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Comments on Proposed FDA Rule on Determining Donor Suitability 7802 300 550 11 :25

### C. General Requirements:

#### 4 Quarantine and Disposition

We believe that the exceptions for directed donor reproductive tissue is appropriate. With regards to use of anonymous donor reproductive tissue from a donor with known high risk behavior we believe that the exception should apply for women seeking a second child by the same donor with the same conditions as apply to directed donors.

### D Donor Screening

#### 1271.75(d) abbreviated donor screening

Many anonymous semen donors donate 2-3 times per week. We believe it is impractical to conduct abbreviated screening at each donation. Our current practice is to conduct abbreviated screening every 3 months at which time we obtain an updated health history, perform infectious disease testing and obtain a high risk behavior history. Of course the donors are instructed to inform us at *any time* if they have a change in their health status.

We believe that requiring a complete donor-suitability determination at least every six months is unnecessary and impractical since the health status of active donors is *continually* monitored. We perform an abbreviated physical examination every 12 months on active donors. Since interval health histories and infectious disease testing is performed every 3 months we believe it is necessary to repeat only the physical exam at the 12 month rescreening. A repeat donor medical history is also unnecessary as changes in this area are also identified at the 3 month rescreen interval.

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1271.80 (.d)

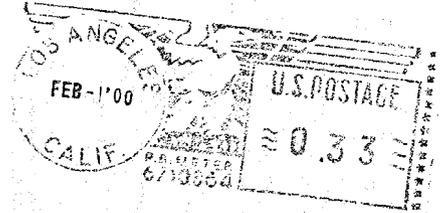
Regarding CMV we believe that, for reproductive cells, it is unnecessary to require that the CMV status accompany the product as about 40% of semen donors are CMV antibody (IgG) positive. It is rare for the inseminating physician to review this information. Therefore this information is provided only upon request.

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21-00

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