§ 660.22 Color coding of reagents. Blood Grouping Reagents may be colored provided the added colorant does not adversely affect the safety, purity, or potency of the product and the colorant is approved by the Director, Center for Biologics Evaluation and Research.

(c) Final containers and dropper assemblies. Final containers and dropper pipettes shall be colorless and sufficiently transparent to permit observation of the contents to detect particulate matter or increased turbidity during use.

(d) Volume of final product. Each manufacturer shall identify the possible final container volumes in the biologics license application.

(e) Date of manufacture. The date of manufacture shall be the date the manufacturer begins the last entire group of potency tests.

§ 660.25 Potency tests without reference preparations.

(a) Potency requirements. Products for which Reference Blood Grouping Reagents are available shall have a potency titer value at least equal to that of the reference preparation.

(b) Reference preparations. Reference Blood Grouping Reagents shall be obtained from the Center for Biologics Evaluation and Research (HFM–407) (see mailing addresses in § 600.2 of this chapter), and shall be used as described in the accompanying package insert for determining the potency of Blood Grouping Reagents.

§ 660.26 Specificity tests and avidity tests.

Specificity and avidity tests shall be performed using test procedures approved by the Director, Center for Biologics Evaluation and Research.

§ 660.28 Labeling.

In addition to the applicable labeling requirements of §§ 610.62 through 610.63