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February 17, 2004

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

RE: Docket Nos. 92N-0297 and 88N-0258

Dear Sir/Madam:

On December 1, 2003, the Pharmaceutical Distributors Association ("PDA") filed a Petition For Continuation of Stay of Action and Suspension Of Effective Date And For Issuance of a Draft Agency Guidance Document Setting Forth The Recommended Guidelines For Pharmaceutical Distribution System Integrity ("Petition"). FDA acknowledged receipt of this Petition by letter dated December 3, 2003.

The Petition included two Appendices. We have determined that the incorrect document was inadvertently included as Appendix B, and herein seek to correct the record by enclosing the document that was intended to be set forth as Appendix B. Please remove existing Appendix B from all copies of the Petition, replacing it with the enclosed.

We note that the attached, correct Appendix B document was previously submitted to FDA as noted in the Petition. It was filed in the above referenced docket on September 5, 2003, and available at: http://www.fda.gov/ohrms/dockets/dailys/03/Sept03/090503/92n-0297-m000001-01-vol8.pdf and http://www.fda.gov/ohrms/dockets/dailys/03/Sept03-/090503/88n-0258-m000001-vol6.pdf

Sincerely,

Anthony L. Young

Enclosure

88N-0258

CR 2

APPENDIX B

MEMORANDUM

TO: The Food and Drug Administration

FROM: The Pharmaceutical Distributors Association

DATE: July 23, 2003

SUBJECT: Authority Under the Prescription Drug Marketing Act of 1987, as amended, to Promulgate Regulations Mandating that the Prescription Drug Pedigree Report Sales Back to the Last Authorized Distributor or to the Manufacturer (Docket Nos. 92N-0927 and 88N-0258)

I. Introduction

In December of 1999, the Food and Drug Administration ("FDA") promulgated final regulations to implement the prescription drug pedigree provisions of the Prescription Drug Marketing Act, as amended. These regulations required that the prescription drug pedigree go back to the manufacturer in all instances, despite the fact that authorized distributors are not required to provide a pedigree to their customers. These regulations have been stayed pending legislative action to address the language of the statute.

Representatives of the Pharmaceutical Distributors Association ("PDA") have met with staff of the Subcommittee on Health, House Committee on Energy and Commerce, who have requested that PDA meet with FDA to ascertain whether FDA, on reflection, could revisit whether, under current law, the prescription drug pedigree can go back to the authorized distributor, as permitted under FDA guidance from 1988 to 1999.

II. Background

The Prescription Drug Marketing Act of 1987 ("PDMA"), Pub. L. 100-293, as amended by the Prescription Drug Amendments of 1992 ("PDA of 1992"), Pub. L. 102-353, provides, in pertinent part:

> (A) Each person who is engaged in the wholesale distribution of a drug subject to subsection (b) and who is not the manufacturer or an authorized distributor of record of such drug shall, before each wholesale distribution of such drug (including each distribution to an authorized distributor of record or to a retail pharmacy), provide the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or

trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction).

Federal Food Drug & Cosmetic Act ("FFDCA"), § 503(e)(1)(A).

It is clear (and undisputed) that under § 503(e)(1)(A), prescription drug manufacturers and authorized distributors of record are exempted from the requirement to provide "a statement . . . identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction)" (hereinafter referred to as "pedigree").[1] Instead, the pedigree requirement applies to all other licensed wholesalers of prescription drug products.[2]

In 1988, following the enactment of PDMA but prior to the promulgation of any proposed rules to implement this legislation, FDA issued an August 1, 1988 Letter to Regulated Industry and Other Interested Persons ("1988 Guidance"), interpreting the scope of the pedigree requirement as requiring, among other things, "all necessary identifying information regarding all sales in the chain of distribution of the product, *starting with the manufacturer or authorized distributor of record* . . ." (emphasis added). 1988 Guidance, p. 12.[3]

