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September 26, 2005

Division of Dockets Management (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**Re: Docket No. 2004D-0333, OC 200461: Draft Guidance: Emergency Use
Authorization of Medical Products**

Dear Sir or Madam:

Elusys Therapeutics, Inc. (Elusys) is pleased to submit comments on the draft guidance identified above, and understands that the intention of this draft guidance is to provide information on the Agency's general recommendations and procedures for issuance of Emergency Use Authorization (EUA). Further, Elusys agrees with and understands the Agency's decision/suggestion to allow a wide degree of flexibility in the amount of data on efficacy and safety for an agent submitted for EUA under Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Elusys provides the following comments for your consideration.

1. Elusys agrees that the "may be effective" standard rather than the "effectiveness" standard is appropriate. Similarly, the Company agrees that the decision for granting EUA should be on a case-by-case basis.
2. Elusys suggests that the standard for safety in this guidance, the above notwithstanding, should be a requirement for an allowed Investigational New Drug (IND) or Investigational Device Exemption (IDE). With such a standard, the population exposed to the drug or served by the device would be assured that toxicity data were on file with the Food and Drug Administration. The population served would also be assured that the control of the manufacture of the drug or device met minimum FDA standards.
3. If the Agency decides to allow the standard to be less than an IND or IDE, Elusys strongly suggests that the minimum safety data be set as toxicity study(s), GLP or non-GLP.
4. Similar to comment #3, if the Agency decides to allow the standard to be less than an IND or IDE, Elusys also strongly urges that the minimum efficacy data to meet the "may be effective" standard be set as preclinical animal data, not merely *in vitro* demonstration of activity.
5. Similar to comment #3, if the Agency decides to allow the standard to be less than an IND or IDE, Elusys strongly suggests that the minimum standard for manufacturing to be that the EUA applicant demonstrate the ability to provide

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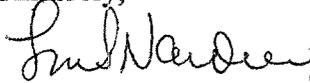
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material that meets purity and impurity criteria required in an IND by the Agency and Division for that class of investigational agent.

Elusys appreciates the opportunity to comment on this document and looks forward to further information from the Food and Drug Administration, its Office of Counterterrorism Policy and Planning, and the Department of Health and Human Services in their attempts to fulfill their responsibilities regarding the emergency use of medical products under Section 564 of the FD&C Act.

If you have any questions regarding the enclosed comments, please contact the undersigned at (973) 808-0222 or lnardone@elusys.com

Sincerely,



Linda L. Nardone, Ph.D., RAC
Vice President, Regulatory and Clinical Affairs and Quality