

MCGRATH & BREITFELLER, LLP

ATTORNEYS AT LAW
140 EAST TOWN STREET
SUITE 1070
COLUMBUS, OHIO 43214

4 287 5 SEP -1 A9:55

TELEPHONE (614) 464-4201 EXT 13
FACSIMILE (614) 464-0572

RALPH E. BREITFELLER

August 29, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5360 Fishers Lane
Rockville, MD 20857

Re: Draft Guidance on Expiration Dating of Unit-Dose Repackaged Drugs,
Docket No. 2005-0174.

Dear Sir or Madam:

I represent two drug repackaging firms that repackage in unit dose form, as a shared service, for a closed group of affiliated pharmacies.

These firms welcome consideration of a revised policy regarding dating of drugs repackaged in unit dose form. The draft Guidance, however, does not result in the efficiency or saving intended. Because of the requirement of Class A packaging, the new policy will not save money or create an incentive for pharmacies to move repackaging operations to FDA regulated repackagers.

Pharmacies can repackage in unit dose packaging and assign one year (not to exceed manufacturer's) date under United States Pharmacopiae standards. Pharmacies do not repackage according to current Good Manufacturing Practices. FDA regulated repackaging facilities, without stability data, are limited to six months or 25% of the remaining expiry period, in order to avoid waste, pharmacies have an incentive to repackage in house. *CPG 7132b.11.*

Several comments have suggested that the Guidance will encourage pharmacies to delegate repackaging to FDA registered facilities, resulting in a safer repackaged product. Repackaging according to GMPs in a facility regulated by the FDA is more desirable than repackaging at pharmacies, but these comments do not recognize the increased cost imposed by the Guidance. The cost of repackaging under the proposed Guidance may mean that it will be economically disadvantageous to repackage at an FDA registered repackager, as opposed to the pharmacy.

The Guidance proposes to permit one year or the remainder of the manufacturer's expiry period if the product is repackaged in a Class A package. Currently, most repackaged solid oral products are being packaged in Class B material. The use of Class A packaging will significantly increase the cost of repackaged products. At the same time,

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USP standards allow pharmacies to repackage in Class B packaging as long as it is better than PVC. Depending on the thickness of the material, materials better than PVC may not meet Class A standards.

The firms I represent have extensive experience with different types of unit dose repackaging materials. They also have stability data for solid oral drugs repackaged in Class B unit dose packaging. This data establishes that for the majority of solid oral drugs Class B packaging is sufficient for dates that exceed the one-year proposed in the Guidance.

The FDA is urged to consider expanding the Guidance to allow one year dating on unit dose packages using Class B material. Without this change, there are three choices open to pharmacies that need to repackage in unit dose form, all of which choices will increase cost or decrease quality:

1. Repackage at the pharmacy using inferior materials and processes that do not comply with GMPs;
2. Purchase more expensive repackaged product in Class A material with longer expiration periods; or,
3. Purchase less expensive repackaged product in Class B materials with shorter dates and an increased likelihood of waste.

Allowing use of Class B packaging will permit the economical repackaging of solid oral drugs according to Good Manufacturing Practices at FDA registered repackaging sites.

Very truly yours,



Ralph E. Breitfeller