The Agency's 1988 interpretation and policy remained unchanged until 1994, when FDA published proposed rules to implement the pedigree requirement. 59 Fed. Reg. 11842 (March 14, 1994). In those proposed rules and in final rules published in early December 1999, FDA reinterpreted the statute and required pedigree to report all prior sales back to the manufacturer in every instance. *Id.*, at 11857, 11868 (proposed 21 C.F.R. § 203.50(a)(6)); 64 Fed. Reg. 67720, 67761 (December 3, 1999) (final 21 C.F.R. § 203.50(a)(6)). The effective date of the final regulation has since been stayed. *See e.g.*, 68 Fed. Reg. 4912 (January 31, 2003) (staying the effective date for 21 C.F.R. § 203.50(a)(6) until April 1, 2004).

In the preamble to its 1994 proposal, FDA infers (but never states directly) that the requirement that a pedigree go back to the manufacturer somehow evolves out of the PDA of 1992:

> As Congress stated in the section-by-section analysis that accompanied the PDA [of 1992] when it was introduced and passed, the stricter language in the PDA [of 1992] revision "makes it clear" that any wholesale distribution of a prescription drug by an unauthorized distributor, including any sale to another unauthorized distributor, an authorized distributor of record, or a retail pharmacy, must be preceded by a full and complete identifying statement. "The identifying statement," the analysis added, "must in all cases include the dates of each transaction involving the drug and the names and the addresses of all parties to the transaction, and must contain any such other information as

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[1] *See e.g.*, FDA's June 2001 Report to Congress on the Prescription Drug Marketing Act ("Report"), pp. IX, 9, 22 ("FDA does not have the authority to require authorized distributors to maintain and pass on pedigree.").

[2] The issue as to who properly is an "authorized distributor of record" is not the subject of this memorandum.

[3] FDA's guidance was issued prior to the amendments made by the PDA of 1992. For the reasons set forth herein, nothing in the PDA of 1992 required FDA to change its 1988 policy permitting the prescription drug pedigree to start with an authorized distributor of record.

the Secretary may require." (Congressional Record, page S 12061, August 10, 1992; page H 6107, August 12, 1992).

> Passage of the PDA [of 1992] thus gave added emphasis to Congress' intent, as stated in the legislative history of PDMA, to restore accountability to the wholesale sector of the pharmaceutical market and to regulate the wholesale distribution of prescription drug products. (H. Rept. 100-76, pp. 16-17; S. Rept. 100-202, p. 7).
>
> Proposed § 203.50(a) would restate the statutory requirement that, before the completion of any wholesale distribution by an unauthorized wholesaler to another wholesale distributor or retail pharmacy, the seller is required to provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug. It would require that the drug pedigree include: (1) The proprietary and established name of the drug; (2) the dosage; (3) the container size; (4) the 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 drugs, starting with the manufacturer; and (7) the date of each previous transaction involving the drug.

59 Fed. Reg. 11842, 11857.

In the Preamble to the final rule, FDA again expressed its general view that the language of the statute as amended compelled the Agency to require pedigree back to the manufacturer:

> Section 503(e)(1)(A) of the act requires that, prior to completion of a wholesale distribution of a prescription drug by a person who is not the manufacturer or an authorized distributor of the drug, a statement must be provided to the recipient identifying *each prior sale, purchase, or trade of the drug*, including the date of the transaction, and the names and addresses of all parties to the transaction. There is no indication in PDMA that Congress intended that the statement include only those sales, purchases, or trades since the drug was last handled by an authorized distributor. Thus, an unauthorized distributor is required to provide a full drug origin statement in accordance with PDMA and the final rule whether or not it has purchased a prescription drug from an authorized distributor of record. Although the agency encourages authorized distributors to provide a drug origin statement to unauthorized distributors, they are not required to do so under PDMA or the final rule.

64 Fed. Reg. 67720, 67747 (emphasis added). Neither FDA's proposal nor the final rule discussed in any detail FDA's contrary interpretation in the 1988 Guidance. The failure of the Federal Register notices to explain the basis for this important change is stunning.

