Variable: D_i - The average duration of time for interval i (months) (same variable used above in section A-IV. C. 1.)

Variable: $DR_{R\text{-}EU(age),y}$ - The number of recovered plasma donors who traveled to countries in Europe (other than the UK and France) in year y by age group

Variable: $Perc_{BIDR\text{-}EU/FEU}$ - The percentage of blood donors who traveled for a specific duration interval i among all donors who have ever traveled to countries in Europe (other than the UK and France) (calculated in A-IV. C. 1. c. i).

Variable: $DR_{R\text{-}EU(age)y,i}$ - Number of recovered plasma donors within a specific age group who have traveled to countries in Europe (other than the UK and France) in year, y ,for duration of i.

$$DR_{R-EU(age)y,i} = DR_{R-EU(age)y} \times Perc_{DR-EU/EU} \qquad \text{(IV.C.1.c-13)}$$

A-IV.C. 1. c. iii. US recovered plasma donors who traveled to countries in Europe: Adjustment of relative risk for the proportion of exposure to the BSE agent per year and by duration of travel and by age group

As indicated in previous sections the FDA model assumed that the relative vCJD risk for UK residents residing for any five-year period or longer from 1980 through 1996 is assumed to have a value of 1, because exposure to BSE in the UK was greater than that of any other country. The relative risk value of 1 equates to 100% of the UK asymptomatic and symptomatic vCJD prevalence, which is difficult to estimate. Again, based on information in FDA guidance (2002), the relative risk value for France was assumed to be 0.05 (or 5% of the UK risk). The relative risk value is assigned based on factors such as domestic UK beef consumption, and the rate and number of vCJD cases, and indigenous BSE cases that may have occurred (FDA 2002). Countries in Europe (other than the UK and France) received meat and bone meal from the UK during the BSE epidemic and approximately 1.5% of their beef was imported from the UK. Additionally, the model included calculations on the estimated duration of travel or residence in Europe by US plasma donors to generate a more accurate vCJD risk estimate. Current US vCJD geographic deferral policy defers blood donors with a history of residence in countries in Europe (other than the UK and France) for a period of 5 years or more since 1980; this policy does not include Source Plasma donors.

A-IV. C. 1. c. iii. a. Number of US recovered plasma donors with a history of travel to countries in Europe: Average accumulated vCJD risk for donors since 1980, assuming that the average accumulated risk for a UK individual since 1980 is 1

This section calculates the number of US plasma donors with a history of travel to countries in Europe (other than the UK and France) and their average accumulated vCJD risk since 1980, assuming that the average accumulated risk for a UK individual since 1980 is 1.

Variable: R_{EU} - Ac– The cumulative vCJD risk of an individual resident of countries in Europe (other than the UK and France) from 1980 till now; assuming the accumulated risk of a UK individual from 1980 through 1996 is 1.

Assumption used in the model: The average accumulated vCJD risk for travel to countries in Europe (other than the UK and France) by an individual resident since 1980 was assumed to be 0.015 relative to 1, the average accumulated risk of UK individual since 1980, based on UK. It was assumed that approximately 1.5% or less of the beef imports, imported into many countries since 1980 was imported from the UK. The 0.015 relative risk value also considers the number of human vCJD cases present and the presence of indigenous BSE in European countries (other than the UK and France) since 1980.

A-IV. C. 1. c. iii. b. US plasma donors with a history of travel to countries in Europe: Proportional risk per individual resident per year since 1980

Variable: Y_{epi} –*y* Years of BSE epidemic in countries in Europe (other than the UK and France).

Variable: BSE_{UKy} Annual numbers of reported BSE cases in the UK.

Variable: BSE_{EUy} - Annual numbers of reported BSE cases in European countries other than the UK and France.

Data used in the model: Data on the annual number of reported cases of BSE in cattle in European countries was obtained from the Orgainization Internationale de Epizootics (OIE) (2005).

