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APPENDIX F

333.455 Labeling of antiseptic handwash or health-care personnel handwash drug product

(c) *Directions.* The labeling of the product contains statements, under the heading “Directions,” that reflect the conditions used when the product was tested according to 333.470(b)(2) or:

(c) (1) *For products to be used with water.* “Wet hands and forearms. Apply 5 milliliters (teaspoonful) or palmful to hands and forearms. Scrub thoroughly for” (insert wash duration used when tested according to 333.470(b) (2)). (Insert any applicable statements about also using a device, such as a scrub brush.) “Rinse and repeat.”

(c) (2) *For products to be used without water.* “Place a ‘palmful’ (5 grams) of product in one hand. Spread on both hands and rub into the skin until dry (approximately 1 to 2 minutes). Place a smaller amount (2.5 grams) into one hand, spread over both hands to wrist, and rub into the skin until dry (approximately 30 seconds)” or “Wet hands thoroughly with product and allow to dry without wiping.”

333.460 Labeling of patient preoperative skin preparation drug products

(d) *Directions.* The labeling of the product contains statements, under the heading “Directions,” that reflect the conditions used when the product was tested according to 333.470(b)(3) or:

(d) (1) *For products containing any ingredient identified in 333.412 (a), (d), and (e) that are intended to remain on the skin after application.* “Clean the area. Apply product to the operative site prior to surgery (insert method of application, including any device used when tested according to 333.470 (b) (3).) If appropriate, insert “Dry and repeat procedure.”

(d) (2) *For products containing any ingredient identified in 333.412 (b) or (c) that are intended to be removed from the skin after application.* “Apply product to the operative site prior to surgery” (insert method of application, including any device used, when tested according to 333.470 (b) (3).) “When product dries, remove immediately with 70 percent alcohol or, or use as directed by a physician.”

333.465 Labeling of surgical hand scrub drug products.

(c) *Directions.* The labeling of the product contains statements, under the heading "Directions," that reflect the conditions used when the product was tested according to 333.470(b)(1) or:

(c) (1) *For product to be used with water.* "Clean under nails with a nail pick. Nails should be maintained with a 1 millimeter free edge. Wet and and forearms. Apply 5 milliliters (teaspoonful) or palmful to hands and forearms. Scrub thoroughly for (insert scrub duration used when tested according to 333.470 (b) (1)) "with a sterile" (insert applicable device), "paying particular attendtion to the nails, cuticles, and interdigital spaces. Rinse and repeat scrub" (if applicable, insert instructions for second scrub used when tested according to 333.470 (b) (1), if different from the first).

(c) (2) *For products to be used without water.* "Clean under nails with a nail pick. Nails should be maintained with a 1 millimeter free edge. Place a 'palmful' (5 grams) in one hand. Spread on both hands, paying particular attention to the nails, cuticles and interdigital spaces, and rub into the skin until dry (approximately 1 to 2 minutes). Place a smaller amount (2.5 grams) into one hand, spread over both hands to wrist, and rub into the skin until dry (approximately 30 seconds)"