



Ohio Department of Mental Health

Office of Support Services

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September 2, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

Dear Sir or Madam:

Our operation would like to express support for adoption of the Guidance on Expiration Dating of Unit-Dose Repackage Drugs as published May, 2005. Allowing a one-year expiration dating on the products that we repackage into unit dose would help make our operation more efficient.

However, we have had difficulty locating materials that would comply with the USP Class A standard. These materials appear to be available for large manufacturing processes, but we are a smaller operation. The Pharmacy Service Center repackages only those medications that are not commercially available for limited distribution to nine inpatient facilities of the Ohio Department of Mental Health. We currently use a table top unit dose for unit dose packaging that does not provide Class A packaging. This system uses a foil on side and a tinted film on the other side of the package. We have not been able to find a film that can be used in our unit dose machine that would provide a moisture barrier that meets the Class A standard.

We would like the guidance to provide more information on what materials would meet USP Class A requirements and what would be required to meet USP Class A packaging standards. If the packaging materials themselves meet the Class A standard (e.g. foil, Aclar™ film), could it be assumed that the formed package would meet that standard? Would the re-packager be required to test the final formed container as described in the USP General Chapter 671 for moisture permeation if all the materials used for the package met USP Class A and there was a tight seal?

Although in-house operations are not covered by this guidance, it would be helpful if the Guidance could require that suppliers of systems for unit dose for hospitals and smaller operations to provide specific information on the class of packaging provided by their systems.

Thank you very much for considering these comments.

Sincerely,

Connie Hammond, R.Ph.
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