Variable: R_{EUy} - Proportional vCJD risk for European countries (other than the UK and France) in a specific year

Assumptions used in the model:

- The risk of vCJD and BSE in European countries (other than the UK and France) has been present since 1980 and continues to present day. As of August 2006, very few cases of BSE continue to be reported in European countries (other than the UK and France)..
- The vCJD risk is assumed to be additive, and can be prorated on a yearly or monthly basis.
- The yearly rate of the vCJD risk in European countries (other than the UK and France) is proportional to the reported BSE annual cases in Europe (including indigenous and imported cases)

A-IV. C. 1. c. iii. b. US recovered plasma donors with a history of travel to countries in Europe: Potential vCJD risk for an individual in year y for a period of i since 1980

Variable: $R_{DR\text{-}EUy_{n,i}}$ - Risk for individual US donors who traveled to countries in Europe other than the UK and France in a specific year for a specific duration, assuming the accumulative risk of a UK person resident in the years 1980 through 1996 is 1.

The vCJD risk for the US plasma donors with less than 5 years accumulated stay in Europe was calculated based on travel to European countries other than the UK and France in a specific year for a specific duration of travel. Potential exposure risk was calculated using a prorated monthly rate, which was calculated based on the yearly rate of the risk (1 month = 1/12 x yearly risk) in Europe during the year of travel. US plasma donors with a total accumulated stay in countries in Europe (other than the UK or France) of 5 years or more is assumed to have average risk of 0.015, which is the same as the risk of an individual citizen or long-term resident of a country in Europe (other than the UK or France). Information on duration of accumulated stays was collected in the blood donor travel survey; however, for simplicity we assumed all travel was consecutive. The blood donor travel survey (TSEAC 2000) collected information on the accumulated stay of US donors who stayed in Europe (other than the UK or France) from 1980 through 1996. For simplicity, these data were used to estimate the duration of consecutive stay, which was used to calculate the potential vCJD risk for recovered plasma donors.

Assumptions used in the model:

- Risk is proportional to the duration of the stay
- All the travelers' stays were assumed to be single and consecutive stays.
- US plasma donor subpopulation having 5 or more years accumulated stay in countries in Europe (other than the UK or France) have an average risk of 0.015, which is the same as the average risk of individual European resident.

For < 1 year;

$$R_{DR-EUy,i} = (Average(R_{EUy} : R_{EU(y+1)})/12) \times D_i \qquad \text{(IV. C. 1. c-14)}$$

for 5 years <i>=1 year;

$$R_{DR-EUy,i} = 0.015 \qquad \text{(IV. C. 1. c-15)}$$

for i>= 5 years

A-IV. C. 1. c. iv. US recovered plasma donors with a history of travel to countries in Europe: Probability of vCJD infection for a donor of a specific age group, who traveled in a specific year for a specific duration, i

This section describes the portion of the model that estimates the potential probability that a US plasma donor in a specific age group, who traveled to countries in Europe (other than the UK or France) for a specific duration since 1980 was infected with vCJD.

Variable: $Pr_{vCJD\text{-}UK(age)}$ – the probability of infection for an individual UK resident of a specific age group (calculated in A-IV. C. 1. a. iv.).

Variable: $Pr_{vCJD\text{-}DR\text{-}EU(age)y,i}$ - Probability of infection for an individual US plasma donor of a specific age group who have traveled to countries in Europe other than the UK and France in a specific year with specific duration.

Assumption used in the model: The probability of vCJD infection is proportional to the risk of exposure

$$\Pr_{vCJD-DR-EU(age)y,i} = \Pr_{vCJD-UK(age)} \times R_{DR-EUy,i} \quad \text{(IV.C.1.c-16)}$$

A-IV.C. 1. c. v. Number of US recovered plasma donors with a history of travel to countries in Europe: Number potentially infected with vCJD.

Variable: $DR_{vCJD\text{-}R\text{-}EU(age)y,i}$ - Number of recovered plasma donors potentially infected with vCJD during travel to countries in Europe (other than the UK and France) since 1980 by age, year and duration of travel

$$DR_{vCJD-R-EU(age)y,i} = Bionomial(DR_{R-EU(age)y,i}, \Pr_{vCJD-DR-EU(age)y,i}) \quad \text{(IV.C.1.c-26)}$$

Variable: $DR_{vCJD\text{-}R\text{-}EUy}$ - Total number of recovered plasma donors potentially infected with vCJD in year y

$$DR_{vCJD-R-FRy} = \sum_{Age=18-19}^{50-54} \sum_{i=1day-3months}^{>=5years} DR_{vCJD-R-FR(age)y,i} \quad \text{(IV.C.1.c-27)}$$

