別紙様式第２－１

医薬品　研究報告 調査報告書

識別番号・報告回数			報告日	第一報入手日	新医薬品等の区分	総合機構処理欄
一般的名称	－		研究報告の公表状況	http://www.fda.gov/cber/gdlns/wnvguid.pdf	公表国 米国	
販売名（企業名）	－					

研究報告の概要	使用上の注意記載状況・その他参考事項等
輸血によるウェストナイルウイルス（WNV）伝播リスクに対する手段として、供血者から「供血後の疾患の報告」または「受血者における WNV 感染の報告」に基づく成分の回収・隔離に関する改訂勧告を提案。 供血者が後に WNV の医学的診断を報告した場合、関連する血液からの有効期限内の成分を迅速に隔離し、回収すること。最近、WNV に関する症状がなく、WNV 抗体試験の結果のみが陽性である場合、採血時点でミニプール（MP）または個別（IDT）の NAT 試験結果が WNV 陽性でなかったのであれば、隔離・回収の理由とはならない。 以前に採取した有効期限内の血液の隔離・回収を決定した場合は、迅速にそれを行い、供血者が症状を発現するまでの 14 日間の無症状潜伏期間から症状発現後 120 日までの期間の供血血液を回収すること。 発熱を伴わない軽度の上気道感染の症状を報告した供血者または蚊に刺されたことのみを報告した供血者については、その血液または血液成分の隔離・回収を行う必要はない。 原料血漿、回収血漿または原料白血球の隔離・回収を行うことを決定した場合、それらが既に分画のためにプールされていたとすれば、その製品を隔離・回収する必要はない。全ての血漿分画製剤のウイルス除去工程を審査した結果、適切な方法で WNV と関連するフラビウイルスが不活性化されることを確認できた。	

報告企業の意見	今後の対応
血漿分画製剤での WNV 感染伝播の報告はなく、製造工程中に WNV と同じフラビウイルスであるウシ下痢症ウイルス（BVDV）の不活化除去が確認された工程を設けているが、今後とも関連情報に注意していく。	今後とも WNV に関連する情報の収集に努めていく。

Guidance for Industry

Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection

Additional copies of this guidance are available from the Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448 or by calling 1-800-835-4709 or 301-827-1800, or from the Internet at http://www.fda.gov/cber/guidelines.htm.

For questions on the content of this guidance, contact the Division of Blood Applications, Office of Blood Research and Review at 301-827-3524.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
June 2005

Contains Nonbinding Recommendations

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Guidance for Industry

Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate FDA staff. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance document finalizes the draft "Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection," dated April 2005, and provides revisions to our previously published final guidance entitled "Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection," dated May 2003. We, FDA, recommend that these revised recommendations be applied prospectively, i.e., that actions taken under previous guidance do not need to be reconsidered subject to the additional provisions of this guidance. This guidance revises the final May 2003 West Nile Virus (WNV) guidance to add a recommendation to defer donors suspected of having WNV infection or diagnosed with WNV infection for 120 days after diagnosis or onset of illness, whichever is later.

This guidance further recommends that donors be deferred on the basis of a reactive investigational screening test for WNV. At their discretion, blood establishments may reenter such donors after 120 days from the date of their reactive donation. Although we are not at this time recommending additional testing of the donor during the recommended 120 day deferral period, individual donation testing using a nucleic acid test (IDT NAT) for WNV on a follow-up sample obtained during the 120 day deferral period will provide useful additional scientific information on the duration of WNV viremia in donors. If such a follow-up sample is reactive for WNV, we recommend that the donor be deferred for an additional 120 days from the date the sample was collected.

This guidance applies to Whole Blood and blood components intended for transfusion and blood components intended for use in further manufacturing into injectable products or non-injectable products, including recovered plasma, Source Leukocytes and Source Plasma. Within this document, "donors" refers to donors of all such products, and "you" refers to blood establishments. We use the term "typical WNV season" to mean May 1 to November 30; however, isolated WNV infections may occur at any time during the year. We recommend that