

June 27, 2000

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Docket Nos. 92N-0297 and 88N-0258
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20857

Dear Sir or Madam:

I am writing to you on behalf of Henry Schein, Inc. (HSI) regarding certain sections of the Prescription Drug Marketing Act final rule in so far as they apply to the wholesale distribution of prescription drugs. The provisions of the final rule go into effect on December 4, 2000. A stay is in effect until October 1, 2001 with regard to other sections of the rule. HSI is a licensed wholesale distributor of medical, dental and veterinary supplies, including prescription drugs, serving hundreds of thousands of healthcare professionals nationwide.

We believe that the goal of the PDMA is to assure that only quality pharmaceutical products are distributed in the United States and that prescription drugs are not diverted to "grey markets". However, we are concerned with the serious impact that certain requirements in the final rule will pose on the industry and ultimately the final consumer. We do not believe that it was the intent of the Federal policymakers in enacting the PDMA to create an undue burden on the distribution of pharmaceutical products. Therefore, HSI would like to submit the following comments:

Section 203.23(a) requires that a hospital, health care entity or charitable institution document the return of prescription drugs by issuing a credit memo. Section 203.23(b) states that the returning entity must forward to the manufacturer a copy of that "credit memo". We believe that the intent of Congress was to allow legitimate returns of prescription drugs and that FDA is not authorized to place burdensome requirements on returns.

Accordingly, HSI agrees that returned drugs must be maintained under proper conditions for storage, handling and shipping and that documentation reflecting the maintenance of proper conditions must be provided to the **supplier/distributor** to ensure that, if the returned drug is redistributed, it remains safe and effective for its intended use. This goal can be achieved via the written statement provided by the returning entity to the supplier/distributor to

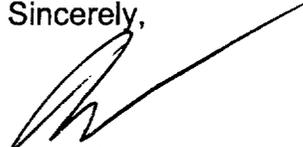
which the drugs are returned. The provision of notice to the manufacturer when drugs are returned to a wholesale distributor, constitutes an unreasonable administrative burden for the returning entity, the distributor and the manufacturer. Moreover, it is incongruous that a product lot or control number is required on the credit memo accompanying a return and on the drug pedigree, but not otherwise required under the final rule. Furthermore, it violates the distributors right of customer confidentiality. The distributor should not be placed in a position necessitating that it reveal its customer list to the manufacturer. Certainly in the case of product recalls, a distributor is afforded the opportunity to notify its customers of an FDA or manufacturer initiated recall without the mandate to turn over such list to the manufacturer. Therefore, HSI suggests that section 203.23 be revised to disregard the requirement of notice, to the manufacturer with regard to returns of prescription drugs.

Section 203.50(a) of the final PDMA regulation establishes that before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an "authorized distributor of record" to another wholesale distributor or retail customer, the seller shall provide to the purchaser a statement identifying each prior sale, purchase or trade of such drug. This statement requires the tracking of the product by lot or control number by the wholesale distributor.

While HSI recognizes the need for this requirement, allegedly to avoid the diversion of pharmaceutical products, FDA needs to recognize that the tracking of products by lot or control number is not a current practice in the wholesale industry and it would mean costly and significant modifications to the majority of healthcare distributors current operations. Therefore, the FDA should be sensitive to the fact that most of the prescription drug distributors will need to implement new tracking systems and it may take a lengthy time period to achieve compliance with the new requirement. HSI recommends that section 203.50(a) be reviewed and FDA allow a period of 2 to 3 years for wholesalers to implement the necessary changes to comply with the final regulations.

Please consider these comments and re-evaluate the possible consequences of implementing the related provisions. We appreciate the opportunity to comment on this matter.

Sincerely,



Mark Bond R.Ph.
Vice President Medical Division