Variable: $DR_{vCJD\text{-}R\text{-}EU\text{-}Defy}$- Number of recovered plasma donors potentially infected with vCJD in year y and deferred by current policy

Current FDA guidance (FDA 2002) recommends deferral of individuals who have history of travel to countries in Europe (other than the UK or France) since 1980 for an accumulated stay of 5 years or more from donating blood. The number of potential vCJD-infected recovered plasma donors who meet current deferral criteria (FDA 2002) was calculated by the equation:

$$DR_{vCJD-R-EU-Defy} = \sum_{Age=18-19}^{50-54} DR_{vCJD-R-EU(age)y,i>=5years} \quad \text{(IV.C.1.c-28)}$$

Variable: $DR_{vCJDS\text{-}EU\text{-}Resy}$ – The residual risk associated with recovered plasma donors potentially infected with vCJD that meet deferral criteria but because of limitations in the donor screening process and are not deferred by current policy; is represented by the equation:

$$DR_{vCJD-R-EU-Resy} = \sum_{Age=18-19}^{50-54} \sum_{i=1-30days}^{>=3-5years} DR_{vCJD-R-EU(age)y,i} \quad \text{(IV.C.1.c-29)}$$

A-IV. C. 1. c. vi. Number of US recovered plasma donors who traveled to countries in Europe: Number potentially infected and vCJD agent is present in the blood

The most critical component of the model is the estimation of whether a plasma donation was collected from a vCJD infected donor that contained infectious vCJD agent in their blood (or was prionemic) at the time of donation. Based on data from animal studies, the model assumes that vCJD infectious individuals have infectious vCJD agent present in the blood during the last half of the incubation period. This portion of the model calculates the number of recovered plasma donors who may potentially contain infectious vCJD agent in their blood at the time of donation.

Variable: Pr_{LH-y} -The probability an individual was prionemic in year 2002.

Variable: $DR_{vCJD\text{-}R\text{-}EUy}$- Total number of recovered plasma donors potentially infected with vCJD in year y during travel/residence in European countries (other than France).

Variable: $DR_{vCJD\text{-}R\text{-}EU\text{-}LHy}$ - Total number of recovered plasma donors potentially infected with vCJD in year y during travel/residence in a country in Europe (other than the UK or France) and are in the last half incubation period of the disease (and has vCJD agent present in their blood).

$$DR_{vCJD-R-EU-LHy} = Binomial(DR_{vCJD-R-EUy}, \Pr_{LH-y}) \qquad \text{(IV.C.1.c-30)}$$

Variable: $DR_{vCJD\text{-}R\text{-}EU\text{-}defy}$- Total number of recovered plasma donors potentially infected with vCJD in year y during travel/residency in European countries (other than the UK or France) and met deferral criteria and were presumably deferred from donation .

Variable: $DR_{vCJD\text{-}R\text{-}EU\text{-}def\text{-}LHy}$ - Total number of recovered plasma donors in the last half incubation period of the disease (and presumably has vCJD agent present in their blood) who met deferral criteria and were presumably deferred from donation.

$$DR_{vCJD-R-EU-Def-LHy} = Binomial(DR_{vCJD-R-EU-Defy}, \Pr_{LH-y}) \qquad \text{(IV.C.1.c-31)}$$

Variable: $DR_{vCJD\text{-}R\text{-}EU\text{-}Resy}$- Total number of recovered plasma donors potentially infected with vCJD in year y during travel/residency in countries in Europe (other than the UK or France) and did not meet the deferral criteria and were likely not deferred .

Variable: $DR_{vCJD\text{-}R\text{-}EU\text{-}Res\text{-}LHy}$ - Total number of recovered plasma donors in the last half of the incubation period of the disease who did not met the deferral criteria and were likely not deferred from donation:

$$DR_{vCJD-R-EU-Res-LHy} = Binomial(DR_{vCJD-R-EU-Resy}, \Pr_{LH-y}) \quad \text{(IV.C.1.c-32)}$$

A-IV. C. 1. d. Number of US plasma donors deployed by the military in the UK or other countries in Europe and potentially infected with vCJD

A-IV. C. 1. d. i. Percentage of US plasma donors deployed at US military bases in the UK or other countries in Europe during the years 1980 through 1996

Variable: $Perc_{DR-DOD}$ - Percentage of US blood donors who were military residents in countries in Europe for ≥ 6 months from 1980 through 1996.