More recently, in its Report, FDA reiterated its position that 21 C.F.R. §203.50(a)(6) is based on the statutory requirement that pedigree identify "each prior sale, purchase, or trade of such drug." Report to Congress, pp. X-XI. The Agency concluded,

> Because § 203.50 reflects the language of the statute, the FDA believes that it cannot revise the regulation to make it consistent with the *status quo* [i.e., the pedigree need only

> go back to the most recent authorized distributor who handled the drug]. Such a requirement would necessitate a statutory change . . . . Congress could require that the pedigree go back only as far as the last authorized distributor, rather than to the manufacturer.

Id., pp. XI, 23; *see also id.*, p. 24 ("The exact meaning of the phrase "each prior sale" can be addressed only through statutory remedies.")

FDA has also stated that under its final regulation,

> 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 § 203.50.

65 Fed. Reg. 56480, at 56481, n. 2 (Sept. 19, 2000). After commissioning its study resulting in the June 2001 Report, FDA further observed that authorized distributors of record are not, and likely will not be, providing the information that unauthorized wholesale distributors would need to satisfy § 203.50. Report, pp. V & 15 ("the statements submitted to the docket by the primary distributors are generally consistent with those submitted by the secondary distributors, indicating that they generally are not providing pedigrees. In addition, several primary distributors stated that their warehouse operations are not currently set up in a way that facilitates providing pedigrees, and it would be expensive for them to do so. Therefore, as a practical matter, the large distributors do not appear to be willing to voluntarily provide pedigrees."). In addition, FDA received comments and hearing testimony from individuals and entities that purchase drugs from secondary distributors, such as retail grocery stores, pharmacies, and physicians, which indicated that the secondary distribution market is critical to their operations and to the provision of medicine to consumers. FDA described these comments and testimony as follows:

> For example, . . . pharmacists frequently use more than one distributor to meet their supply needs and secondary wholesale distributors are used extensively by pharmacies, particularly to obtain unusual products or to purchase drugs when a pharmacy is in a remote area not served by one of the larger distributors. Although pharmacies do purchase directly from manufacturers and authorized distributors, secondary distributors are often used as backups to ensure access to a full range of products when they are needed.

Report, pp. V & 15.

The fact that authorized distributors of record will not, for all practical purposes, give the secondary market the information they would need to comply with the pedigree information required by the final rule, coupled with the fact that the secondary market is a critical part of the prescription drug supply chain, necessarily results in the FDA's final regulations having a crippling economic impact. If the final rules are implemented as currently drafted, over 6,000 businesses (most of them small businesses) that are critical to the distribution of prescription

drugs will either operate in violation of the regulation, subjecting themselves to regulatory action and significant product liability exposure, or be forced out of business due to their inability to obtain and provide the required pedigree.

To date, other than the passages quoted above, the Agency has provided neither any legal analysis nor any legal authority to support its position that the pedigree requirement must, in order to be consistent with the statute, include documentation of prior purchases of a prescription drug back to the manufacturer in every instance. In fact, and as is demonstrated herein, established principles of statutory construction compel the opposite result. Indeed, the plain language of the statute shows that in PDMA/PDA of 1992 Congress intended that the pedigree include only those sales, purchases, or trades since the drug was last handled by an authorized distributor. Accordingly, FDA's original interpretation of the pedigree requirement embodied in its 1988 Guidance permitting pedigree to report back to the last purchase from an authorized distributor is mandated by the statute. Even if not so mandated, FDA's 1988 Guidance is certainly the only reasonable interpretation of § 503(e)(1)(A). Contrary to the course followed by the FDA since 1994, agencies of the United States government do not usually interpret the statutes under which they operate to force most of an industry out of its business. Accordingly, FDA's 1988 Guidance permitting pedigree to start with the manufacturer or authorized distributor of record should be reinstated through reconsideration and publication of a revised proposed 21 C.F.R. § 203.50(a)(6).

