



HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

Serving Medical Products Distributors Since 1902

Dockets and Management Branch
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Re: FDA Final Rule 92N-0297/88N-0258, 64 Fed. Reg. 67720 (December 3, 1999)

April 25, 2000

Dear Sir or Madam:

On behalf of the Health Industry Distributors Association (HIDA), I am writing to request that the Food and Drug Administration grant the Petition for Stay of Action filed on March 29, 2000 by the Pharmaceutical Distributors Association with respect to the Final Rule referenced above.

Founded in 1902, HIDA is the national trade association representing medical products distributors who serve the nation's long term care, hospital, imaging, and physician/alternate care markets.

The Final Rule will implement certain requirements for wholesale drug distribution as regulated by the Prescription Drug Marketing Act of 1987 (PDMA). HIDA believes that in its current form, this Final Rule unnecessarily targets secondary prescription drug wholesalers. Most of the distributors affected by this Final Rule are small and mid-size firms that prescription drug manufacturers do not designate as Authorized Distributors for economic reasons.

This rule requires secondary wholesale prescription drug businesses to provide extensive drug pedigree information, including documentation of all prior sales, purchases or trades, when they resell a prescription drug. It would apply even when they purchase stock from Authorized Distributors of Record. This represents a substantial burden on secondary distributors because systems are not in place that would easily provide the necessary data to them.

It will also decrease competition and lead to higher prescription drug costs for low-volume buyers such as physicians who maintain prescription drug stocks, and drug repackaging firms. These buyers rarely purchase in bulk quantities sufficient to qualify for large volume discounts offered by Authorized Distributors of Record. Only secondary distributors are in a position to offer discounts to these smaller markets.

We are not aware of any health or safety issues that would be protected by this final rule.

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Therefore, HIDA supports the petitioner's request for a Stay of Action and allow drug distribution to continue in conformance with current FDA industry guidance.

Sincerely,

A handwritten signature in cursive script that reads "Ruth Ann C. Kaiser".

Ruth Ann C. Kaiser
Director, Government Relations

cc: Matthew Rowan, President and CEO
Dan Moskowitz, Chairman