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March 28, 2000

VIA FEDERAL EXPRESS

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

Re: Docket Nos. 92N-0927 and 88N-0258
Final Rule Concerning Policies, Requirements, and Administrative Procedures; Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992

Dear Sir:

Please accept for filing the enclosed letter to the Commissioner of Food and Drugs and Petition for Stay of Action of certain rules in the above-captioned Dockets.

Sincerely yours,

Anthony L. Young

ALY/jek
Enclosures

cc: Jane E. Henney, M.D. (HF-1)
William K. Hubbard (HF-22)
Margaret Jane Porter, Esq. (HF-32)
Jane Axelrad (HFD-5)
Lana Ogram (HFD-330)
(w/ enclosures)

88N-0258

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March 28, 2000

Jane E. Henney, M.D.
Commissioner of Food and Drugs
Food and Drug Administration (HF-1)
5600 Fishers Lane
Rockville, MD 20857

Re: Docket Nos. 92N-0927 and 88N-0258
Final Rule Concerning Policies, Requirements, and Administrative Procedures; Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992

Dear Commissioner Henney:

Please accept for filing the enclosed Petition for Stay of Action by the Pharmaceutical Distributors Association ("PDA"). PDA is a trade association of companies that are state-licensed wholesale distributors of prescription drugs. This petition for stay is with respect to final rules promulgated December 3, 1999 regarding statements of identifying information that must be provided with respect to certain wholesale prescription drug transactions.

This petition for stay is filed more than thirty days after the promulgation of the final rules. In accordance with 21 C.F.R. § 10.35(b), it is PDA's position that "good cause" exists for the Commissioner to permit the petition to be filed for the following reasons:

a) The final rule will have a substantial negative and disruptive impact on the distribution of prescription drugs. PDA members and many other prescription drug wholesalers will be put out of their businesses by the wholesale drug distribution provisions of the final rule.

b) PDA members sought, but were not able to have, a meeting with relevant Center for Drug Evaluation & Research ("CDER") staff regarding the final rule.

c) PDA members sought the assistance of their elected representatives in achieving a meeting with CDER staff.

d) PDA members will be meeting with CDER staff to discuss the issues raised by the final rule, tomorrow, March 29, 2000 in an effort to resolve the serious issues raised by the final rule.

On the basis of the foregoing, PDA respectfully requests the Commissioner to permit this petition for stay to be filed.

Sincerely yours,

Anthony L. Young
Counsel for the
Pharmaceutical Distributors Association

ALY/jek
Enclosure

cc: Jane E. Henney, M.D. (HF-1)
William K. Hubbard (HF-11)
Margaret Jane Porter, Esq. (GFC-1)
Jane Axelrad (HFD-5)
Lana Ogram (HFD-330)
(w/ enclosure)

Honorable Dan Burton, Member of Congress
Honorable John D. Dingell, Member of Congress
Honorable Jo Ann Emerson, Member of Congress
Honorable James M. Talent, Member of Congress
(w/ enclosure)

Docket Nos. 92N-0927
88N-0258

BEFORE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PETITION FOR STAY OF ACTION

BY THE

PHARMACEUTICAL DISTRIBUTORS ASSOCIATION

FINAL RULE CONCERNING POLICIES, REQUIREMENTS, AND

ADMINISTRATIVE PROCEDURES;

PRESCRIPTION DRUG MARKETING ACT

OF 1987; PRESCRIPTION DRUG AMENDMENTS OF 1992

March 29, 2000

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 stay the December 4, 2000, 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)).

A. **Decision Involved**.

On December 3, 1999, the Food and Drug Administration ("FDA") published final rules implementing the Prescription Drug Marketing Act ("PDMA"), as amended. The final rule requires, for the first time since PDMA was passed in 1988, that prescription drug pedigrees include prior sale information back to the manufacturer even though 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.

B. **Action Requested**.

The final rule was published December 3, 1999, and has an effective date of December 4, 2000. 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 stayed until October 1, 2001, to provide PDA and its members time to achieve a legislative resolution to the

present controversy regarding these sections.[1] In granting such a stay, it is requested that FDA issue an interpretation of the stayed effective date for these provisions to state that only drugs **first** shipped by a manufacturer into interstate commerce after October 1, 2001 shall be required to bear information regarding prior sales back to the manufacturer.

During the time that the stay requested by this petition is in effect, it is requested that FDA announce that its 1988 guidance to industry, which is set forth in its August 1, 1988 letter "To Regulated Industry and Other Interested Persons," be deemed to be in effect with respect to these issues.

C. **Statement of Grounds**.

I. Since the Prescription Drug Marketing Act of 1987 was enacted, the wholesale drug distribution industry has operated in the main on the basis of the guidance provided to industry in FDA's letter of August 1, 1988. That letter interpreted PDMA to require that the statement identifying prior sales 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:

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[1] The initiation by PDA and its members of legislative oversight and discussions with respect to amendments to the PDMA should not in any way be construed as an admission by PDA or any of its members that FDA's final rule is lawful or that it properly interprets PDMA.

(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 FDA 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) <u>The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and</u>

(7) <u>The date of each previous transaction.</u>

According to the FDA's own economic impact analysis, about 4,000 small business distributors will be directly affected by the regulation regarding statements identifying prior sales which is now scheduled to go into effect on December 4, 2000. Very few of these distributors purchase directly from manufacturers the pharmaceuticals that they then wholesale to others. Because PDMA does not require the full line wholesalers from whom other wholesalers purchase to provide prior sales history information, these "secondary" wholesaler distributors cannot continue to do business because to do so would violate the

regulation. They cannot pass on the required information about sales that occurred prior to the last authorized distributor of record selling the product because those authorized distributors of record do not provide this information to their customers.

