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VIA E-mail and U.S. Mail:

August 23, 2005

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

RE: Draft Guidance: "Expiration Dating of Unit-Dose Repackaged Drugs: Compliance Policy Guide" Docket Number 2005D-1074 (70 Fed. Reg. 30953; May 31, 2005)

Dear Sir or Madam:

Please accept this letter as our comments to the Food and Drug Administration (FDA) draft *Guidance: Expiration Dating of Unit-Dose Repackaged Drugs: Compliance Policy Guide*. Given Cardinal Health's role as a leading provider of healthcare products and services (including our activities as a FDA-approved repackager), we strongly support the Agency's proposal that involves increasing the expiration dating to one year for nonsterile solid and liquid dosage form products that are repackaged into unit-dose containers.

We have long advocated the position that the FDA should support such a change. This is especially beneficial today where the Agency has required that bar coding be utilized in hospital settings. Various commentators, as well as the FDA itself, have acknowledged the public health benefit associated with having bar code labeling in place on prescription drug products. However, the ongoing availability of unit-dose drug product in institutions such as hospitals and nursing homes has been an issue. This view is echoed in the July 26, 2002, comments provided by the American Society of Health-System Pharmacists (ASHP) to the Agency:

Bar codes should be required on all pharmaceutical product packages ***down to the unit-dose – single unit level***. This should include prescription and over-the-counter medications, as well as vaccines and blood products. For bar coding to be effective in hospitals and health systems, products in unit-dose packages ***must*** be made available by pharmaceutical manufacturers. While we have received reports that some major pharmaceutical manufacturers are about to make a public commitment to add bar coding to all packaging, including unit-dose, some of our members report a disturbing trend whereby fewer and fewer pharmaceutical manufacturers are producing products in unit-dose, leaving repackaging up to individual hospitals. This is a major concern of ASHP. Not only does repackaging introduce new opportunities for mistakes to be made, it adds an additional cost, which most average- to small-size hospitals cannot afford. Repackaging also takes pharmacists away from their most important duty in hospitals—*managing patients' drug therapy*.

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That being the case, it is abundantly clear that the lack of unit-dose product availability is trending in a negative fashion as far as drug manufacturers are concerned.¹ Furthermore, the requirement that bar coding be placed on product at unit-dose level may very well further exacerbate this problem as even more drug manufacturers choose not to produce product in unit-dose packaging so as to avoid the additional expense associated with bar coding drug product at this level. The change proposed here by the FDA to permit one year expiration dating for repackaged unit dose product will allow for the use of bar coding to increase.

The tangible benefits to the public health in allowing FDA-regulated repackagers to repack drug product into unit-dose bar coded containers having at least one year expiration dating are as follows: (1) provides for a far wider range of available drug products in bar coded unit-dose format; (2) provides for entities utilizing FDA mandated parameters such as cGMP's to be conducting manufacturing-type activities as opposed to pharmacies performing similar tasks without such safeguards and controls; (3) will lessen the number of pharmacies choosing to undertake such internal repackaging activities given that such services would be available from authorized third-party vendors (i.e., FDA-regulated repackagers); and, (4) provides for greater overall utilization and benefits envisioned from the proposed bar code rule in terms of preventing medication errors.

If you have any additional questions or need anything further, please feel free to contact me at (614) 757-7721 or e-mail at robert.giacalone@cardinal.com. On behalf of Cardinal Health, we thank you for considering our comments and the efforts the Agency has made in crafting this rule.

Yours very truly,



Robert P. Giacalone, R.Ph., J.D.*
Vice President, Regulatory Affairs

CC: Thomas Napolitano (Cardinal Health)
Carolyn McPherson (Cardinal Health)
Gary Dolch (Cardinal Health)

¹ Bar code experts have noted this deficiency on a number of occasions. "At present, only about 35% of medications in a typical hospital have labels containing a bar code at the unit-dose level. Automating the point of care would require hospital pharmacies to apply bar-coded labels (or to arrange for them to be applied by a repackager) to roughly two thirds of their inventory." *Neuenschwander M, Cohen M, Vaida A, et. al. Practical Guide to Bar Coding for Patient Medication Safety. Am J Health-System Pharmacists; 2003; 60: 774.*

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Docket Management Comment Form

Docket: 2005D-0174 - Draft Guidance for Industry: Expiration Dating of Unit-Dose Repackaged Drugs; Availability

Temporary Comment Number: 19519

Submitter:	Mr. Robert Giacalone	Date:	08/23/05
Organization:	Cardinal Health		
Category:	Drug Industry		
Issue Areas/Comments			
General			
See Attachement.			
Attachments			
No Attachments			

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