0910-0500 FDA's Rapid Response Survey Summary of Survey Conducted

FDA's Center for Biologics Evaluation and Research sought to use the Rapid Response Generic Survey to develop in collaboration with the blood collecting organizations a system to rapidly survey and analyze the responses of past and potential future blood donors from donor lists maintained by blood collecting organizations using electronic means (e.g. email, web surveys). It was entitled: "Hepatitis E virus-exposure rapid survey of blood donors".

## What was the problem to be investigated?

Hepatitis E virus (HEV) is an EID that causes 20 million cases worldwide and is estimated to cause 56,600 Hepatitis E related deaths per year. HEV prevalence in the U.S. general population is low, but HEV represents a threat because of its prevalence in U.S. swine herds and potential exposures to blood donors who travel to developing parts of the world. Transfusion-transmitted HEV is a problem in the U.S. because some blood donors who have HEV can be asymptomatic and there are no approved screening tests for HEV contaminated blood at present. The survey asked past blood donors on their likelihood of exposure to HEV.

## The method used to obtain the convenience sample.

Each of five BCO's constructed a sample frame from their organizational list of blood donors. The sample frame included only individuals who were at least 18 years of age, are allogeneic donors, and have donated blood at least once in the last year. In addition, the sample frames were limited to those individuals who have provided contact information including either email address or cell phone number. Each BCO selected a random sample of donors from its sample frame. The selected donors were contacted by email and asked to complete a short web-survey on the NORC web site on potential exposures to HEV. Response to the survey was entirely voluntary and donors will be asked for consent to participate. There was no incentive offered to participate.

## Burden imposed.

Candidate respondents received an email message from their BCO directing them to the NORC website. At the NORC website, candidate respondents read the introduction to the survey and consent form. After consenting to the survey, respondents answered as few as 4 questions or as many as 7 questions presented to them depending on their state of residence and/or behavior. The total burden for this collection of information was estimated to take 417 hours.