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Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Re: Docket: 2003N-0361

One aspect of the Anti-Counterfeit Drug Initiative that seems to be generally agreed is the need to move to unit-dose dispensing (i.e. blister paks) of prescription pharmaceuticals. Not only would such a change provide greater opportunities for the application of trace/track technology, but would provide a measure of tamper-evidence for consumers at little additional cost to manufacturers.

The European Union (EU) moved to unit dosage dispensing over a decade ago. Although this system has worked well, there is one aspect of the European experience which might be instructive to the U.S.

Initially, most pharmaceutical drugs dispensed under this regime in the EU were within their patent lives, and generic substitutes were uncommon. As products came "off patent", however, many generics were substituted for brand-name tablets. Since there were several manufacturers of the generics, they had distinctive packaging for their products. This, in turn, has caused a degree of consumer confusion. When patients were used to receiving their dosages in one format (color, appearance etc.) they are often concerned when the presentation changes. Even where there is no question of authenticity or safety, this confusion persists.

One idea which may be considered in the EU to reduce this problem should be considered by the FDA in formulating its final rules concerning unit dose packaging:

Packages (and individual unit doses) should be color-coded (example below) together with the generic name of the product and its weight. These markings would be required on all prescription drugs, and be uniform for the same generic formulation, whoever the manufacturer. The codes should be simple, easily recognizable, and obvious. While this concept adds nothing to the objective of counterfeit reduction, it does provide consumer confidence at no or minimal cost to manufacturers. This method would be particularly useful to elderly people who are often

imbibing several drugs, and could take advantage of generics while being assured they are taking their prescribed medication.

I appreciate the opportunity to participate in this exercise.

Very truly yours,

Donald E. deKieffer

20 mg

Oxycodone