMID-PR2004-01
'Neutralizing Monoclonal Antibodies Type A for Botulinum Neurotoxins'

Note to Offeror: Due date for the referenced RFP is November 5, 2004. There will be no extension to the due date. We are urging that all questions to the above RFP are submitted to NIAID Contract Office by 5:00 p.m. EST Monday, October 25, 2004.

The RFP is hereby amended as follows: Section L.c.3. Other Administrative Data, item (d) Incremental Funding is removed.

Below are additional Questions and Answers:

Q9. The deliverables for the program include 7 grams of each of the three antibodies. Are these antibodies intended for injection into humans?

Answer: Yes

Q10. Is the initial formulation a liquid formulation, and to what parameter of time (months), do the individual antibodies need to be stable in order to ensure integrity for the intended use?

Answer: The initial formulation is liquid. The offeror should propose an expected stability based on industry standards.

Q11. If stability study is not performed at this time, with concentration of 30mg/ml, there are some concerns about precipitation, depending on storage conditions. What assumptions should we be using to address this?

Answer: The Offeror should propose the best conditions including storage and concentration for stability of the product and storage as a bulk drug substance suitable for eventual vialing.

Q12. You advised that we should be ready for a pre-award inspection for IND readiness. who (what organization) will be doing the inspection (FDA, consultant, NIAID, other ?) and when?

Answer: Pre-award inspection is likely to be performed by NIAID contract consultants and NIAID staff.

Q13. In reference to RFP-NIH-NIAID-DMID-PR2004-01, on page 5, Deliverable 3 reads: "Master production records for non-GMP pilot lots prior to initiation of non-GMP pilot lot production". Is this the deliverable or was there a typo, intending to ask for "Master production records for non-GMP pilot lots prior to initiation of cGMP pilot lot production"?

Answer: It is not a typo.