481—554.6(155A) Standards for outsourcing facilities.

554.6(1) *Preparation standards.* Compounded preparations will be prepared in accordance with the standards of CGMP in accordance with 21 CFR Part 210 as amended on December 10, 2009, and Part 211 as amended on November 18, 2016.

554.6(2) *Labeling standards.* Labels for compounded preparations will include:

a. The statement "This is a compounded drug" or a reasonable comparable alternative statement that prominently identifies the drug as a compounded preparation.

b. The statement "Not for distribution or resale."

c. The name, address, and telephone number of the outsourcing facility that compounded the preparation.

d. The established name, strength, dosage form, and quantity of the preparation.

e. The date the preparation was compounded.

f. The beyond-use date of the preparation.

g. Storage and handling instructions.

h. The lot or batch identification or control number.

i. The national drug code number, if applicable.

j. The following additional information, which can be included on the labeling of a container from which individual units of the preparation are removed for administration or dispensing:

(1) Directions for use, including, as appropriate, dosage and administration;

(2) A list of the active and inactive ingredients, identified by established name and quantity or proportion of each ingredient;

(3) FDA contact information (www.fda.gov/medwatch and 1.800.FDA.1088 or successor website or telephone number) to facilitate adverse event reporting; and

(4) The name of the practitioner or pharmacy to which the preparation is distributed.

[**ARC 9340C**, IAB 6/11/25, effective 7/16/25; see Delay note at end of chapter]