§ 660.30

(14) The statement: “MEETS FDA POTENCY REQUIREMENTS.”

(15) If human blood was used in manufacturing the product, the statement: “CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED IN ACCORDANCE WITH CURRENT FDA REQUIRED TESTS. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.”

(16) A statement of an observable indication of an alteration of the product, e.g., turbidity, color change, precipitate, that may indicate possible deterioration of the product.

(c) Package insert. Each final container of Blood Grouping Reagent shall be accompanied by a package insert meeting the requirements of § 809.10. If two or more final containers requiring identical package inserts are placed in a single package, only one package insert per package is required.

(d) Names of antibodies.

BLOOD GROUP DESIGNATION FOR CONTAINER LABEL

| Anti-A | Anti-Jka
| Anti-Aa | Anti-Jka
| Anti-A, B | Anti-Jka
| Anti-A and B | Anti-K
| Anti-B | Anti-K
| Anti-C | Anti-Kp
| Anti-Cr | Anti-Kp
| Anti-c | Anti-Le
| Anti-CD | Anti-Le
| Anti-CDE | Anti-Le
| Anti-Co | Anti-Le
| Anti-D | Anti-M
| Anti-DE | Anti-M
| Anti-Di | Anti-N
| Anti-E | Anti-P1
| Anti-e | Anti-S
| Anti-Fy1 | Anti-s
| Anti-Fy2 | Anti-U
| Anti-I | Anti-Wr
| Anti-Jka | Anti-Xe