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July 11, 2001

HAND DELIVERY

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

Re: Docket Nos. 92N-0927 and 88N-0258

To Whom It May Concern:

Please accept for filing the enclosed Petition For Continuation of Stay of Action and Suspension of Effective Date in Docket Nos. 92N-0927 and 88N-0258. Four copies are enclosed herewith.

Sincerely yours,

Anthony L. Young
General Counsel
Pharmaceutical Distributors Association

ALY/jek
Enclosures

88N-0258

PSA 2

Docket Nos. 92N-0927

1054 '01 JUL 12 P1:05 88N-0258

BEFORE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PETITION FOR CONTINUATION OF STAY OF ACTION AND SUSPENSION OF EFFECTIVE DATE

BY THE

PHARMACEUTICAL DISTRIBUTORS ASSOCIATION

FINAL RULE CONCERNING POLICIES, REQUIREMENTS, AND ADMINISTRATIVE PROCEDURES; PRESCRIPTION DRUG MARKETING ACT OF 1987; PRESCRIPTION DRUG AMENDMENTS OF 1992

July 12, 2001

The Pharmaceutical Distributors Association ("PDA"), a trade association of state-licensed wholesale distributors of prescription drugs, submits this petition pursuant to 21 C.F.R. § 10.35 to request the Commissioner of Food and Drugs to continue the stay and to suspend the effective date of those parts the final rule in Docket Nos. 92N-0297 and 88N-0258 which require a prescription drug pedigree to list all prior sales back to the manufacturer (21 C.F.R. § 203.50(a)(6)) and which require a written agreement to evidence an ongoing relationship between a wholesale distributor and a manufacturer (21 C.F.R. § 203.3(u)). Those parts of the final rule are presently scheduled to go into effect on April 1, 2002.

A. Decision Involved.

The Prescription Drug Marketing Act ("PDMA") was enacted on April 22, 1988 (Pub. L. 100-293) and amended on August 26, 1992 (Pub. L. 102-353). Promptly after PDMA was enacted, the Food and Drug Administration ("FDA"), on August 1, 1988, issued a letter to industry to provide guidance on compliance with the new law ("1988 guidance"). Also in 1988, FDA proposed regulations setting forth minimum requirements for state licensure of wholesale drug distributors. These regulations were made final in September of 1990 and appear at 21 C.F.R. Part 205. It was not until March of 1994, however, that FDA proposed rules regarding the paperwork requirements of PDMA. And, five years later, on December 3, 1999, the FDA made these into a "final rule." 64 Fed. Reg. 67720.

The final rule requires, for the first time since PDMA was passed in 1988, that the paperwork accompanying wholesale distributions of prescription drugs ("prescription drug pedigree") include prior sale information back to the manufacturer even though some wholesale distributors, known as authorized distributors, are not

required to provide pedigrees when they sell drugs to other distributors. 21 C.F.R. §203.50(a)(6). In addition, these regulations, also for the first time, require a written agreement between a wholesaler and manufacturer to be in place as evidence of the ongoing relationship necessary to achieve authorized distributor status. 21 C.F.R. §203.3(u).

B. Action Requested.

The final rule 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. This petition requests that those portions of the regulation regarding the need for a written agreement as evidence of an ongoing relationship between a manufacturer and a distributor (21 C.F.R. § 203.3(u)) and those that require that the "identifying statement for sales by unauthorized distributors" identify "all parties to each prior transaction involving the drug, starting with the manufacturer" (21 C.F.R. §203.50(a)(6)), be further stayed until one year after the Administration completes its reconsideration of these parts of the regulations by publication of a reconsidered final rule in the Federal Register.