III. Legal Analysis

A. FDA Has the Authority to Revisit Its Interpretation of the Pedigree Requirement and Issue A Revised Proposed Regulation

The Agency has the authority to revisit and to change 21 C.F.R. § 203.50(a)(6) through formal notice and comment procedures. Such activity is far from unprecedented: as recently as last October, FDA reconsidered and proposed to amend its final regulations regarding new drug application patent listing requirements and proposed to revise final regulations regarding the effective date of approval for certain abbreviated new drug applications and certain applications submitted under § 505(b)(2) of the FFDCA. *See* 67 Fed. Reg. 65448 (October 24, 2002). Indeed, these reconsiderations were the basis for Congressional staff's suggestion that the PDA ask that FDA revisit its position regarding the scope of the pedigree requirement.

It is therefore plainly apparent that there is no regulatory hurdle that prevents FDA from revisiting and revising its position currently set forth in the final rule. PDA agrees with the proposition that FDA is constrained, as it always is, to implement the law as written. However, for reasons stated below, the Agency is simply incorrect in its position that the statute prohibits them from returning to their previous position that pedigree can commence with the manufacturer or authorized distributor of record.

B. Under *Chevron* and Well-Established Principles of Statutory Construction, § 503(e)(1)(A) Requires Unauthorized Distributors To Obtain Pedigree Back To Either The Manufacturer *Or* An Authorized Distributor Of Record

Chevron provides that where Congress speaks directly to an issue, an Agency is not entitled to any deference on a differing interpretation: the agency must give effect to the unambiguously expressed intent of Congress. *Chevron, U.S.A., Inc. v. Natural Resources Defense Counsel, Inc.*, 467 U.S. 837, at 842-3 (1984). A court will not defer to the agency's reading of a statute if that interpretation is not reasonable, is inconsistent with the statutory purpose, or is in conflict with the with the statute's plain language.

As explained in more detail below, the plain language of § 503(e)(1)(A) is clear that Congress unambiguously intended that licensed wholesale distributors that are not "authorized" need obtain pedigree only back to either the manufacturer or an authorized distributor of record. However, assuming *arguendo* that the statute is not clear on its face, the only reasonable interpretation proffered by FDA that can withstand judicial scrutiny is the interpretation supplied by the Agency its 1988 Guidance.

(1) The Plain Language in § 503(e)(1)(A) Speaks Directly To The Scope of the Pedigree Requirement For Secondary Wholesalers and Exempts Secondary Wholesalers From a Requirement To Identify Prior Sales of Product that It Purchases From a Manufacturer or An Authorized Distributor

The cannons of statutory construction include among them the fundamental principle that each provision of a statute must be given meaning in the context of the statute as a whole. *See United States v. Wilson*, 290 F.3d 347, 355 (D.C. Cir. 2002), *cert. denied*, 123 S.Ct. 581 (2002) (citations omitted). Indeed, "[i]t is the 'classic judicial task" of construing related statutory provisions "to 'make sense' in combination." *Id.* (quoting *United States v. Fausto,* 484 U.S. 439, 453 (1988)).

Section 503(e)(1) contains three distinct clauses or sections. Taken individually, each clause does the following:

The first clause in § 503(e)(1)(A), "Each person who is engaged in the wholesale distribution of a drug subject to subsection (b) and who is not the manufacturer or authorized distributor of record of such drug . . ." establishes a categorical exemption for manufacturers and authorized distributors of record from the pedigree requirements that follow.

The next section of § 503(e)(1)(A), " . . . shall, before each wholesale distribution of such drug (including each distribution to an authorized distributor of record or to a retail pharmacy), provide the person who receives the drug a statement (in such form and containing such information as the Secretary may require)," establishes that a statement must be provided by all

other wholesaler distributors to recipients (whether such recipients be authorized distributors of record or retailers or others) before wholesale distribution of the drug.

