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

Subject: Docket No. 2005N-0403

PharMEDium Services, LLC would like to thank you for the opportunity to comment on the proposed rule for the Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application and Animal Drugs.

PharMEDium is an outsourcer for compounded admixtures to institutional pharmacies, specifically hospital and alternate site pharmacies. Given the current shortage of qualified pharmacists and the recent focus on medication errors, PharMEDium provides an important outsourcing option to these pharmacy customers. The clinical aspects of pharmacy practice remain with the institutional pharmacist. We participate in the traditional physician/pharmacist/patient triad only as an outsource contractor to the pharmacist member of that relationship. The PharMEDium role as an outsourced pharmacy compounding service for custom admixtures is not that of a traditional drug manufacturer.

PharMEDium would like to make you aware of some of the special circumstances for pharmacy compounders. As a pharmacy compounder, we are exempted from both the proposed rule and the existing rule. However, some pharmacy compounders have chosen to obtain a Drug Establishment Registration and Labeler Code from the FDA in order to assign an NDC number to their compounded preparations. This is also consistent with current DEA regulations. The NDC number assigned is unique for the compounded preparation by specifying the company labeler code, drug, drug concentration, diluent and type of container.

PharMEDium believes that the public is benefited by this approach since it allows for a very specific identification by the hospital of what exactly is contained in the compounded preparation. In fact, we have recently augmented our NDC numbers by providing them in a barcode which is being used by hospitals to link specific patients to the received medication (Point of Care). This has the potential to improve patient safety by reducing medication errors at the bedside.

In the pharmacy compounding business, it is important to be responsive to the changing needs of the patients. New compounded preparations are requested by

physicians and hospitals that require a rapid response. If we need to wait for the FDA to assign the NDC number, PharMEDium is concerned that the timing to receive a number would be inadequate. Additionally, as explained above, compounded preparations are unique and highly specific. Consequently, we believe it is critical to allow the pharmacy compounding company to continue to assign the NDC number. This provides efficiency, flexibility and control of the unique NDC number.

PharMEDium's concern with the proposed regulation is that the continued use of its unique NDC number might be considered misbranding under the Proposed Rule.

Pharmacy compounders should continue to be exempt from the proposed regulation, and be allowed to maintain the practice of self assignment of NDC numbers, subsequently submitting them to the NDC database. This allows for responsiveness to customers, transparency of compound preparations to the FDA, and enhances patient safety through the detailed identification of the medication.

We would welcome the opportunity for any additional dialogue with the Agency on this topic. Thank you for your consideration of our comments.

Sincerely,

Lynn Dressler
Director of Central Operations and Regulatory