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Joint Medi-Dose/EPS & Medical Packaging Inc. Statement on Beyond-Use Dating of Unit Dose Medication

(10/01/2019) - Both Medical Packaging Inc. and Medi-Dose/EPS have seen an increase in questions pertaining to beyond-use dating. Since both companies manufacture and market products for repackaging oral solid and liquid medication into unit dose, we decided to issue a joint statement of our shared position on this topic.

We understand the confusion. Some sources recommend assigning the lesser of 1-year or the manufacturer's dating to repackaged medication. Others recommend the lesser of 6-months or 25% of the manufacturer's dating. Some of these sources have been noted as "draft guidance", are still being distributed for comments, are marked as not yet binding, or are separate from and do not apply to the in-house re-packaging that a hospital performs.

First and foremost, we always recommend that pharmacists defer to their appropriate governing body (i.e., state board, etc.) and the medication's package insert. With that in mind, it is our joint position that USP Guidelines allow for up to 1-year or the manufacturer dating, whichever is less, to be placed on extemporaneously packaged solid oral medications. We recommend this dating for all our packaging products deemed Class "A" or Class "B" according to the testing procedures of USP <671>, with the consideration that this recommendation does not conflict with the guidance of your governing body or the medication's package insert.

Medi-Dose/EPS and Medical Packaging Inc. strive to help pharmacists maintain the highest standard of professionalism and adherence to the proper guidelines and regulations. In the event USP changes its guidance on this topic, we will address this issue and comply accordingly.