New York *Blood Center*

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Office of the General Counsel

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September 26, 2001 ***via Fax and Express Mail***

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. 97D-0318

Dear Sir or Madame:

The New York Blood Center, Inc. (**"NYBC"**), FDA License No. 465, welcomes the opportunity to submit these comments regarding the Draft "Guidance for Industry: Revised 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 (**"Draft Revised vCJD Guidance"**), the availability of which was announced in the August 29, 2001 Federal Register. *66 Fed. Reg. 45683.*

One of the country's largest independent blood centers, NYBC supplies approximately 10% of the nation's blood supply, and is the primary blood supplier to a metropolitan area of twenty million people. For almost thirty years, NYBC has augmented its collection of blood within the United States by importing blood through NYBC's Euroblood Program, under which European collection centers enter into collaborative relationships with NYBC and collect under NYBC's FDA license. Because this imported blood accounts for approximately 25% of the blood supplied by NYBC each year, we are keenly interested in the new restrictions contained in the Draft Revised vCJD Guidance.

I. General Comments

NYBC appreciates the difficult task undertaken by the U.S. Food and Drug Administration (**"FDA"**) in formulating and issuing the Draft Revised vCJD Guidance. FDA's continuing challenge is to balance the unknown and theoretical risk of potential transmission of a fatal disease against the known and indisputable risk of significant shortages in the supply of blood in the United States. The Draft Revised vCJD Guidance demonstrates FDA's conscientious effort to protect patients by revising and expanding current preventive measures, while at the same time endeavoring to ensure an adequate supply of blood nationwide.

As FDA has acknowledged, the greatest risk to the blood supply is in the New York metropolitan area, where approximately 25% of the available blood has been imported

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from Europe through NYBC's Euroblood Program. Although the importance of ensuring an adequate supply of blood in the New York area has long preceded (and will long outlast) the tragic events of September 11, 2001, the catastrophe at the World Trade Center has helped to focus attention on this critical issue. Because of the New York area's nearly thirty-year dependency on a plentiful supply of red cells from European collection centers in the Euroblood Program, the difficulties faced by the region and NYBC in maintaining an adequate blood supply are even more acute.

The adoption of a phased timetable (i.e., May 31 and October 31, 2002 deadlines) should help ameliorate to a degree the burdens to healthcare in the New York area. And, as discussed below, NYBC suggests a further revision to that timetable that would reduce the likelihood of significant near-term shortages in the New York area. Nevertheless, the unique risk to the blood supply of the New York metropolitan community may remain for an extended period. When the Revised vCJD Guidance is implemented--if not before--the Euroblood Program will terminate, and there will be no further supply of red cells to the New York metropolitan community pursuant to that Program. It is extremely unlikely that, once dismantled, the infrastructure for the Euroblood Program will ever be reestablished.

The challenge to NYBC, FDA and other U.S. blood collection agencies, then, is to find ways to replace the red cells that the New York metropolitan community currently counts on receiving from NYBC's Euroblood Program partners. This challenge will require an unprecedented effort in vigilant monitoring, significant financial investment and a spirit of cooperation. FDA and the New York metropolitan community can be confident that NYBC will use all of its efforts to meet that challenge, and NYBC will look to FDA and other federal agencies to encourage other blood collection centers to assist NYBC during the difficult months and years ahead. NYBC also urges FDA to continue to monitor the nation's and the region's blood supply, and to review the risk/benefit analysis in light of such information and developments in the diagnosis and treatment of vCJD. NYBC encourages FDA and other federal agencies to make every effort to support the introduction of appropriate devices to screen blood and blood products.

II. Phase In

The phased implementation proposed by FDA should help establish an orderly transition to an interim period (i.e., prior to the development and implementation of blood screening measures for vCJD) for which this Draft Revised vCJD Guidance may be appropriate. As a general matter, the implementation date for Phase II, October 31, 2002, is the date by which the Euroblood Program must cease, because Euroblood donors live in Germany, Switzerland and The Netherlands, countries which FDA has designated as "BSE risk countries."

In weighing the theoretical risk of vCJD transmission to recipients of blood and blood products in the United States, NYBC notes the absence of any cautionary reference in the Draft Revised vCJD Guidance to recipients of blood from transfusions in the BSE risk countries, whether these recipients are residents, American travelers or military personnel

stationed there who may require transfusions of blood not collected under these guidelines.

France. FDA calculated the reduction of the theoretical risk of vCJD transmission from blood and blood products in terms of "reduction in total person-days of risk-weighted donor exposure to the agent of vCJD...(based on) the sum of relative risk-weighted donor exposure to the agent of vCJD." FDA also calculated the projected donor loss under this policy. Based on its calculation and judgment, FDA determined that the first phase-in date of May 31, 2002, would be appropriate for the implementation of the extension of the ban on collections from donors who have visited or lived in France for five (5) years or more since 1980.

