

## Citizen Petition

3364 '02 MAR 20 12:38

The undersigned submits this petition under the Federal, Food, Drug and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10 to request the Commissioner of Food and Drugs to amend the following regulation and or guideline.

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

"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."

The policy only applies to solid and liquid oral dosage forms in unit dose containers. We will continued 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.

Issued: 2/84  
Revised: 3/95

### Statement of Grounds

The present Guideline and enforcement by the agency places several FDA registered and inspected Repackaging Firms at a distinct disadvantage.

02P-0116

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**The USP XXIV allows a Drug Store, a Clinic, a Hospital, or a Long Term Nursing Home to repackage unit dose drug products utilizing a one year date from the date of repackaging.**

**The referenced facilities are not under the regulatory authority of the Federal Food and Drug Administration but have the advantage in some instances of being under the protection of "the practice of pharmacy" The repackaging of drug products in the back room of Drug Stores, Hospitals, Nursing Homes & Long Term Care Institutions without adequate controls does not protect the integrity of the drug product and does not provide protection for the public health of those patients utilizing such services.**

**The repackaging firms who are registered with the FDA as "Manufacturers/Repackagers" operate under the watchful eye of the Federal Food and Drug Administration, following the CGMP (Current Good Manufacturing Practice Regulations) along with the Drug Listing Requirements and provide assurance that the drug products repackaged under these rules and regulations are safe and efficacious. In addition these repackagers are inspected routinely by the FDA whereas the repackaging performed without adequate safeguards by Drug Stores and other facilities are not subject to such inspections and controls.**

**The repackaging firms requesting this amendment and or revision to the above stated rules are repackaging drug products for use by Hospitals and Clinics. In many instances the repackager receives drug products owned by the Hospital and Clinic and repackages these drug products into unit dose packaging for the convenience of the Hospital and Clinic to assure accurate dosing for the patient. They are performing the same task as these other facilities, but they are operating under much tighter control and security and provide greater assurance for the end user, the patient.**

**Many of the back room repackaging operations are using packaging materials that are not equal to those required by the FDA registered firms. The repackaged drug products are not tested for "light transmission resistance" or "tight container system (leakers) and there truthfully is no guarantee that the repackaged drug product meets its required parameters. Those drug products repackaged by FDA registered firms provide a much greater degree of safety to the public.**

**The disadvantage discussed previously refers to the fact that the FDA registered repackagers are losing business to the back room operators due to the FDA ruling in regards to expiration dating. This ruling places the FDA regulated repackagers at a disadvantage. Hospitals and clinics who utilize outside packaging services prefer to receive at least a one year expiration date and those we have discussed this with do not understand why the FDA treats the two types of operations differently. The end user is a patient receiving a repackaged drug**

product that may not meet the full parameters required and may not provide the patient with proper therapy, due to the Federal FDA ruling.

Many of the FDA regulated repackagers will cease operation due to the inability of providing a one year expiration date on the repackaged unit dose drug products. The FDA ruling is detrimental to the health and welfare of the very patients who should be protected.

According to the Federal Food, Drug and Cosmetic Act, the Federal Food and Drug Administration is required to enforce the standards set forth by the United States Pharmacopeia. In this instance it seems that the agency selects and chooses what sections of the USP requirements it intends to abide by.

### Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relied, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



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### C. Environmental impact

The actions requested in this Citizen Petition will have no environmental impact if approved by the Commissioner.

This petition is exempted from filing an Environmental Impact statement under Section 25.30 (h) & (k)

"The classes of actions listed in this section and Sec 25.31 through 25.34 are categorically excluded and therefore ordinarily to not require the preparation of an EA or an EIS."

(h) "Issuance of amendment, or revocation of procedural or administrative regulations and guidance documents including procedures for submission of applications for product development, testing and investigational use, and approval."

(k) "Establishment or repeal by regulation of labeling requirements for marketed articles if there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes."

**1 From** This portion can be removed for Recipient's records.

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Company PEISER & ASSOCIATES INC

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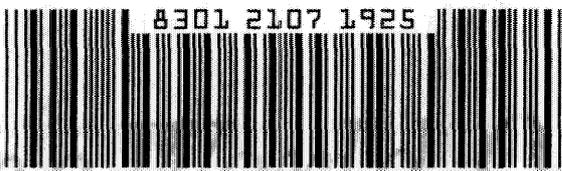
**2 Your Internal Billing Reference**

**3 To**  
Recipient's Name Dockets Management Branch

Company Food & Drug Administration

Address 5630 Fishers Lane Room 1061

City Rockville State MD ZIP 20852



0194920191

**4a Express Package Service**

FedEx Priority Overnight  
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 FedEx First Overnight  
 FedEx 2Day  
 FedEx Express Saver  
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**4b Express Freight Service**

FedEx 1Day Freight\*  
 FedEx 2Day Freight  
 FedEx 3Day Freight

**5 Packaging**

FedEx Envelope\*  
 FedEx Pak\*  
 Other Pkg.

**6 Special Handling**

SATURDAY Delivery  
 HOLD Weekday at FedEx Location  
 HOLD Saturday at FedEx Location

Does this shipment contain dangerous goods?  
 No  Yes  
Dry Ice:  Dry Ice, 9 UN 1845 x kg  Cargo Aircraft Only

**7 Payment Bill to:**

Sender Acct. No. in Section 1 will be billed.  
 Recipient  Third Party  Credit Card  Cash/Check

Total Packages: [ ] Total Weight: [ ] Total Charges: [ ]  
Credit Card Auth. [ ]

**8 Release Signature**

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.  
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