Subpart D—Medical Devices

§ 73.3100 1,4-Bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester copolymers.

(a) Identity. The color additives are 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester (CAS Reg. No. 109561–07–1) copolymerized either with glyceryl methacrylate, methyl methacrylate, and ethylene glycol dimethacrylate monomers, or with N,N-dimethyl acrylamide, methyl methacrylate, and ethylene glycol dimethacrylate monomers to form the contact lens material.

(b) Uses and restrictions. (1) The substances listed in paragraph (a) of this section may be used in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lens made from the color additives.

(c) Labeling. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) Exemption from certification. Certification of these color additives is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[61 FR 51586, Oct. 3, 1996]

§ 73.3105 1,4-Bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone copolymers.

(a) Identity. The color additive is 1,4-bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone (CAS Reg. No. 121888–69–5), copolymerized with hydroxyethyl methacrylate monomer, or a blend of hydroxyethyl methacrylate and N-vinyl pyrrolidone monomers, or a blend of 3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate (CAS Reg. No. 134072–99–4) and N-vinyl pyrrolidone monomers to form the contact lens material.

(b) Uses and restrictions. (1) The substances listed in paragraph (a) of this section may be used in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to contact lenses made from the color additives.

(c) Labeling. The label of the color additives shall conform to the requirements of § 70.25 of this chapter.