In isolation, the remaining text in § 503(e)(1)(A), "identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction)," describes the information that needs to be contained in the drug statement. As we understand it, FDA's current position is that in the absence of additional language in this part of § 503(e)(1)(A) limiting "each prior sale, purchase, or trade" back to the last authorized dealer of record, the pedigree requirement must refer to "each prior sale" back to the first sale by the manufacturer in every instance. *See e.g.,* Report to Congress, p. XI.

However, under the fundamental principle that each provision of a statute must be given meaning in the context of the statute as a whole, the third section of § 503(e)(1)(A) cannot be read in isolation. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060 at 1067 (quoting *Pilot Life Insurance Co. v. Dedeaux*, 481 U.S. 41, 52 (1987): "[I]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy."). Specifically, this portion of § 503(e)(1)(A) must be read in the context of the fact that authorized distributors of record are unquestionably exempted from pedigree requirements through the first clause of §503(e)(1)(A). Significantly, this is the case whether the authorized distributor has purchased the product directly from the manufacturer, or whether the authorized distributor buys product later in the distribution chain.[4] In sum, what the plain language of § 503(e)(1)(A) provides is an unqualified exemption for the authorized distributors of record: authorized distributors of record are not required to produce a drug statement when they make wholesale distributions of product, irrespective of the source of the product that they are distributing.

Reading the provision as a whole as we must, the "each prior sale, purchase, or trade" language and the "names and addresses of all parties to the transaction" language in the third clause of § 503(e)(1)(A) are *on their face necessarily qualified by the existence of the unequivocal exemption for manufacturers or authorized distributors.* Stated differently, the

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[4] In its Report, FDA indicates that the market has changed dramatically since 1987: noting that contrary to the Agency's earlier understanding, today "some drugs may go through several transaction cycles involving multiple primary and secondary wholesalers before arriving at their retail destination. Report, p. IX; *see also id.,* pp. 5, 20-21. It is clear, however, that *Congress* understood that this was occurring when it enacted the PDA of 1992. Specifically, through the PDA of 1992 Congress added the following language to describe the scope of wholesale sales subject to pedigree requirements: "(including each distribution to an authorized distributor of record or to a retail pharmacy)", making it clear that Congress understood that there were situations where licensed wholesalers who are not "authorized" would sell prescription drug products to authorized distributors of record. Pub. L. 102-353, § 4. Armed with this appreciation of the market, Congress nevertheless chose to leave unaltered its comprehensive exemption for authorized dealers from pedigree requirements, and authorized dealers who then resell product that they buy from secondary dealers need not provide any pedigree to subsequent purchasers. The Agency raises for Congressional consideration whether the exemption for authorized distributors is correct as a policy matter. *See e.g.,* Report, pp. 21-22. We do not understand FDA to be currently pursuing this position with Congress, but even if it were, FDA remains obligated to issue regulations that implement the pedigree requirements under the language of the statute as it currently stands, and cannot, because it has a larger policy problem with Congress' statutory exemption for authorized distributors, distort the statute in such a way as to require pedigree on secondary distributors in excess of the statutory mandate. *See e.g., Backcountry Against Dumps v. EPA,* 100 F.3d 147, 151-2 (D.C. Cir. 1996).

exemption that FDA seems to be saying needs to be added to the statute in the last clause in order to support PDA's position *is already there* by virtue of the exemption in the first clause.[5] *See Robinson v. Shell Oil Co.,* 519 U.S. 337, 341 (1997) ("The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole.")(citations omitted).

Instead of relying on what the statute specifically requires (prior transaction details) and exempts ("authorized" distributors), and giving meaning to both of these provisions together, FDA implies, wrongly, a negative – "there is no indication" Congress did not want the pedigree to go back to the manufacturer. This is word play and nothing more.[6]

(2) Even if the Statute is Ambiguous, FDA's Current Interpretation Is Not Entitled To *Chevron* Deference

If a statute is silent or ambiguous with respect to the specific issue, an agency's construction will not be disturbed if it is "'a reasonable accommodation of conflicting policies ... unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned.'" *Chevron,* 467 U.S. at 844 (citations omitted). Assuming *arguendo* that § 503(e)(1)(A) is ambiguous as to the scope of the pedigree requirement for secondary wholesale distributors, the Agency's 1988 Guidance indicating that prior sales can commence with an authorized distributor provides the only reasonable interpretation of that statute. By contrast, the agency's final regulation is not reasonable, and cannot withstand a *Chevron* prong-two analysis.

