January 2025 Final Sepsis Guidance	May 2025 Draft Sepsis Guidance
This guidance is for immediate implementation. FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2) without initially seeking prior comment because the agency has determined that prior public participation is not feasible or appropriate. **January 2025**	**This guidance is for comment purposes only.** **May 2025**
INTRODUCTION This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. This guidance supersedes information regarding sepsis included in . . .2007 HCT/P DE Guidance, by updating recommendations . . . FDA is implementing this guidance without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (see 21 CFR 10.115(g)(2)). FDA made this determination because there is an urgent public health need for updated recommendations in making a donor eligibility determination to reduce the risk of transmission of infections due to sepsis by HCT/Ps. This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices (see 21 CFR 10.115(g)(3)).	**INTRODUCTION** This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. This guidance updates information regarding sepsis included in . . . 2007 HCT/P DE Guidance, and when finalized, will update recommendations ... FDA has determined that there is a need for updated recommendations in making donor eligibility determinations to reduce the risk of transmission of infections due to sepsis by HCT/Ps. When finalized, this guidance will provide specific recommendations to reduce the risk of transmission of disease agents associated with sepsis by HCT/Ps and supersede information in the August 2007 HCT/P DE Guidance regarding sepsis.

BACKGROUND In addition, the CDC reports that, in a typical year, at least 1.7 million adults in America develop sepsis, at least 350,000 adults who develop sepsis die during their hospitalization or are discharged to hospice, and 1 in 3 people who die in a hospital had sepsis during that hospitalization (Ref. 4).	**BACKGROUND** In addition, the CDC reports that, in a typical year, sepsis contributes to at least 1.7 million adult hospitalizations, and at least 350,000 deaths annually. (Ref. 4).
Screening a Donor for Risk Factors and Conditions of Sepsis In accordance with 21 CFR 1271.75(d), you must determine to be ineligible any potential donor who is identified as having a risk factor for sepsis. The following conditions should be considered a risk factor: 1. Persons who, currently, are known to have a medical diagnosis of sepsis or suspicion of sepsis (Refs. 1-6).	**Screening a Donor for Risk Factors and Conditions of Sepsis** In accordance with 21 CFR 1271.75(d), you must determine to be ineligible any potential donor who is identified as having a risk factor for sepsis. The following condition should be considered a risk factor: 1. Persons who currently, are known to have a medical diagnosis of sepsis or suspicion of sepsis from their most recent healthcare facility stay or visit preceding HCT/P recovery that is not documented as resolved. (Refs. 1-6).
Screening a Donor for Clinical Evidence of Sepsis 1. medical records of a potential donor from their current hospital stay or other healthcare facility stay preceding HCT/P recovery, that document sepsis, bacteremia, septicemia, sepsis syndrome, systemic infection, systemic inflammatory response syndrome (SIRS) due to infection, or septic shock (Refs. 1-6, 19-22);	**Screening a Donor for Clinical Evidence of Sepsis** 1. medical records of a potential donor from their current healthcare facility stay preceding HCT/P recovery, that document sepsis, bacteremia, septicemia, sepsis syndrome, systemic infection, systemic inflammatory response syndrome (SIRS) due to infection, or septic shock, that is not resolved. (Refs. 1-6, 19-22);

2. clinical evidence exhibited by a potential donor that is consistent with risk of systemic infection and whose immune system was weakened and unable to respond to infection (i.e., immunocompromised or immunosuppressed, such as due to age, a medical condition, or medication), or who is a sepsis survivor. In this scenario, you should document your communication with the patient's primary treating physician to obtain additional information regarding their patient's potential for higher risk of sepsis (Refs. 1-6, 19-22).	2. clinical evidence of current systemic infection exhibited by a potential donor whose immune system was weakened and unable to respond to infection (i.e., immunocompromised or immunosuppressed, such as due to age, a medical condition, or medication), or who is a recent sepsis survivor. In this scenario, when feasible and appropriate, you should communicate (and document your communication) with the patient's primary treating physician to obtain additional information regarding their patient's potential for higher risk of sepsis (Refs. 1-6, 19-22).
If available medical records did not document sepsis risk as described in listing 1. above, and your communication with the patient's primary treating physician in listing 2. above was not conclusive, you should consider the following indicators of higher risk for sepsis when making a donor eligibility determination (Refs. 1, 19-25): • Possible signs of sepsis may include altered mentation, hypoxemia, elevated lactate, oliguria, hypotension, renal dysfunction, elevated bilirubin, and/or multi-system organ failure. • Prolonged stays (>7 days) in an intensive care unit. • Positive blood cultures, although sepsis may be present without a positive blood culture.	If available medical records did not document sepsis risk as described in listing 1. above, and any applicable communication with the patient's primary treating physician in listing 2. above was not conclusive, you should consider the following indicators of higher risk for sepsis when making a donor eligibility determination (Refs. 1, 19-25): • Possible signs of sepsis may include altered mentation, hypoxemia, elevated lactate, oliguria, hypotension, renal dysfunction, elevated bilirubin, and/or multi-system organ failure. • Prolonged stays (>7 days) in an intensive care unit. • Positive blood cultures, although sepsis may be present without a positive blood culture.

Screening a Donor for Physical Evidence of Sepsis Unless an exception identified in 21 CFR 1271.90(a) applies, in accordance with 21 CFR 1271.75(d)(1), you must determine to be ineligible any potential donor who has a risk factor for or clinical evidence of sepsis. The following is an example of physical evidence associated with disease agents that can cause sepsis: 1. Unexplained generalized rash or fever (Refs. 26-27).	**Screening a Donor for Physical Evidence of Sepsis** Identical verbiage
Testing a Donor for Evidence of Sepsis As stated previously, there are no specific testing measures that detect sepsis that serve to prevent the transmission of a pathogen that causes sepsis. However, testing for pathogens that may cause sepsis is available and results of testing should be considered when making a donor eligibility determination.	**Testing a Donor for Evidence of Sepsis** Identical verbiage
IMPLEMENTATION FDA recommends that you implement the recommendations in this guidance as soon as feasible, but not later than 4 weeks after the guidance issue date.	Section omitted
REFERENCES **1 - 27**	**REFERENCES** Identical