Assumption used in the model: Approximately 2% of US blood donors have been military residents in European countries between 1980-1996 (TSEAC 2002). There were no data for plasma donors, therefore, data for US blood donors was used to estimate the number of US donors stationed in US military facilities during the period 1980-1996

- The FDA model assumed that the same percentage of plasma donors have been in the military and deployed in European countries as blood donors.

A-IV. C. 1. d. ii. Number of US plasma donors deployed by Military in the UK or other countries in Europe by year of deployment since 1980

A-IV. C. 1. d. ii. a. Number of US Source Plasma donors stationed at US military facilities in the UK or countries in Europe during the period from 1980 -1996 by year of deployment

Variable: y - Calendar year of deployment

Variable: $DODy$ - Number of US military residents, their family and dependents who resided on US military facilities in Europe by year from 1980 through 1996.

Assumption used in the model: The risk of BSE exposure and vCJD infection for donors previously deployed to US military facilities in the UK or countries in Europe after 1996 was assumed to be negligible, because it is assumed that most of the risk was associated with imported UK beef. Food chain controls put in place in the UK after 1996 were assumed to reduce the BSE exposure risk to negligible levels (TSEAC, 2002) and shipment of UK beef to US military facilities had stopped in 1996 or earlier.

Variable: *age* - age of donors in grouped by five-year increments (e.g., 20-24, etc.) and the 18-29 year old group (same variable used above in section A-IV.C.1.a.ii.)

$$Perc_{DR-DOD_y} = (DOD_y / \sum_{y=1980}^{1996} DOD_y) \times 100\% \quad \text{(IV.C.1.d-1)}$$

Variable: $DR_{S(age)}$ – Age of donors of Source Plasma (calculated in section A-IV.B. 1.)

Variable: $Perc_{DR\text{-}DOD}$ – Percentage of Source Plasma donors who have a history of military deployment in Europe since 1980 (calculated in section A-IV. C. 1. d. ii. a.)

Variable: $DR_{S\text{-}DOD(age)}$ - Estimated annual number of Source Plasma donors who have history of military deployment in the UK or Europe by age

Assumption about variable: We assumed 3% of Source Plasma donors have a history of military deployment and residence in the UK, France or other countries of Europe during any of the years from 1980-1996 and would have similar donation demographics and characteristics as whole blood donors.

The estimated annual number of Source Plasma donors who have a history of military deployment in Europe by age is represented by the equation:

$$DR_{S-DOD(age)} = DR_{S(age)} \times Perc_{DR-DOD} \qquad \text{(IV.C.1.d-2)}$$

Variable: $DR_{S\text{-}DOD(age)y}$ – Number estimated annual number of Source Plasma donors who have resided on military bases in Europe by age and deployment year

$$DR_{S-DOD(age)y} = DR_{S-DOD(age)} \times Perc_{DR-DODy} \qquad \text{(IV.C.1.d-3)}$$

A-IV. C. 1. d. ii. b. Number of recovered plasma donors with a history of military deployment at US military facilities in the UK or other countries in Europe during the period 1980-1996 by year of deployment

Variable: *age* - Age of donors grouped by five-year increments (e.g., 20-24, etc.) and the 18-29 year old group. No data for the yearly distribution of deployment of military plasma donors in the UK, France or other countries in Europe was available. The age distribution of donors in the military was estimated from Department of Defense (DOD) data (2005). The donation rate for military staff was estimated using the blood donor survey data (TSEAC, 2002).

Variable: $DR_{R\text{-}(age)}$ - Annual number of recovered plasma donors by age

Assumption used in the model: We assumed 3% of recovered plasma donors were grouped by deployment year based on the yearly distribution of military deployment and residence in the UK or Europe during 1980-1996 .(DOD 2005).

$$DR_{R-DOD(age)y} = DR_{R-DOD(age)} \times Perc_{DR-DODy} \qquad \text{(IV.C.1.d-4)}$$

Variable: $DR_{R(age)}$ - Annual number of recovered plasma donors by age (calculated in section A-IV.B. 2.) grouped by five-year increments (e.g., 20-24, etc.) and the 18-29 year old group

Variable: $Perc_{DR\text{-}DOD}$ - Percentage of recovered plasma donors who have a history of military deployment in the UK and countries in Europe since 1980 (calculated in section A-IV. C. 1. d. ii. a.)