Under the 1988 FDA 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 prior sales history be provided by those wholesalers who are not authorized and that its provision that those who are authorized need not provide such information. The effect of the FDA's final rule will be to limit wholesalers who are not authorized to purchasing from manufacturers. Since many of these manufacturers will not do business with small wholesalers, the effect of the rule will be to drive thousands of small wholesalers out of business, disrupting the supply of prescription drugs to consumers and affecting prices.

II. In the final rule, 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 manufacturer's 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 is 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 manufacturer's 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.]

Under the final regulation, prescription drug manufacturers will be able to control which of its customers are authorized and which are not. This means such manufacturers may determine which wholesalers are to be burdened by PDMA's requirement for a statement identifying prior sales and which are not. This is a power that cannot be delegated by Congress or by FDA to private companies.

It is the experience of PDA member companies that manufacturers decline to make wholesalers "authorized" for a variety of reasons. One such reason is that the wholesaler is too small to carry a full line of the manufacturers products. Another is that it is too small to maintain a required line of credit. Another reason is that the manufacturer already has adequate coverage in the area where the wholesaler is located. Each of these reasons work against small businesses and, with the change in the requirement for a statement identifying prior sales as described above, will cause many of these small businesses to go out of business because they will no longer have a source of supply.

III. PDA is a trade association of companies that are wholesalers of prescription drugs. These companies buy drugs directly from manufacturers, from full line wholesalers who are authorized distributors for manufacturers, and from wholesalers who are not authorized distributors of all the drugs they sell. PDA members in turn resell the drugs they buy to other wholesale distributors, to retail pharmacies, to health care entities and to physicians. These companies are sometimes called "secondary" wholesalers because the do not carry a full line of pharmaceuticals as do major wholesalers like McKesson. Like full line wholesalers, PDA members are licensed by each state in which they are authorized to do business and PDA member facilities are subject to inspection by FDA and state authorities. When these companies have two transactions in two years with a manufacturer, they are considered to have a continuing relationship

with such manufacturer and are "authorized distributors of record" in accordance with FDA's 1988 PDMA Guidance Information. If they cannot be considered to be authorized distributors of record, they provide a statement identifying prior sales to their customer, as required by PDMA.

It is important for PDA members to be able easily to determine from prior transactions whether they have achieved a continuing relationship that allows them to be an "authorized distributor of record." This is because written distribution contracts between manufacturers and wholesalers are the exception and not the rule in the pharmaceutical industry. Moreover, it is not by choice that PDA members are not contractually authorized by manufacturers to be their distributors. While manufacturers may do business with PDA members, they may not choose to make these companies contractually authorized distributors for reasons such as adequate existing relationships, credit requirements that smaller companies cannot meet, territorial distribution agreements, and the fact that smaller distributors may not wish to carry the manufacturer's full line of products. Because FDA's regulation has no standards, a manufacturer can determine, for any reason whatsoever, not to enter into a written agreement with a licensed distributor and cause that licensed distributor to be burdened by the requirement of a statement identifying prior sales.

Not being an authorized distributor of record puts PDA members at a competitive disadvantage in the wholesale marketplace. This is because of PDMA's extraordinary requirement that distributors who are not authorized must disclose to their customer, in the statement accompanying the sale, prior sales of that drug, including the source of the drugs they have sold. This requirement is extraordinary because it provides the wholesaler's customer the opportunity to deal directly with the wholesaler's source of supply the next time they wish to buy that drug or drugs.

Presently, when PDA members are required to provide a statement identifying prior sales, they do so back to the last authorized distributor in the chain of distribution, as they are permitted to do under

FDA's 1988 Guidance Information's contemporaneous interpretation of PDMA. This is as far back in the chain that they can go because authorized distributors of record are not required by PDMA to provide prior sales information to their customers and they do not do so. Under FDA's final rule, PDA member distributors who are not authorized are required to provide prior sales information back to the manufacturer even though FDA has acknowledged that authorized distributors are not required to provide that information to their customers. FDA's final rule has created an impossible situation for distributors who are not authorized, one which was avoided by FDA in its 1988 contemporaneous interpretation of PDMA. PDA members who buy from authorized distributors will not be able to comply with FDA's final rule and will now be shut out of doing business with those authorized distributors. If manufacturers refuse to sell to them as well, as many now do, they will be out of business entirely.

IV. Unless a stay is granted as requested herein, PDA members will suffer irreparable injury because they will no longer be able to purchase prescription drugs from the authorized distributors with which they have done business in the past. In addition, there is no guarantee that these companies, all of which are licensed wholesalers in the states where they do business, will be able to purchase these drugs directly from their manufacturers. Because of the effect of this regulation, these companies businesses will be severely disrupted and many will be forced out of business.

V. The legislative discussions initiated on these subjects by PDA are not frivolous and are being pursued in good faith. The issue presented 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. FDA in its 1988 letter to industry interpreted PDMA in the same manner that PDA seeks to be the standard for going forward while these discussions take place.

VI. There is a substantial public policy in favor of small businesses. It is 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. That public policy as well will be advanced if the relief requested herein is granted.

VII. 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 wholesales industry have operated under the guidance of FDA's 1988 letter for almost twelve years. Operating under that guidance as requested herein, until PDA's efforts to receive legislative relief is 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 regulation without any public health explanation. 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 rules go into effect. Accordingly, we request the regulations noted above be stayed until October 1, 2001.

Respectfully submitted,

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