



National Wholesale Druggists' Association

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

RE: Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date; Reopening of Administrative Record.
[Docket Nos. 92N-0297 and 88N-0258]

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Dear Sir or Madam:

I am writing on behalf of members of the National Wholesale Druggists' Association (NWDA) to respond to the agency's invitation, published in the May 3, 2000, *Federal Register* (65 FR 25639), for additional comments on certain provisions of the final rule implementing the Prescription Drug Marketing Act of 1987 (PDMA), as amended. After publication of the final rule on December 3, 1999 (64 FR 67720), NWDA joined several industry groups in expressing concerns about the wholesale distribution provisions and their potential impact on the distribution of prescription drugs. We appreciate FDA's delay of the effective date of these provisions, and the opportunity to provide additional input into the agency's deliberations on these requirements.

NWDA is the national trade association representing distributors of pharmaceuticals and related health care products. NWDA active members operate over 200 distribution centers throughout the country, distributing over \$77 billion in these products to every state, the District of Columbia and U.S. territories. By concentrating health care products, dispersing them in economic quantities and then transporting them to thousands of pharmacies, hospitals and other health care delivery sites, drug wholesalers dramatically reduce the overall number of transactions required to service the pharmaceutical distribution system, thereby saving the health care system billions of dollars in transaction costs.

The drug distribution industry is subject to numerous federal and state regulations meant to ensure the integrity and security of the pharmaceutical products that reach American consumers. All NWDA member distributors, including those that would be most acutely impacted by the delayed provisions of the final regulation, are licensed by state authorities

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under PDMA requirements, found at 21 CFR Part 205, which went into effect in 1992. As a condition of licensure, drug wholesalers must have detailed storage and handling requirements in place that include appropriate temperature and humidity settings in the warehouse, specific procedures for inspecting and accepting product into inventory, and a system for maintaining records related to the receipt and disposition of prescription drug products.

Wholesale drug distributors must be licensed in every state in which a facility is located, and these facilities are subject to inspections by both state and FDA officials. In addition, at least 44 states require prescription drug wholesalers to be licensed in their state if they do business there, even if the facility is located elsewhere. Drug distribution is also subject to extensive regulation and inspection by the Drug Enforcement Administration (DEA), the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA) and their state counterparts.

Given the numerous requirements currently in place, NWDA is concerned about the impact and unnecessary consequences that the “authorized distributor” and so-called “drug pedigree” requirements could have on the entire drug distribution industry. As currently drafted, §203.3(u) and §203.50 of the December 3, 1999, final rule would impose a significant additional regulatory burden that the agency does not seem to have seriously considered. We know of no public health problems or FDA enforcement experiences with this already highly regulated industry that would justify these negative impacts.

Available evidence suggests that the system allowed to develop over the last 12 years in response to PDMA has worked well and is appropriately addressing any potential problems within pharmaceutical distribution channels. Most provisions of PDMA, including prescription drug sample controls, a ban on most reimportation activity and the wholesale distribution requirements went into effect on July 22, 1988, shortly after passage of the law. Since then, industry has put programs into place following the language of the statute, along with formal and other interpretation offered by the agency. This interpretative material included the August 1988 letter to industry stating the agency’s “interpretation of how the legislation should be implemented” (the August 1988 letter), a series of six “PDMA Enforcement Educational Conferences” held by FDA during 1991 and 1992, numerous letters from FDA to individuals in industry, and the March 14, 1994 proposed rule and preamble descriptions of its provisions.

Authorized Distributors of Record: The Written Agreement is Unfair and Burdensome

As published on December 3, 1999, the final rule includes two important departures from FDA’s previous interpretations of the PDMA wholesale distribution requirements, and these two changes are contained in the provisions delayed by the May 3, 2000 announcement. The first change is the critical determination of who is considered an “authorized distributor of record.” The PDMA statute made the general statement that an authorized distributor is one with whom the manufacturer has established an “ongoing

relationship” (21 U.S.C. 353(e)(4)(A)). The statute did not define this relationship, but report language accompanying the law stressed the notion of an ongoing business relationship with a manufacturer to distribute their products (see H. Rept. 100-76, p. 17). Shortly after the law passed, FDA defined the term on page 12 of its August 1988 letter and in subsequent guidance, allowing a *variety* of evidence to prove the relationship, including ongoing sales (“two transactions in any 24-month period”) or written distribution agreements given as possible pieces of evidence to prove that an ongoing relationship exists.