Variable: $DR_{R\text{-}DOD(age)}$ - Estimated annual number of recovered plasma donors who have a history of military deployment in the UK and countries in Europe by age.

Assumption used in the model: The same percentage of recovered plasma donors have a history of military deployment as blood donors.

The estimated annual number of recovered plasma donors who have history of military deployment in the UK and countries in Europe by age is represented by the equation:

$$DR_{R\text{-}DOD(age)} = DR_{R(age)} \times Perc_{DR\text{-}DOD} \quad \text{(IV.C.1.d-5)}$$

Assumption used in the model: The annual distribution of US military service members and their dependents residing on US military bases in Europe represents the yearly distribution of deployment in the UK and countries in Europe of US military recovered plasma donors

$$DR_{R\text{-}DOD(age)y} = DR_{R\text{-}DOD(age)} \times Perc_{DR\text{-}DODy} \quad \text{(IV.C.1.d-6)}$$

A-IV. C. 1. d. iii. Adjustment of the Relative Risk for the proportional variation in the BSE exposure risk in the UK and the military deployment duration per specific year during the period from 1980 - 1996

Variable: R_{Base} - The cumulative vCJD risk of individual military personnel who were deployed and resided in the UK or Europe for the entire period from 1980 through 1996: it is assumed that the accumulated risk is equal to that of a UK resident and is assumed to be 1 (or equal to the UK vCJD prevalence) for this period.

Assumption used in the model: The cumulative risk of US military residents in Europe from 1980 through 1996 is 0.35. This estimate is based on the assumption that approximately 35% of the beef consumed by military personnel in Europe between 1980-1996 was imported from the UK (FDA 2002).

Variable: y – Year of deployment (same variable used above in A-IV. C. 1. d. ii. a.)

Variable: y_{epi} – The specific year of BSE epidemic in the UK.

Assumption about variable: The BSE epidemic in the UK was assumed to have started in 1980 and at first was not detected. The first cases of BSE were reported in 1986.

Variable: BSE_{UKy} - Number of diagnosed BSE cases in the UK by year from 1980 through 1996

Data used in the model: Data are from the World organization for animal health (OIE 2005). Data were not collected for individual years prior to 1997. A total of 446 cases of BSE were reported by European countries (other than the UK) during the time period from 1980 through 1996 and were allocated to individual years by assuming the cases were increasing in a linear fashion by year.

Variable: R_{Basey} - Proportional vCJD risk for donors that resided on US military bases in Europe in a specific year

Assumptions used in the model:

- The vCJD risk for US military facilities in Europe was present from 1980 through 1996. There was negligible vCJD risk after 1996 – the model assumed the major source of vCJD risk for US military bases in Europe was associated with imported UK beef. When food chain controls were implemented in the UK in 1996 – the model assumed the risk to be negligible.
- It was assumed that the vCJD risk was additive and can be prorated on a yearly base.
- The vCJD risk in a specific year was assumed to be proportional to the reported BSE cases in the UK in that specific year.

Proportional vCJD risk in the US military bases in a specific year was calculated by the equation:

$$R_{Basey} = R_{Base} \times BSE_{UKy} / \sum_{y=1980}^{1996} BSE_{UKy} \qquad \text{(IV.C.1.d-7)}$$

Variable: $R_{DR\text{-}DODy}$ - Risk of individual military personnel who lived in Europe for a period of two years starting from deployment year y, and assumes the cumulative risk of a UK individual from 1980 through 1996 is 1.

Assumption used in the model: The model assumed an average of two consecutive years of deployment:

$$R_{DR-DODy} = R_{Basey} + R_{Base(y+1)} \qquad \text{(IV.C.1.d-8)}$$

Variable: $Pr_{vCJD\text{-}UK(age)}$ - Probability of infection for individual UK resident of a specific age group (calculated in A-IV. C. 1.).

