Food and Drug Administration, HHS

PART 226—CURRENT GOOD MANUFACTURING PRACTICE FOR TYPE A MEDICATED ARTICLES

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Source: 40 FR 14031, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 226.20 Buildings.

Buildings in which Type A medicated article(s) are manufactured, processed, packaged, labeled, or held shall be maintained in a clear and orderly manner and shall be of suitable size, construction and location in relation to surroundings to facilitate maintenance and operation for their intended purpose. The building shall:

(a) Provide adequate space for the orderly placement of equipment and materials used in any of the following operations for which they are employed to minimize risk of mixups between different Type A medicated article(s), their components, packaging, or labeling:

(1) The receipt, sampling, control, and storage of components.
(2) Manufacturing and processing operations performed on the Type A medicated article(s).
(3) Packaging and labeling operations.

(b) In addition to maintaining records and reports required in this part, Type A medicated articles requiring approved NADAs are subject to the requirements of §514.80 of this chapter. Similarly, Type A medicated articles listed in the index are subject to the requirements of §516.165 of this chapter.

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