NYBC requests that FDA move the ban on donors who have lived in/visited France to Phase II, i.e., October 31, 2002. While this suggested change in timing may help to reduce donor confusion by applying Phase II exclusions to continental Europe, this change would have a significant impact on the New York metropolitan area. Swiss donors to the Euroblood Program contribute nearly 80,000 units of red cells to New York area patients each year. NYBC believes that FDA's calculations of the impact on the blood supply did not account for the fact that most of the Swiss donors have lived in/visited France for five years or more since 1980. These Swiss donors would be excluded from donating to NYBC as early as May 31, 2002, not October 31, 2002. NYBC does not believe it would be able to replace the Swiss donations quickly enough if the Phase I deadline for France is retained. For that reason, NYBC urges FDA, in adopting its final guidance, to move to Phase II the ban on donors who have visited or lived in France for five years or more since 1980.

III. Pilot Program for More Stringent Policies

NYBC shares FDA's concern that blood establishments implementing geographic donor deferrals more stringent than the FDA-recommended policy may severely affect the availability of blood. Therefore, NYBC agrees with FDA that any more stringent policy should be the subject of a pilot program that includes, among other things, a mechanism to monitor and assess the loss of donors, the nature and effectiveness of donor recruitment efforts and fluctuations in hospital demand for blood products, as well as the development of contingency measures. NYBC suggests that any pilot program should also include prompt and regular public reporting of the results of such monitoring. These reports should be made at each meeting of BPAC and/or TSEAC, as part of the public record. This reporting could help FDA monitor the adequacy of the blood supply, and would also be of use to other blood establishments, providing early warning of problems in the availability of blood and blood products, thus helping to avoid crises in medical care.

IV. Comparative claims

As noted above, NYBC shares FDA's views on the importance of data collection and assessment as a basis for evaluating measures intended to address the theoretical risk of

vCJD transmission through human blood and blood products. As FDA has recognized, the state of knowledge simply would not support a blood establishment making a claim (express or implied) that its blood supply is somehow safer because that blood establishment had adopted measures more stringent than those proposed by FDA.

NYBC is concerned about the impact such unsupported comparative safety claims might have on healthcare providers and patients. Given the current state of knowledge regarding the risk of vCJD transmission through blood, it is not surprising that there is a great deal of confusion on the part of healthcare providers about the efficacy of preventive measures. Without data from adequate and well-controlled comparative studies (as FDA typically requires for comparative claims), such comparative safety claims by a blood establishment would only add to that confusion.

NYBC therefore suggests that the final guidance include specific language stating that, unless supported by adequate and well-controlled studies, a statement is false or misleading if it represents or suggests, directly or by implication, that blood collected under standards more stringent than those recommended by FDA is safer than blood collected under FDA standards.

NYBC also asks that FDA take enforcement action against those blood establishments that make comparative safety claims (whether explicit or implicit), unless those claims are based on adequate and well-controlled studies. Such enforcement by FDA is necessary to prevent further confusion and disruption to the availability of blood, especially in areas served by blood establishments that follow FDA's guidance.

IV. Clarification/Other Suggestions

Below are a few additional instances in which NYBC seeks clarification or suggests a revision:

1. Section IV. D. states that "a trained staff member should administer the...criteria by face-to-face interview...." Does FDA intend for each question to be asked of each potential donor? NYBC suggests that a more efficient approach would be to ask, "*Since 1980, have you visited or lived in Europe or the Falkland Islands?*" If the donor answers "NO," the remaining questions can be skipped, and one could move directly to other questions.

2. At what time are questions to be asked of donors? There appears to be a conflict between the first and third paragraph of Section IV.D. The former speaks of administering the criteria "at the time of first use for each donor, to include both new and repeat donors,"while the latter says the question should be asked of whole blood donors "at each donation."

3. What are the timeframes for deferral? For example, Question 1 of Section IV.D.1. refers to the timeframe for the deferral as "from 1980 through 1996," while Questions 2 refers"between 1980 and 1990" and Question 3 refers to

"between 1980 and 1996." Is the difference "from…through" and "between" intentional? If not, the phrasing of Question 1 seems preferable.

4. What type of documentation is needed regarding bovine insulin? Section IV.D.3. provides for deferring individuals who answer "yes" or "I don't know" to the question of whether they have injected bovine insulin since 1980. NYBC would prefer that the reference to documentation be deleted. It is sufficient that blood collection agencies rely on the donor's report.

5. The first two sentences in SectionVI. are nearly identical with respect to blood components prepared from prior collections, except that the first sentence begins with "You should identify," and the second sentence begins with "It may be appropriate to identify." What is the significance of these two sentences with respect to blood components?

* * *

NYBC shares FDA's goal of enhancing the safety of our nation's blood supply without creating shortages, and we look forward to continuing to work with FDA on these important matters.

Respectfully Submitted,

Miriam Sparrow, Esq.
General Counsel

Cc: Dr. Dorothy Scott

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