

Inspections, Compliance, Enforcement, and Criminal Investigations

CPG Sec.480.200 Expiration Dating of Unit Dose Repackaged Drugs (CPG 7132b.11)

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BACKGROUND:

Unit dose packaging systems are currently widespread in health care. Some unit dose containers are available directly from manufacturers and repackagers, and some drugs are packaged into unit dose containers by hospital/community pharmacies or shared service establishments. A shared service repackaging operation is one which exclusively serves one or more hospitals and/or related institutions, each having separate or no pharmacy services, and each having responsibility for restricting distribution of those drugs received from the shared service to the institution.

The nature of drug distribution within hospitals in particular has made such packaging useful and convenient in assuring proper administration of medication to patients. Questions have arisen, however, as to whether drugs thus repacked need expiration dates based on stability data on the drugs in the unit dose containers. The issue gained sharper focus with the inclusion of pharmacopeial standards for Single Unit Containers and Unit Dose Containers for Capsules and Tablets published in the General Tests section of the Fifth Revision to the Nineteenth Edition of the United States Pharmacopeia (changes official May 1, 1979). In light of these standards, under certain conditions the Food and Drug Administration would not ordinarily deem it necessary for health protection, nor for assurance of stability of the drug, to require that stability studies be done on the drug in the unit dose container.

The Current Good Manufacturing Practice Regulations require that, with certain exceptions, drug products must bear expiration dates derived from tests conducted on samples stored in the same immediate container closure system in which the drug is marketed. This is to ensure the drugs' safety and efficacy over their intended *shelf-life*. Concerning the issue of repackaging into unit dose containers, we interpret compliance with the conditions enumerated in this guide to meet the stability requirements of the CGMP regulations.

POLICY:

No action will be initiated against any unit dose repackaging firm, including shared services, or drug product in a unit dose container meeting all other

conditions of FDA's repackaging requirements solely on the basis of the failure of the repackaging firm to have stability studies supporting the expiration dates used, provided:

1. The unit dose container complies with the Class A or Class B standard described in the twentieth Edition of the United States Pharmacopeia, General Tests, Single-Unit Containers and Unit-Dose Containers for Capsules and Tablets (page 955)
2. The expiration date does not exceed six months; and
3. The six month expiration period does not exceed 25 per cent of the remaining time between the date of repackaging and expiration date shown on the original manufacture's bulk container of the drug repackaged, and the bulk container has not been previously opened.

This policy only applies to solid and liquid oral dosage forms in unit dose containers. We will continue to impose all requirements on other dosage forms and other types of packages.

EXCEPTIONS:

This policy does not apply to antibiotics or to nitroglycerin sublingual tablets which are known to have stability problems that preclude them from being repackaged.

Material between asterisks is new or revised

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