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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

§ 600.21 Time of inspection.

CROSS REFERENCE

Link to an amendment published at 84 FR 12508, Apr. 2, 2019.

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. In case the license is denied following inspection for the original license, no reinspection need be made until assurance has been received that the faulty conditions which were the basis of the denial have been corrected. An inspection of each licensed establishment and its additional location(s) shall be made at least once every 2 years. Inspections may be made with or without notice, and shall be made during regular business hours unless otherwise directed.

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