The continued stay and suspension of effective date requested herein will provide PDA and its members and other interested parties time to achieve a legislative resolution to the present controversy regarding the PDMA prescription drug pedigree requirement. In granting such a stay, it is requested that FDA issue an interpretation to state that only drugs first shipped by a manufacturer into interstate commerce after any new effective date shall be required to be in compliance with the reconsidered

final regulation and that the new final regulation be made to be effective one year after its publication, the same time that was provided for affected parties to come into compliance that was granted with respect to the December 3, 1999 final rule.

C. Statement of Grounds.

After the final rule was promulgated in December of 1999, PDA and other adversely affected trade associations met with FDA on March 29, 2000 to express their concerns regarding the final rule. On that same date, PDA filed a petition for stay of those parts of the final rule that are the subject of this petition. A similar petition was submitted to the FDA by the Small Business Administration. In a Notice discussing the meeting, the petitions and other communications received from various associations and from Members of Congress, FDA stayed those parts of the final rule sought to be stayed herein until October 1, 2001. 65 Fed. Reg. 25639 (May 3, 2000).

On May 16, 2000, in its report accompanying the FDA Appropriations bill for 2001 (Rept. 106-619), the House Appropriations Committee stated that the FDA should thoroughly review the potential impact of its PDMA regulations on the secondary wholesale pharmaceutical industry. The Committee directed the FDA to provide a report to the Committee by January 15, 2001, to summarize the comments and issues raised by the public and to propose FDA plans to address those concerns.

In order to gather information about the impact of the PDMA and the final rule, the FDA held a public hearing on October 27, 2000 to receive comment and to dialog with wholesale distributors, representatives of manufacturers and public interest groups. Written comments were received through November 20, 2000. The FDA's

Congressional Report on Prescription Drug Marketing Act, House Report 106-619, ("PDMA Report to Congress") was signed and sent to the Congress on June 5, 2001.

1. In its original petition, PDA challenged the final rule where FDA has defined 'ongoing relationship" for purposes of determining whether one is an authorized distributor of record, in 21 C.F.R. § 203.3(u) as follows:

> Ongoing relationship means an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturers products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.

This final rule was a complete departure from FDA's 1988 guidance which stated:

> "Ongoing relationship," as used in the definition of "authorized distributors of record,' may be interpreted to mean a continuing business relationship in which it is intended that the wholesale distributor engage in wholesale distribution of a manufacturers prescription drug product or products. Evidence of such intent would include, but not be limited to, the existence of a written franchise, license, or other distribution agreement between the manufacturer and wholesale distributor; and the existence of ongoing sales by the manufacturer to the distributor, either directly or through a jointly agreed upon intermediary. The Agency would consider two transactions in any 24-month period to be evidence of a continuing relationship. [Emphasis added.]

In its PDMA Report to Congress, the FDA agreed that the ongoing relationship definition of the final rule "is restrictive and places control of who can be an authorized distributor in the hands of manufacturers," and that "it could prohibit many secondary distributors, including those who make regular purchases from manufacturers, from qualifying as authorized distributors of record. PDMA Report to Congress at 19. The

FDA also concluded that "this could have anticompetitive consequences without the corresponding benefit of protecting the public health." Id. Moreover, the FDA determined it "could broaden the definition of *authorized distributor* – although this change could result in even fewer wholesalers than before maintaining and passing on pedigrees for prescription drugs."

PDA has provided FDA with extensive comments on the anticompetitive impact of §203.3(u) as it is presently drafted. Those comments conclude that two transactions in the previous twenty-four month period should be sufficient evidence of the on-going relationship required by PDMA and in the PDMA Report to Congress, FDA stated that it "believes that an on-going relationship could be demonstrated by evidence of two sales within the previous 24-month period." PDMA Report to Congress at 20. Because there is agreement on the anticompetitive impact of §203.3(u) in its present form, this provision should be stayed and its effective date suspended until a new regulation can be promulgated in its place.

