This is an amendment to 16.19.30 NMAC, Section 7 effective 8/12/2025

16.19.30.7 DEFINITIONS: In addition to the definitions for specific license classifications, the following words and terms, when used in this section, shall have the following meanings unless the context clearly indicates otherwise.

A. "Active pharmaceutical ingredient (API)" any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.

B. "Beyond-use date (BUD)" the date after which a compounded preparation should not be used and is determined from the date the preparation was compounded.

C. "Component" any ingredient intended for use in the compounding of a drug product, including those that may not appear in such product labeling.

D. "Compounding" the preparation, mixing, assembling, packaging, or labeling of a drug or device (reconstitution of commercial products is not considered compounding for purposes of this article).

(1) as the result of a practitioner's prescription order, based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(2) preparing limited quantities of prescription orders based upon a history of receiving valid prescriptions issued within an established practitioner-patient-pharmacist relationship in the course of professional practice;

(3) reconstitution of commercial products is not considered compounding for purpose of this article.

(4) the addition of a flavoring agent to a conventionally manufactured product is not considered compounding as long as the following conditions are met:

(a) the flavoring agent is inert, nonallergenic, and produces no effect other than the instillation or modification of flavor;

(b) the flavoring agent does not alter a medication's concentration beyond USP's accepted level of variance;

(c) the addition of flavoring agent(s) is documented in the prescription record;

(d) the BUD criteria of Paragraph 5 of Subsection D of 16.19.30.9 NMAC shall apply.

E. "FDA" Food and Drug administration.

F. "SOP's" standard operating procedures.

G. "USP/NF" the current edition of the United States Pharmacopeia/National Formulary.

[16.19.30.7 NMAC - N, 9/15/2006; A, 12/13/2015; A, 9/14/2021; A, 8/13/2024; A, 8/12/2025]