6800.3200 PREPACKAGING AND LABELING.

Subpart 1. **Prepackaging.** Pharmacies may prepackage and label drugs in convenient quantities for subsequent complete labeling and dispensing. Prepackaging into unit-dose containers shall be done according to United States Pharmacopeia, chapter 1146. Such drugs shall be prepackaged by or under the direct supervision of a pharmacist. The supervising pharmacist shall cause to be prepared and kept a packaging control record containing the following information:

A. date;

B. identification of drug: name, dosage form, manufacturer or distributor, lot number assigned by manufacturer or distributor, strength, and expiration date assigned by manufacturer or distributor, if any;

C. container specification;

D. copy of the label;

E. unique identifier of the packager;

F. unique identifier of the supervising pharmacist;

G. quantity per container; and

H. internal control number or date.

Subp. 2. **Labeling.** Each prepackaged container shall bear a label containing the following information:

A. name of drug;

B. strength;

C. name of the manufacturer or distributor of the finished dosage form of the drug;

D. a beyond-use date as provided in part 6800.3350, or any earlier date which, in the pharmacist's professional judgment, is preferable;

E. internal control number or date;

F. after July 1, 2008, a physical description, including any identification code that may appear on tablets and capsules or a bar code based on the National Drug Code (NDC). Such a description does not need to be placed on individual unit-doses, provided that the pharmacy dispenses the unit-doses in outer packaging that contains a physical description of the drug or the pharmacy dispenses less than a 72-hour supply of the unit-doses; and

G. radiopharmaceuticals must be labeled according to the requirements of part 6800.8550.

Statutory Authority: *MS s 151.06; 152.02*

History: *18 SR 1145; 31 SR 1673; 36 SR 237*

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