

10412 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

6505-890-2010 (P. D. No. 3)

5.2.2 Circular.

5.2.2.1 For FSN 6505-890-2010. A quantity of not less than 4 circulars, brochures, or other printed matter shall be packaged within each intermediate package for FSN 6505-890-2010, setting forth as a minimum: Indications for use, dosage and administration, precautions and contraindications, and side effects. The circulars shall be packaged in a manner acceptable to the Food and Drug Administration for individual issue of the bottle. Full disclosure information may be included on the label of the immediate container and each intermediate package, or on the unit package, if furnished, in lieu of the individual circulars.

5.2.2.2 For FSN 6505-926-9026. A circular, brochure, or other printed matter shall accompany each immediate container for FSN 6505-926-9026, setting forth as a minimum: Indications for use, dosage and administration, precautions and contraindications, and side effects.

5.3 Packaging.

5.3.1 Unit of issue. One (1) bottle containing 4 fl oz or 1 gal, as specified, constitutes one unit of issue.

5.3.2 Packaging quantities. The number of units of issue indicated in the following table shall be packaged in each unit, intermediate, and exterior container, as applicable, for the required level of protection specified in the procurement document.

Packaging quantities			
Size	Unit package	Intermediate package	Exterior container
4 fl oz	1 unit	12 units	48 units
1 gal	1 unit	Not required	4 units

5.3.2.1 Packing variation permitted. If the required number of units in the entire shipment is less than the number of units specified to be overpacked in an exterior container, such units may be packed in an exterior container of suitable size and design, acceptable to a common carrier, which shall insure safe delivery to destination.

5.3.3 Level A.

5.3.3.1 Unit package.

5.3.3.1.1 Four fl oz. At the option of the contractor, each unit shall be packaged in a box of appropriate size constructed in accordance with PPP-B-566, PPP-B-676 or PPP-B-636, type CF, class domestic. Commercial colors are acceptable on unit boxes. Closure shall be adequate to prevent spilling of contents under normal handling.