Variable: $Pr_{vCJD\text{-}DR\text{-}DOD(age)y}$ - Probability of infection for individual US plasma donor of a specific age group that lived on or near a US military bases in Europe starting from year y with duration of two years

Assumption used in the model: Probability of infection is proportional to the risk of exposure

$$\Pr_{vCJD-DR-DOD(age)y} = \Pr_{vCJD-UK(age)} \times R_{DR-DODy} \qquad \text{(IV.C.1.d-9)}$$

A-IV. C. 1. d. iv. Number of all US plasma donors potentially infected with vCJD during residence at a US military base in the UK or other countries in Europe from 1980 to 1996

The section estimates the number of Source and recovered plasma donors with a history of deployment in the UK or countries in Europe during the period from 1980 through 1996 and sums the number of vCJD cases that may have vCJD agent in their blood (or be prionemic) at the time of donation from each pathway to derive the total number of all donors potentially infected with vCJD that may have vCJD agent in their blood (or be prionemic).

A-IV. C. 1. d. iv. a. Potential number of US Source Plasma donors with a history of military deployment in the UK or other countries in Europe from 1980 to 1996 potentially infected with vCJD

Variable: $DR_{vCJD\text{-}S\text{-}DOD(age)y}$ - Potential number of Source Plasma donors infected during residency on US military facilities in the UK or Europe from 1980-1996 by age, and year of deployment

$$DR_{vCJD\text{-}S\text{-}DOD(age)y} = Binomial(DR_{S\text{-}DOD(age)y}, Pr_{vCJD\text{-}DR\text{-}DOD(age)y}) \qquad \text{(IV.C.1.d-10)}$$

Variable: $DR_{vCJD\text{-}S\text{-}DOD}$ - Potential number total of Source Plasma donors infected during residency on US military bases in Europe from 1980-1996 is represented by the expression:

$$DR_{vCJD\text{-}S\text{-}DOD} = \sum_{y=1980}^{1996} \sum_{age=18-19}^{70-74} DR_{vCJD\text{-}S\text{-}DOD(age)y} \qquad \text{(IV.C.1.d-11)}$$

A-IV. C. 1. d. iv. b. Potential number of Source Plasma donors with a history of deployment to a US military facility in the UK or other countries of Europe from 1980 to 1996 in the last half incubation period of the disease

This section estimates the number of Source Plasma donors that may potentially be infected with vCJD who may have vCJD agent in their blood (or be prionemic) at the time of donation.

Variable: y-The calendar year in which a plasma donor was deployed to a US military base in Europe.

Assumption used in the model: This risk assessment assesses the vCJD risk for pdFVIII product made in 2002 but it is assumed that the potential vCJD risk is similar to the present day risk in 2006.

Variable: $T_{Inf\text{-}2002y}$-Time period between infection/travel and the year 2002 when the plasma was collected.

Variable: $Pr\text{-}LH_y$- Probability that the vCJD disease is in the last half of the incubation period of the disease, if infected in year y and the individual has infectious vCJD agent present in their blood and plasma (or was prionemic).

Variable: $T_{Inf\text{-}2002y}$ - Time period between infection/travel and 2002 when the plasma was collected is represented by the expression:

$$T_{Inf-2002y} = 2002 - y \qquad \text{(IV.C.1.d-12)}$$

For an individual to be prionemic in 2002, the remaining period of time since infection up to 2002 ($I_{Inf-2002y}$) should be equal to or less than the half of incubation period of the disease.

Assumption used in the model: The variability and uncertainty of the incubation period of vCJD is represented mathematically by a gamma distribution, specifically Gamma (4.7, 3.6). A gamma distribution is usually used to represent processes that occur sequentially or the time between events. In this case it would be the time from infection to the time until the appearance of clinical disease (incubation period of the disease). The distribution is defined by two parameters: one that produces the shape of the curve; and a second generates the scale for the distribution, which in this case is represented by the mean incubation period of 14 years.

Variable: Pr_{LH-y} -The probability an individual was prionemic in year 2002-was calculated by using the cumulative frequency of Gamma (4.7, 3.6), at x=2×(1997-y)

Variable: $DR_{vCJD\text{-}S\text{-}DODy}$- Total number of Source Plasma donors potentially infected with vCJD in year y during military deployment on European bases (calculated in A-IV. C. 1. d. v. a.).