2. Since PDMA was enacted, the wholesale 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 noted that that 83 percent of the estimated 6500 prescription drug wholesalers in this country have fewer than twenty employees. The vast majority of these are "secondary wholesalers" who do not purchase directly from manufacturers the drugs that they then wholesale to others and do not otherwise meet 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 "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." 65 Fed.Reg. at 25640.

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.* As 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." PDMA Report to Congress at 5.

In its PDMA Report to Congress, the FDA has concluded that 21 C.F.R. §203.50, one of the final rules for which this petition seeks a continued stay and suspended effective date, "reflects the language of the statute," and that 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, "Such a requirement would necessitate a statutory change." Id. And "The 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.

While there has been legislation introduced, HR 68 and S 1132, that would address the PDA's concerns regarding 21 C.F.R. §203.50, the fact that the FDA PDMA Report to Congress was held up at the Secretary's office and at the Office of Management and Budget and came out almost five months after its due date, has made it extremely difficult the appropriate committees of Congress to consider the legislation on a timely basis. PDA has been advised that HR 68 will not be taken up until sometime after the August recess because the subcommittee of jurisdiction has

other important matters to address and has only begun to review the PDM matter at the staff level.

3. Unless a continued stay and suspension of the effective date is granted as requested herein, PDA members will soon begin to suffer irreparable injury. In its October 27, 200 hearing testimony and in a letter submitted on November 3, 2000 to the FDA docket in this proceeding, PDA noted that if the final rule were to apply to drugs already in distribution as of the effective date of the final rule, a significant number of these drugs would have to be taken out of distribution because of the absence of a proper pedigree as defined by the final rule. What PDA stated in November of 2000 -- that if the final rule as published were to go into effect October 1, 2001, distributors would need to stop buying drugs that do not have the required pedigree under the final rule and would have to begin to exhaust existing inventories of drugs that do not have acceptable pedigrees by the beginning of the year 2001 to avoid economic harm – is equally true now with respect to the April 1, 2002 effective date. As its is doing now, PDA then sought a decision by FDA that the final rule not apply to prescription drugs already in distribution as any new effective date so those drugs could be continue to be distributed. FDA granted an extension of the effective date from October 1, 2001 to April 1, 2002 but did not interpret the effective date to apply only to drugs first entering commerce on that date as PDA had requrested.

FDA granted the extension of the effective date from October 1, 2001 to April 1, 2002 based on the time necessary to evaluate comments and other information

regarding the PDMA final rule. In particular, FDA noted In the March 1, 2001 Federal Register, that the House Committee on Appropriations had directed the agency to provide a report to the Committee by January 15, 2001 (the Report was already one and one-half months late), summarizing the comments and issues raised about the PDMA final rule and FDA's proposals to address them. FDA has now completed its PDMA Report to Congress, but it was submitted to the Congress almost five months later than requested. In its March 1, 2001 Federal Register notice, the FDA noted that even if its PDMA Report to Congress were timely submitted, it would take a significant amount of time beyond January 15, 2001, to initiate and carry out either an administrative modification to the final rule or to achieve a legislative change. Thus, assuming a PDMA report submitted on January 15, 2001, FDA stated that it believed " that a legislative change to the act could take well into the 2001 calendar year." 66 Fed. Reg. At 12852.

The FDA decision of March 1, 2001 to extend the final rule effective date applies equally now, almost five months later. Futher delay will allow Congress to evaluate the PDMA Report to Congress, FDA's recommendations, and to consider legislative change to address the issues raised both by FDA and by the PDA.

4. The legislative discussions initiated on these subjects by FDA and by PDA are not frivolous and are being pursued in good faith. The issue presented by the FDA's PDMA Report to Congress and by PDA to the Congress is a serious issue regarding the effect of FDA regulation on a significant number of businesses, most of them small businesses.

5. There is a substantial public policy in favor of small businesses, small businesses that will be most adversely impacted by the final rule unless the stay requested herein is granted. Moreover, there is a substantial public policy against concentration in the wholesale prescription drug industry. FDA's PDMA Report to Congress describes five major wholesalers but if presently in process mergers are approved, those five will become three. The public policy against concentration will be advanced if the relief requested herein is granted.

