

INFORMATION PAPER

DASG-HCA
5 March 2003

SUBJECT: Expected Appearance of *Dryvax*-brand Smallpox Vaccine

1. Purpose. To describe the acceptable physical appearance of smallpox vaccine (*Dryvax*, Wyeth Laboratories).

2. Facts.

a. Overview. *Dryvax*-brand smallpox vaccine is stored as a freeze-dried (i.e., lyophilized) powder until use. Before administration, the powder is returned (i.e., reconstituted) to the liquid state by addition of a diluent (i.e., diluting fluid) containing 50% glycerin, 0.25% phenol, plus sterile water. The reconstituted vaccine ready for administration is a suspension of viral particles in the diluent.

b. As a Powder. The color of the freeze-dried pellet of *Dryvax* powder typically ranges from yellow to gray.

c. Reconstitution of Powder into Suspension. To reduce viscosity of cold diluent, warm by holding the diluent container in the palm of the hand for a minute or so. Because the diluent syringe will not be used to give an injection, expelling the air in the syringe serves no clinical purpose and could result in losing some of the diluent. Note that for latex-allergic people, the diluent can be added into the open mouth of the vial, rather than through the stopper-cap. Add diluent to vaccine vial. Allow vaccine vial to stand undisturbed for 3 to 5 minutes. Swirl vial gently to effect complete reconstitution. Clumps that do not go into suspension may be dispersed with gentle stirring with a sterile bifurcated needle. In isolated circumstances, additional time may be needed to achieve uniform suspension.

d. As a Liquid (i.e., Suspension). Reconstituted *Dryvax* typically appears as a shiny and cloudy suspension, ranging in color from light straw to manila or light yellow. The vaccine has been variously described as being gray or slate in color or having a slightly greenish hue. The vaccine should not be used if it is discolored (a color other than an acceptable color) Unacceptable colors include chocolate brown. The vaccine is not expected to be transparent. The vaccine can be described as glossy or opalescent. Reconstituted smallpox vaccine has a viscosity similar to a thin syrup or thin oil, a little thicker than water. Because smallpox vaccine is a suspension, suspended particles may settle at the bottom of the vial after several hours. Swirl the vial every few hours to maintain a uniform suspension. If an unsuspendable precipitate develops, do not use the vial.

MAJ Patrick Garman/USAMMA/301-619-4307
COL John D. Grabenstein/DASG-HCA/703-681-5059
Approved by COL Randolph