Variable: $DR_{vCJD\text{-}S\text{-}DOD\text{-}LHy}$ - Total number of Source Plasma donors potentially infected with vCJD in year y during military deployment to US military bases in European countries and in the last half incubation period of the disease.

$$DR_{vCJD-S-DOD-LHy} = Binomial(DR_{vCJD-S-DODy}, \Pr_{LH-y}) \qquad \text{(IV.C.1.d-13)}$$

A-IV. C. 1. d. iv. c. Number of US recovered plasma donors with a history of deployment to a US military base in the UK or other countries in Europe during the period 1980-1996 and potentially infected with vCJD

Variable: $DR_{vCJD\text{-}R\text{-}DOD(age)y}$ - Potential number of recovered plasma donors infected during deployment and residency on or near US military bases in Europe from 1980-1996 by age, and year of deployment

$$DR_{vCJD-R-DOD(age)y} = Binomial(DR_{R-DOD(age)y}, \Pr_{vCJD-DR-DOD(age)y}) \qquad \text{(IV.C.1.d-14)}$$

Variable: $DR_{vCJD\text{-}R\text{-}DOD}$ - Potential number of recovered plasma donors infected during residency on US military bases in Europe from 1980-1996 is represented by the equation:

$$DR_{vCJD-R-DOD} = \sum_{y=1980}^{1996} \sum_{age=15-19}^{70-74} DR_{vCJD-R-DOD(age)y} \qquad \text{(IV.C.1.d-15)}$$

A-IV. C. 1. d. iv. d. Recovered plasma donors with a history of deployment to a US military base in the UK or other countries in Europe: Potential number of donors in the last half of vCJD incubation period and vCJD agent is present in the blood

This portion of the model calculates the potential number of vCJD infected recovered plasma donors who are in the last half incubation period of the disease and presumably may contain vCJD agent in their blood (or are prionemic).

Variable: Pr_{LH-y} -The probability a vCJD-infected donor had vCJD agent present in their blood and plasma at the time of donation (was prionemic) in the year 2002 (calculated in A-IV.C.1.d.v.b).

Variable: $DR_{vCJD\text{-}R\text{-}DODy}$- Total number of recovered plasma donors potentially infected with vCJD in year y during military deployment on or near bases in Europe (calculated in A-IV. C. 1. d. v. c.)

Variable: $DR_{vCJD\text{-}R\text{-}DOD\text{-}LHy}$ - Total number of recovered plasma donors potentially infected with vCJD in year y during military deployment on or near bases in Europe and in the last half incubation period of the disease.

$$DR_{vCJD-R-DOD-LHy} = Binomial(DR_{vCJD-R-DODy}, \Pr_{LH-y}) \quad \text{(IV.C.1.d-16)}$$

A-IV. C. 1. d. iv. e. Number of all vCJD infected plasma donors during deployment to a US military base in a country in Europe from 1980-1996

Variable: $DR_{vCJD\text{-}DOD}$ - Potential number of total plasma donors infected during residence on US military bases in Europe from 1980-1996

$$DR_{vCJD-DOD} = \sum_{y=1980}^{1996} DR_{vCJD-S-DOD} + \sum_{y=1980}^{1996} DR_{vCJD-R-DOD} \quad \text{(IV.C.1.d-17)}$$

Variable: $DR_{vCJD\text{-}DOD\text{-}Def}$ - Potential number of total plasma donors infected during residence on US military bases in Europe from 1980-1996 and meet deferral criteria

Assumption used in the model: Current policy defers individuals who have been deployed or resided on a US military base in Europe from 1980 to 1996 for a cumulative stay of 6 months or more. We assumed all US Department of Defense (DOD) deployments are 6 months or longer, and therefore, all individuals have a history of deployment to a US military base in Europe are deferred.

$$DR_{vCJD-DOD-Def} = DR_{vCJD-DOD} \quad \text{(IV.C.1.d-18)}$$

A-IV. C. 1. d. iv. f. Potential number of all plasma donors in the last half of vCJD incubation period

This portion of the model estimates the potential number of all vCJD infected plasma donors with a history of military service posted at a US military base in the UK or countries in Europe fron 1980-1996 who are in the last half incubation period of the disease and their blood and plasma presumably contain infectious vCJD agent (or are prionemic).