6. The stay requested herein and the resulting delay in the implementation of the portions of the final rule that are being discussed in the legislative arena is not outweighed by public health or other public interests. FDA and the prescription drug wholesale industry have operated under the 1988 guidance for almost thirteen years. And FDA has already stayed the effective date of the final rule from December 4, 2000 to April 1, 2002. Continuing to operate under the 1988 guidance as requested herein, until PDA's efforts to receive legislative relief are resolved, do not disserve the public interest.

D. **Conclusion.** There are no public health or other public interest considerations that would justify the disruption in the wholesale pharmaceutical distribution system that will occur if the provisions discussed above are stayed pending legislative discussions. The industry has operated since 1988 under the FDA guidance that has been changed in the final rule without any public health impact. The wholesale distributors that may be put out of their businesses by these provisions ought to be allowed to seek relief in Congress before the final rule goes into effect.

Accordingly, we request the regulations noted above be stayed and suspended until one year after the Administration issues the reconsidered final regulations implementing the PDMA.

Respectfully submitted,

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July 12, 2001

Ms. Jane S. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research
Food and Drug Administration (HFD-5)

Seth S. Ray, Esq.
Associate Chief Counsel for Drugs
Office of the Chief Counsel
Food and Drug Administration (GCF-1)
5600 Fishers Lane
Rockville, MD 20857

Re: PDMA Final Rule Effective Date

Dear Ms. Axelrad and Mr. Ray:

Enclosed herewith for your information is a petition of the Pharmaceutical Distributors Association for continuation of the stay of action and or suspension of the April 1, 2002 effective date for the presently stayed PDMA regulations related to the wholesale distribution of prescription drugs. 21 C.F.R. §§ 203.3(u) and 203.50. The original of this petition and a copy of this cover letter was filed today in Dockets Nos. 92N-0297 and 88N-0258 in the Dockets Management Branch (HFA-305).

The petition requests that those portions of the regulation regarding the need for a written agreement as evidence of an ongoing relationship between a manufacturer and a distributor (21 C.F.R. § 203.3(u)) and those that require that the "identifying statement for sales by unauthorized distributors" identify "all parties to each prior transaction involving the drug, starting with the manufacturer" (21 C.F.R. §203.50(a)(6)), be further stayed until one year after

the Administration completes its reconsideration of these parts of the regulations by publication of a reconsidered final rule in the Federal Register.

The continued stay and suspension of effective date requested in the petition will provide PDA and its members and other interested parties time to achieve a legislative resolution to the present controversy regarding the PDMA prescription drug pedigree requirement. In granting such a stay, it is requested that the Administration issue an interpretation to state that only drugs first shipped by a manufacturer into interstate commerce after any new effective date shall be required to be in compliance with the reconsidered final regulation and that the new final regulation be made to be effective one year after its publication, the same time that was provided for affected parties to come into compliance that was granted with respect to the December 3, 1999 final rule.

PDA is submitting this petition now because of the time it has taken for the Administration to prepare, staff and achieve clearance for the two prior Federal Register notices that have extended the effective date in this matter. PDA asks in this petition that the effective date of these provisions be suspended pending the Administration's and the Congress' reconsideration of PDMA and its requirements. In PDA's view, this will obviate repetition of this exercise until a final decision is made or proposed on these issues.

PDA's members need a decision by September 1 or they must begin the process of liquidating inventories and otherwise rearranging their businesses and considering other options. We expect other trade associations that supported PDA's position at last year's hearing will support this petition as well.

Thank you very much for your consideration of this petition.

Sincerely yours,

Anthony L. Young
General Counsel
Pharmaceutical Distributors Association

/ALY

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cc: Mr. Sal Ricciardi
Lyle S. Genin, Esq.