Food and Drug Administration, HHS

§ 866.305 Blastomyces dermatitidis serological reagents.

(a) Identification. Blastomyces dermatitidis serological reagents are devices that consist of antigens and antisera used in serological tests to identify Blastomyces dermatitidis in serum. The identification aids in the diagnosis of blastomycosis caused by the fungus Blastomyces dermatitidis. Blastomycosis is a chronic granulomatous (tumor-like) disease, which may be limited to the skin or lung or may be widely disseminated in the body resulting in lesions of the bones, liver, spleen, and kidneys.

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §866.9. [69 FR 56936, Sept. 23, 2004]

§ 866.3065 Bordetella spp. serological reagents.

(a) Identification. Bordetella spp. serological reagents are devices that consist of antigens or proteases used in serological assays. The device can be used as an aid in the diagnosis of deep seated mycoses and fungemias.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §866.9. [47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989; 66 FR 38791, July 25, 2001]