Variable: $DR_{vCJD\text{-}DOD\text{-}LH}$ - Potential number of total plasma donors infected during residence on US military bases in Europe from 1980-1996 and are in the last half incubation period of the disease

$$DR_{vCJD-DOD-LH} = \sum_{y=1980}^{1996} DR_{vCJD-S-DOD-LH} + \sum_{y=1980}^{1996} DR_{vCJD-R-DOD-LH} \qquad \text{(IV.C.1.d-19)}$$

Variable: $DR_{vCJD\text{-}DOD\text{-}Def}$ - Potential number of total plasma donors infected during residence on US military bases in Europe from 1980-1996 and meet deferral criteria

$$DR_{vCJD-DOD-Def} = DR_{vCJD-DOD} \qquad \text{(IV.C.1.d-20)}$$

A-IV. C. 1. d. i. Percentage of US plasma donors deployed at US military bases in the UK or other countries in Europe during the years 1980 through 1996

Variable: $Perc_{DR\text{-}DOD}$ - Percentage of US blood donors who were military residents in countries in Europe for $\geq$ 6 months from 1980 through 1996.

Assumption used in the model: Approximately 2% of US blood donors have been military residents in European countries between 1980-1996 (TSEAC 2002). There were no data for plasma donors, therefore, data for US blood donors was used to estimate the number of US donors stationed in US military facilities during the period 1980-1996

- The FDA model assumed that the same percentage of plasma donors have been in the military and deployed in European countries as blood donors.

A-IV. C. 1. d. ii. Number of US plasma donors deployed by Military in the UK or other countries in Europe by year of deployment since 1980

A-IV. C. 1. d. ii. a. Number of US Source Plasma donors stationed at US military facilities in the UK or countries in Europe during the period from 1980 -1996 by year of deployment

Variable: y - Calendar year of deployment

Variable: ***DODy*** - Number of US military residents, their family and dependents who resided on US military facilities in Europe by year from 1980 through 1996.

Assumption used in the model: The risk of BSE exposure and vCJD infection for donors previously deployed to US military facilities in the UK or countries in Europe after 1996 was assumed to be negligible, because it is assumed that most of the risk was associated with imported UK beef. Food chain controls put in place in the UK after 1996 were assumed to reduce the BSE exposure risk to negligible levels (TSEAC, 2002) and shipment of UK beef to US military facilities had stopped in 1996 or earlier.

Variable: ***age*** - age of donors in grouped by five-year increments (e.g., 20-24, etc.) and the 18-29 year old group (same variable used above in section A-IV.C.1.a.ii.)

$$Perc_{DR-DODy} = (DOD_y / \sum_{y=1980}^{1996} DOD_y) \times 100\% \qquad \text{(IV.C.1.d-1)}$$

Variable: $DR_{S(age)}$ – Age of donors of Source Plasma (calculated in section A-IV.B. 1.)

Variable: $Perc_{DR\text{-}DOD}$ – Percentage of Source Plasma donors who have a history of military deployment in Europe since 1980 (calculated in section A-IV. C. 1. d. ii. a.)

Variable: $DR_{S\text{-}DOD(age)}$ - Estimated annual number of Source Plasma donors who have history of military deployment in the UK or Europe by age

Assumption about variable: We assumed 3% of Source Plasma donors have a history of military deployment and residence in the UK, France or other countries of Europe during any of the years from 1980-1996 and would have similar donation demographics and characteristics as whole blood donors.

The estimated annual number of Source Plasma donors who have a history of military deployment in Europe by age is represented by the equation:

$$DR_{S-DOD(age)} = DR_{S(age)} \times Perc_{DR-DOD} \qquad \text{(IV.C.1.d-2)}$$

Variable: $DR_{S\text{-}DOD(age)y}$ – Number estimated annual number of Source Plasma donors who have resided on military bases in Europe by age and deployment year

$$DR_{S-DOD(age)y} = DR_{S-DOD(age)} \times Perc_{DR-DODy} \qquad \text{(IV.C.1.d-3)}$$