When Congress revisited a number of the PDMA wholesale distribution provisions in 1992 during deliberations on the Prescription Drug Amendments of 1992 (Pub. L. 102-353), it indicated no intent to alter either the definition of “authorized distributors of record” or FDA’s guidance on the definition of “ongoing relationship” contained in the 1988 letter. It wasn’t until publication of the 1994 proposed rule that FDA required there be a specific written agreement expressing the ongoing relationship (proposed §203.3(r)). NWDA and others commented on this proposed requirement, explaining that this was not normally done and would be a new and burdensome requirement, and an inappropriate intrusion by FDA into the supplier-distributor business relationship. FDA dismissed NWDA’s concerns in the final rule document noting that the agreement would be “easy” to do and would help the agency in its enforcement efforts (see 64 FR 67728).

NWDA continues to believe that requiring the distributor to enter into a specific written arrangement with a manufacturer is an intrusion into the business relationship between manufacturer and distributor, and would be an expensive new recordkeeping burden. Written agreements of the type described in the final rule are not typically part of doing business. Individual purchase agreements, invoices, shipping documents and the like currently serve as documentation of the sales arrangement. With NWDA full-line members distributing, on average, over 900 individual suppliers’ products, a requirement that separate written agreements be maintained for each of these vendors would pose an expensive recordkeeping hardship.

We also believe this recordkeeping burden is not necessary to carry out the enforcement purposes cited by the agency. As noted above, FDA stated on page 67728 of the preamble that it needs the written agreement to stand as a “clear and verifiable expression of the parties’ intent to engage in a continuing business relationship.” We believe such an expression can be found in ordinary business records showing that sales are made directly to the distributor from a manufacturer, and that the distributor’s name appears on the manufacturer’s list of authorized distributors of record. FDA currently has access to numerous other records required under its extensive regulatory scheme that could be used to further support the existence of the manufacturer-distributor relationship. (See, for example, 21 CFR §§211.150, 211.196, and §205.50(f)).

In addition, we believe the requirement for the written agreement, as outlined in the final rule, provides an inappropriate amount of discretion to manufacturers in determining who will be “authorized” under FDA requirements. By making the written agreement the only

acceptable evidence of the requisite “ongoing relationship”, and by leaving entirely up to the manufacturer whether such a formal agreement will be entered into, §203.3(u) of the final rule places the wholesale distributor in an unfair position. NWDA believes this has the potential to impact larger, traditionally “authorized” distributors, as well as smaller distributor companies.

We agree with the Small Business Administration (SBA) when they said on page 4 of their February 29, 2000 letter to FDA Commissioner Henney, “the fact that an agreement is easily created is irrelevant if the manufacturer chooses to limit whom it considers authorized dealers.” The SBA goes on to state, “The fact that FDA did not intend to confer additional discretion on manufacturers (see 64 Fed. Reg. at 67728), does nothing to change the fact that the door is open for manufacturers to “cherry pick” trading partners.”

In order to avoid potential problems related to fairness and the burdens associated with the written agreement required under §203.3(u) of the final rule, and in the absence of evidence of any justifiable reason to do otherwise, NWDA asks that FDA change the definition of “ongoing relationship.” We suggest the following language, which we believe is more consistent with the 1988 FDA guidance letter and resulting current industry practice:

Ongoing relationship means a continuing business relationship in which it is intended that the wholesale distributor engage in wholesale distribution of a manufacturer’s prescription drug product or products. Evidence of this intent would include such things as written agreements under which the distributor is authorized to sell the manufacturer’s products for a period of time or for a number of shipments, at least one sale of prescription drugs from the manufacturer to the wholesale distributor occurs during a calendar year, or the appearance of the name of the distributor on the manufacturer’s list of authorized distributors of record, required under 203.50(d) of the final rule.

