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Jennie C. Butler
Dockets Management Branch
Food and Drug Administration (HFA-305)
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20817

Re: **Docket No. 02N-0486**; Agency Information Collection Activities, Prescription Drug Marketing Act of 1987; 67 Fed., Reg. 71574 (Dec. 2, 2002).

Dear Ms. Butler:

We are counsel to the Pharmaceutical Distributors Association ("PDA"), a trade association of state-licensed wholesale distributors of prescription drugs. These comments are submitted on the Food and Drug Administration's ("FDA") request for comments on recordmaking and recordkeeping requirements under 21 CFR Part 203 – Prescription Drug Marketing, the implementing regulations for the Prescription Drug Marketing Act of 1987 ("PDMA").

PDA's members include state-licensed wholesale distributors of prescription drugs who will be required to comply with 21 CFR Sec. 203.50, should the FDA's stay of that provision expire. The final rule promulgating this regulation was published December 3, 1999, and had an effective date of December 4, 2000. By Notice published May 3, 2000, the FDA stayed the December 2, 2000 effective date to October I, 2001. 65 Fed. Reg. 25639. A further stay of the effective date to April 1, 2002 was promulgated on March 1, 2001. 66 Fed. Reg. 12850. Another stay of the effective date to April 1, 2003 was promulgated earlier this year, on February 13, 2002 (67 Fed. Reg. 6645). A further stay of this regulation to April 1, 2004 will be published in the January 31, 2003 Federal Register.

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It is PDA's position that the FDA should inform the Office of Management that 21 CFR Sec. 203.50 has never gone into effect, and that it has been stayed at the request of the affected industry and interested Members of Congress.

In its December 2, 2002 Federal Register notice on the proposed collection of information, FDA asked for comment on the accuracy of FDA's estimate of the burden that is imposed by recordmaking and recordkeeping requirements of the regulation. In this regard, FDA set forth two proposed Tables (2 and 3) in the Federal Register notice which, in PDA's view, grossly underestimate the number of businesses and the frequency of the recordmaking that these businesses would have to perform under 21 CFR Sec. 203.50. The principal error is in the FDA's estimate that only 125 respondents would provide drug origin statements (pedigrees) under 21 CFR Sec. 203.50(a) and that each would provide only 100 such statements annually. In its June 2001 Report To Congress on The Prescription Drug Marketing Act (copy enclosed), FDA estimated that there are more than 6500 prescription drug wholesalers. Most of these wholesalers do not have an on-going relationship with a manufacturer and would be required under the regulation to provide pedigrees to their customers. And it is fair to say that these wholesalers would engage in at least one sale transaction per day, or about 260 per year. This means that that 1,690,000 pedigrees will be issued annually. Corresponding changes in the burden estimates for recordkeeping under 21 CFR Sec. 203.50 should be made. This is important information that PDA believes should also be provided to the Office of Management and Budget.

In its December 2, 2002 Federal Register notice, FDA also asked whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility. In comments that have been made to the docket from which these regulations were promulgated, PDA has made clear its position that the stayed final regulation is not necessary, and if allowed to go into effect, would have a devastating impact on the prescription drug wholesale industry. In so stating, FDA and the Office of Management and Budget should be aware that since PDMA was enacted, the wholesale prescription drug distribution industry has operated in the main on the basis of the guidance provided to industry in FDA's guidance letter of August 1, 1988. That letter interpreted PDMA to require that the statement identifying prior sales (the "pedigree") contain the following:

> 5. Statement identifying prior sales. FDA requests that the statement identifying prior sales of prescription drugs by unauthorized distributors be in writing, that it bear the title "Statement Identifying Prior Sales of Prescription Drugs by Unauthorized Distributors Required by the Prescription Drug Marketing Act," and that it include all necessary identifying information regarding all sales in the chain of distribution of the product, starting with the manufacturer or authorized distributor of record. FDA also requests that the identifying statement accompany all products

purchased from an unauthorized distributor, even when they are resold. Identifying statements are not required to include information about sales completed before July 22, 1988. FDA requests that the identifying statement include the following information:

(a) The business name and address of the source from which the drug was purchased,

(b) The date of the sale, and

(c) The identity, strength, container size, number of containers, and lot number(s) of the drug. [Emphasis added.]

