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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

§ 600.22 Duties of inspector.

CROSS REFERENCE

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

The inspector shall:

- (a) Call upon the active head of the establishment, stating the object of his visit,
- (b) Interrogate the proprietor or other personnel of the establishment as he may deem necessary,
- (c) Examine the details of location, construction, equipment and maintenance, including stables, barns, warehouses, manufacturing laboratories, bleeding clinics maintained for the collection of human blood, shipping rooms, record rooms, and any other structure or appliance used in any part of the manufacture of a product,
- (d) Investigate as fully as he deems necessary the methods of propagation, processing, testing, storing, dispensing, recording, or other details of manufacture and distribution of each licensed product, or product for which a license has been requested, including observation of these procedures in actual operation,
- (e) Obtain and cause to be sent to the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research (see mailing addresses in § 600.2(c)), adequate samples for the examination of any product or ingredient used in its manufacture,
- (f) Bring to the attention of the manufacturer any fault observed in the course of inspection in location, construction, manufacturing methods, or administration of a licensed establishment which might lead to impairment of a product,
- (g) Inspect and copy, as circumstances may require, any records required to be kept pursuant to § 600.12,
- (h) Certify as to the condition of the establishment and of the manufacturing methods followed and make recommendations as to action deemed appropriate with respect to any application for license or any license previously issued.

[38 FR 32048, Nov. 20, 1973, as amended at 49 FR 23833, June 8, 1984; 55 FR 11013, Mar. 26, 1990; 70 FR 14982, Mar. 24, 2005; 80 FR 18092, Apr. 3, 2015]