Draft QUICK SUMMARY
for the
Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC)

on February 8, 2005

This quick summary provides an unofficial overview of the February 8, 2005 TSEAC meeting until transcripts are available.

The Committee received an update on the USDA, BSE surveillance program in the United States by Dr. Lisa Ferguson, APHIS, USDA

Topic # 1 - Possible vCJD Risk from Investigational Coagulation Factor XI Manufactured before 1998 from Plasma of Donors Residing in the United Kingdom

After listening to Dr. Mark Weinstein, FDA, summarize the issues related to this topic, the Committee listened to a presentation on "Risk Assessment – U.K. plasma derivatives, risk assessment methods and assumptions and U.K. actions based on risk assessment" by Dr. Kate Soldan and Ms. Anna Molesworth, from the U.K. Healthy Protection Agency. The Committee then listened to a presentation entitled "Risk assessment for U.K. Factor XI (FIX)" by Dr. Steven. Anderson, FDA and a presentation on "Current public health recommendations on management of surgical instruments used on patients with TSE or TSE risk" by Dr. Lynne Sehulster, from Center for Disease Control and Prevention. During the open public hearing session the Committee also listened to a presentation from Dr. Samuel O. Coker, of Pall Medical on the effectiveness of new filter technology to remove prions.

The Committee was then asked to comment on the FDA vCJD risk assessment for Factor XI manufactured from U.K. plasma, with regard to the model as applied to FXI; and any additional information that is needed to improve risk estimates for this FXI product.

The Committee stated that the risk assessment model was valid, and logically developed. Members agreed with Dr. Anderson, that there are abundant uncertainties and not everyone will agree with all the assumptions that went into the model. The model is a very good start, however, it will need refining in the future. There was strong agreement that more data are needed for better assessment. This need for more data and testing was restated several times throughout the meeting. Some members expressed concern about how the model would be applied and what the public would be told. There was agreement that the model would help to assess the probability of exposure to infectious agent, if not the actual risk that recipients have been infected, but that planning also had to address the significance of estimated exposure prior to notifying patients.

It was recommended that we find out what the UK has been telling Factor XI recipients. Several members stated that the issues related to Factor XI did not suggest high levels of risk, and they did not want to cause any unnecessary alarm.

Topic # 2 – Developing Risk Assessment Models for Potential Risk of Exposure to variant Creutzfeldt-Jakob Disease (vCJD) Agent in other Plasma Products

The Committee listened to a presentation entitled "Preliminary Risk Assessment – U.S. Potential TSE clearance steps in U.S. products - FVIII, FIX, IGIV" by Dr. Dorothy Scott, FDA and a presentation on "Risk Assessment Model for U.S. plasma derivatives" by Dr. Steve Anderson, FDA.

FDA requested the Committee to discuss and comment on the U.S. risk model per se, and any additional information that is needed to improve risk estimates for the various plasma derivative.

Again the members stated that the risk assessment model was a good model that will need additional refining as more information is collected. Members of the Committee expressed concern that, since there was variability in how U.S. manufacturers produced their products, different products and different methods of production will have different risks that need to be considered. Committee members also recommended that other factors such as travel history of the donors might appropriately be considered in future models. The short period of stay in the UK (one month in 1989) by a Japanese traveler who later came down with vCJD was discussed as an issue of concern, as a reminder that current deferral of blood donors who were in the UK for total periods of three months or more (1980 through 1996), while reducing risk, does not guarantee that every infected donor has been deferred.

Topic # 3 – Potential Deferral of Blood and Plasma Donors for History of Transfusion in European Countries

The Committee listened to presentations on "Epidemiology of vCJD in France and risk assessments for blood and plasma derivatives" written by Dr. Jean-Philippe Brandel, Neurologist, Epidemiosurveillance Network (who could not attend the meeting so the talk was co-presented by Drs. Pedro Piccardo and Stephen Anderson, FDA) and a presentation on "Estimates of blood-borne vCJD risk in the U.K. and other European populations" by Dr. Sheila M. Bird, Medical Research Council Biostatistics Unit, Institute of Public Health, Cambridge University, and a presentation on "Risks and benefits of deferring donors transfused in France and other European countries: potential impact on blood

and plasma supplies" by Dr. Alan Williams, FDA. The Committee also listened to presentations during the open public hearing session from the following organizations, American Association of Blood Banks, America's Blood Centers, and the New York Blood Center. These organizations agreed that deferral of individuals transfused in France would not significantly affect the U.S. blood supply, however, additional restrictions will increase the complexity of the donor questionnaire and might have some additional effect in discouraging blood donors. One organization recommended that, as the epidemics of BSE and vCJD decrease in magnitude, an "exit strategy" to relax current vCJD blood safety policies should be considered.

Committee members noted an earlier decision in France to defer all transfusion recipients, but agreed that any recommendation for the US should be based on the available scientific data and not on the French policy decision per se.

The Committee then discussed the following questions:

1. Based upon the available scientific information, does the committee recommend deferral of blood donors transfused since 1980?

a. In France?

The Committee voted: 12 yes (in favor of deferral), 3 no, 1 abstained. (The industry representative's (IR's) position was not to recommend deferral.)

b. In other countries of Europe?

The Committee voted: 0 yes, 15 no (against deferral), 1 abstained. (The IR's position was not to recommend deferral.)

2. Based upon the available scientific information, does the committee recommend deferral of Source Plasma donors transfused since 1980?

a. In France?

The Committee voted: 5 yes, 7 no, 4 abstained. (The IR's position was not to recommend deferral.)

b. In other countries of Europe?

The Committee voted: 0 yes, 16 no, 0 abstained. (The IR's position was not to recommend deferral.)

Please refer to the committee transcripts for a detailed account of the meeting.