

Medical News

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New FDA Guidance for Blood Donors Exposed to Anthrax or CJD

The Food and Drug Administration (FDA) has released recommendations for assessing blood donor suitability and blood product safety in the event of exposure to anthrax. The document, *Guidance for Industry: Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax*, includes recommendations for donor deferral, product quarantine and retrieval, and notification of prior transfusion recipients. Although the FDA is soliciting public comment, it is implementing this guidance document immediately due to public health concerns.

The FDA also updated recommendations intended to reduce the risk of exposure to Creutzfeldt–Jakob disease (CJD) and the human form of “mad cow disease” known as variant CJD (vCJD). The recommendations minimize the possible risk of transmission of CJD and vCJD from blood and blood products. The document, *Revised FDA Guidance on Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt–Jakob Disease (CJD) and Variant Creutzfeldt–Jakob Disease (vCJD) by Blood and Blood Products*, provides comprehensive guidelines for all registered blood and plasma establishments for deferral of donors at high risk and supersedes documents issued in November 1999 and August 2001.

FROM: U.S. Food and Drug Administration (www.fda.gov).

OSHA Reopens TB Record, CDC Revises TB Guidelines

A proposed regulation for preventing occupational exposure to tuberculosis (TB) has been delayed since the Occupational Safety and Health Administration (OSHA) issued it in 1997. OSHA announced in the January 24, 2002, issue of the *Federal Register* that it is reopening the TB record to obtain public comment on TB risks and the findings of the Institute of Medicine's Committee on Occupational TB Exposure. Comments are limited to the draft final risk assessment and are due by March 25, 2002. Additional information is available in the Federal Register Online via GPO Access (www.access.gpo.gov).

The Centers for Disease Control and Prevention (CDC) is also in the process of revising its 1994 *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Facilities*. Plans are under way for the

CDC revision to address a reduction in the frequency of skin testing for most settings, an expanded scope to include outpatient and non-facility-based services, and expanded information on ultraviolet germicidal irradiation and portable air cleaners.

FROM: Occupational Safety and Health Administration. Occupational exposure to tuberculosis. *Federal Register* 2002;67:3465; Centers for Disease Control and Prevention (www.cdc.gov).

UK Rescinds Recommendation for Disposable Instruments to Reduce Risk of CJD

The United Kingdom's Department of Health recently announced the reintroduction of reusable surgical instruments for tonsillectomy and adenoidectomy surgery. This decision was prompted, in part, by adverse events (eg, increased bleeding in tonsillectomy patients) following the introduction of disposable instruments. The use of reusable surgical instruments was stopped in January 2001 because of concerns related to the risk of transmission of variant Creutzfeldt–Jakob disease (vCJD). The Spongiform Encephalopathy Advisory Committee (SEAC) said there was a theoretical risk of transmission from reusable surgical instruments because the infective prion agent is not completely destroyed by normal sterilization.

The SEAC had endorsed using tonsillectomy as a pilot scheme to assess the impact of using single-use instruments in clinical practice. The Department of Health and Medical Devices Agency investigated the incidents and initially issued a hazard notice in October 2001, but was eventually forced to suspend the routine use of single-use instruments. The Agency said it has found that other single-use instruments have led to adverse incidents that are an actual risk to patients compared with the theoretical risk of vCJD transmission.

FROM: UK Department for Environment, Food & Rural Affairs (www.defra.gov.uk).

Hepatitis B Immunization of Infants: Pediatrician Practices

Researchers from the Centers for Disease Control and Prevention recently conducted a survey of pediatricians to explore practices and attitudes toward administration of the first dose of hepatitis B vaccine to infants.