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Title 21 – Food and Drugs

Chapter I – Food and Drug Administration, Department of Health and Human Services

Subchapter F – Biologics

Part 600 – Biological Products: General

Subpart C – Establishment Inspection

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 356c, 356e, 360, 360i, 371, 374, 379k–l; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 600.21 Time of inspection.

The inspection of an establishment for which a biologics license application is pending need not be made until the establishment is in operation and is manufacturing the complete product for which a biologics license is desired.

[38 FR 32048, Nov. 20, 1973, as amended at 48 FR 26314, June 7, 1983; 64 FR 56449, Oct. 20, 1999; 84 FR 12508, Apr. 2, 2019]