The final regulation published December 3, 1999 changes the 1988 guidance to a regulation requiring the following:

§ *203.50(a) Identifying statement for sales by unauthorized distributors.* 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 pharmacy, the seller shall provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug. This identifying statement shall include:

(1) The proprietary and established name of the drug:

(2) Dosage;

(3) Container size;

(4) Number of containers;

(5) The drug's lot or control number(s);

(6) The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and

(7) The date of each previous transaction.

According to the economic impact analysis performed by the FDA with respect to the final rule, about 4,000 small business distributors will be directly affected by the regulation regarding statements identifying prior sales. In its June 5, 2001 PDMA Report to Congress, the FDA corrected this to an estimated 6500 small businesses and

noted 83 percent of these have fewer than twenty employees. The vast majority of these are "secondary wholesalers" who do not purchase directly from manufacturers the drugs who then wholesale to others, therefore not meeting the definition of "authorized distributor."

The PDMA's pedigree requirement applies only to wholesale distributors who are "not the manufacturer or an authorized distributor" of the drug being distributed. 21 U.S.C. §353(e)(1)(A). Thus, large full line wholesalers are not required to provide a pedigree when they wholesale drugs to others. Because PDMA does not require the full line wholesalers from whom other wholesalers purchase to provide a pedigree containing prior sales history information, the many secondary wholesaler distributors cannot continue to do business because to do so would violate the requirement of the final rule that the pedigree they provide their customers contain a complete sales history back to the manufacturer. As the FDA stated in footnote one to its May 3, 2000 Federal Register notice staying the regulation (65 Fed. Reg. at 25640):

> "An unauthorized wholesale distributor that purchases a product from a manufacturer or authorized distributor of record without an identifying statement showing the prior sales of the drug could not provide an identifying statement to its purchasers and, therefore, could not conduct further wholesale transactions of the drug in compliance with Sec. 203.50."

Under the 1988 guidance, this situation was avoided by FDA's interpretation that the prior sales information go back to "the manufacturer or last authorized distributor of record." This was a reasonable interpretation of PDMA and one which gave effect to both its requirement that a prior sales history be provided by those wholesalers who are not authorized and its provision that those who are authorized need not provide such information. The FDA does not agree that its use of the word "or" represented an intentional effort to assure that commerce in prescription pharmaceuticals through "unauthorized" wholesale distributors would continue without severe disruption that would occur with the final rule. On the contrary, it is the FDA's position (PDMA Report to Congress at 5) that the use of the word "or" in the 1988 FDA Guidance was based on its understanding of how prescription drugs were distributed in 1988:

> In 1988, when PDMA was enacted, the general understanding of the prescription drug distribution system was that most prescription drugs pass in a linear manner from a manufacturer to a retail outlet through a primary, or authorized, distributor of record (an identifiable group of distributors who could be characterized by their on-going relationships with manufacturers). The 1988 guidance letter states that the necessary identifying information regarding all sales in the chain of distribution may start with the manufacturer or authorized distributor of record. It was the

> Agency's understanding at the time that the authorized distributor of record would be the distributor to whom the manufacturer first sold the drugs, not just any authorized distributor who happened to purchase the drugs somewhere along the distribution chain.

Nonetheless, the FDA has also recognized that: "In the years since issuance of the 1988 guidance letter, unauthorized distributors have interpreted the Agency's guidance letter to mean that the pedigree need only go back to the ***most recent*** authorized distributor who handled the drug. This interpretation is what pharmaceutical distributors consider the '*status quo.*" PDMA Report to Congress at 5. This is true. The Report goes on to state that "[a]s a result, under the *status quo,* whenever a prescription drug is sold to an authorized distributor of record, the transaction history prior to that sale is no longer maintained." This is not true since FDA state regulatory schemes modeled on the FDA regulations for licensing prescription drug wholesalers (21 CFR Part 205) require such records to be maintained.

In its PDMA Report to Congress, the FDA has concluded that 21 C.F.R. §203.50 "reflects the language of the statute," and that it therefore cannot "revise the regulation to make it consistent with the *status quo.*" PDMA Report to Congress at 23. According to the FDA, "[s]uch a requirement would necessitate a statutory change." Id. And: "[t]he Agency believes, . . . , that concerns related to continuing to exempt authorized distributors from the pedigree requirement and to the exact meaning of the phrase *each prior sale,* can be addressed only through statutory remedies." PDMA Report to Congress at XII.

All of the above information should be brought to the attention of the Office of Management and Budget as well.

Thank you very much for your consideration of this comment.

Sincerely yours,

Anthony L. Young
Sheldon Krantz
Regulatory Counsel to the
Pharmaceutical Distributors Association

Attachment