“Drug Pedigree” Requirements are Unworkable

The other significant change for industry is FDA’s newly stated clarification of §203.50 of the final rule, regarding what information must be included in the so called “drug pedigree.” Under the statute, the drug pedigree is the statement identifying *each* prior sale of a prescription drug that must be passed along by unauthorized distributors before selling the drug to another party (see 21 U.S.C. 353(e)(1)). However, report language accompanying PDMA emphasized that the drug pedigree requirement “applies only to wholesale distributors who are not authorized distributors for that product. Authorized distributors, as defined, are exempted from this requirement.” (H. Rept. 100-76, p. 17)

FDA handled this potential inconsistency on page 12 of the August 1988 letter, stating that the drug pedigree must include information “regarding all sales in the chain of distribution of the product, starting with the manufacturer or authorized distributor of record” (emphasis added). Industry has reasonably interpreted this to mean that authorized

distributors did not have to provide pedigrees and, therefore, pedigree information should go back to either the manufacturer or the authorized distributor. We believed and continue to believe this approach is consistent with the overall intent of Congress in passing PDMA.

FDA restated the interpretation that pedigree information go back to the manufacturer or authorized distributor throughout the end of the 1980's and into the 1990's. However, the 1994 proposed rule included regulatory language that the drug pedigree must show transactions all the way back to the manufacturer (proposed §203.50(a)). Comments were submitted on the inconsistency between the proposed regulation, legislative history and previous FDA written statements on the matter. FDA's response to these comments, provided on page 67747 of the preamble to the final rule, gives the agency view of Congressional intent, but avoids questions about its own change in interpretation and policy. The response clarifies that the information in the drug pedigree must go back to the manufacturer of the product, even if there is an intervening authorized distributor of record, who does not have to pass along the pedigree.

This will create a very difficult, if not impossible situation for distributors who do not meet FDA's new "authorized distributor of record" definition and must pass along information they cannot get about prior sales of product. Full-line, typically "authorized" distributors are not required to pass along the pedigree under the statute and, as a practical matter, will not be able or willing to participate in the pedigree process beyond the requirements of the current final rule. This is due to the volume of product moved through the warehouse on a daily basis, and the item-level specificity of the information required under §203.50(a) of the final rule. Thus, unauthorized distributors would not always be able to get pedigree information on drugs that were lawfully purchased in the United States and are completely acceptable for resale.

NWDA suggests changing §203.50(a)(6) of the final rule to be more consistent with initial FDA interpretations of the PDMA requirements. The current practice of requiring information back to the authorized distributor is sufficient to provide the required accountability under PDMA. Authorized distributors maintain, as required under the statute and §203.50(b) of the final rule, any pedigree information provided by unauthorized distributor suppliers in their files, available for FDA inspection. In addition, unauthorized distributors can be cited under the terms of the statute for failing to maintain and provide the proper paperwork when they sell affected products. The same provisions of current FDA regulations affecting manufacturers and distributors noted earlier, would also provide the agency with sufficient means to investigate any problems related to product source or quality (see 21 CFR §§211.150, 211.196, and §205.50(f)).

Conclusion

The existing system for the distribution of prescription drugs in the United States is safe, efficient, and highly accountable. NWDA believes that new FDA interpretations of some of the wholesale distribution requirements, as issued and explained nearly 12 years after passage of the law, take a very burdensome approach and do so at great expense to

portions of the health care distribution industry. If allowed to go into effect as currently written, the delayed provisions of the final rule would certainly cause disruptions and may threaten the very existence of some segments of the health care distribution industry.

NWDA believes a more practical approach would be to implement regulations more consistent with FDA's August 1988 interpretive letter and current industry practice, and to use the licensing and registration processes already in place to provide FDA with information needed to proceed with investigative or enforcement actions. We know of no public health problems that would justify adding some incremental increase in FDA enforcement capability alluded to here, at such a huge cost to the health care system.

We appreciate that FDA is taking the time to delay implementation and consider the impacts of §203.3(u) and §203.50 of the December 3, 1999, final rule on the system for distributing prescription drugs in the United States. We are pleased to have an additional opportunity to express NWDA member views on these provisions. Do not hesitate to contact us if you have need for further information.

Sincerely,

A handwritten signature in black ink that reads "Diane Goyette". The signature is written in a cursive, flowing style.

Diane Goyette, Esq.
Director of Regulatory Affairs