(a) Contrary To FDA's Vague Assertions, There is Nothing in the Statute or Its Legislative History That Requires Pedigree Back To The Manufacturer In Every Instance

Contrary to the Agency's vague assertions that the legislative history of the PDMA or the PDA of 1992 require the pedigree to go back to the manufacturer in every instance, the reality is that nothing in the legislative history actually does so.

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[5] Indeed, the fact that the "each prior sale, purchase, or trade" language and the "names and addresses of all parties to the transaction" language does *not* contain a phrase indicating that it is limited back to either the manufacturer or authorized distributor of record is in itself significant, but not for the reasons cited by FDA. The omission of any reference to *either* a manufacturer or authorized distributor in the last section of 503(e)(1)(A) is significant *not* because it suggests that secondary distributors must report prior sales back to the manufacturer in each instance, but because it shows that the "each prior sale, purchase, or trade" language was intended to and is necessarily qualified by the scope of the entire exemption set forth in the first section of § 503(e)(1)(A). In this case, silence in the last section of 503(e)(1)(A) effectuates the unambiguous intent of Congress to qualify the scope of the pedigree requirement to the scope of the exemption set forth in the first section of 503(e)(1)(A).

[6] In the absence of a "clearly expressed legislative intention to the contrary," the language of the statute itself "must ordinarily be regarded as conclusive." *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.,* 447 U.S. 102, 109 (1980). Thus, even if legislative history were relevant to *Chevron* prong one analysis, such legislative history would need to be extremely persuasive in order to justify FDA's reading. *Aaron v. SEC,* 446 U.S. 680, 697 (1980). As is described in greater detail in Section III.B(2)(a) below, there is no legislative history to even remotely support FDA's current interpretation, let alone, any persuasive legislative history that could overcome the plain meaning of the statute. By contrast, quite the opposite is true.

Congress has never enumerated – either in the legislative history for PDMA or the PDA of 1992 – a concern that pedigree be traced to the manufacturer as the Agency would require. In its section by section analysis of PDMA, the Senate Finance Committee indicated that under the PDMA,[7] "[u]nauthorized distributors will be required to certify in writing to drug wholesalers *the source and place* from which they obtained their drugs." S. Rep. 100-303 (March 18, 1988), 1988 U.S.C.C.A.N 57, at 63. There is absolutely nothing in this legislative history that suggests that the PDMA pedigree requirement could be satisfied only by articulation of prior sales back to the manufacturer.

Years after FDA issued its 1988 Guidance, Congress enacted the PDA of 1992 to address issues that had arisen since enactment of PDMA. Specifically, through the PDA of 1992, Congress clarified § 503(e)(1)(A) to make it clear that code systems being utilized by certain secondary distributors to identify source and place was not adequate, and specifically required identification of "the names and addresses of all parties to the transaction." *See 59* Fed. Reg. at 11857; 64 Fed. Reg. at 67747. As FDA has noted, the legislative history of the PDA of 1992 provides: "The identifying statement must in all cases include the dates of each transaction involving the drug and the names and the addresses of all parties to the transaction, and must contain any such other information as the Secretary may require." *See* 59 Fed. Reg. 11842, 11857. FDA places inappropriate weight on the "all cases" language therein, which simply refers to the fact that Congress understood that there were certain cases where codes were being utilized by some secondary distributors in lieu of more detailed origin information, and that that practice was not sufficient.

Thus, although it had the opportunity, and although FDA's 1988 Guidance position regarding the scope of pedigree was available to it, Congress did not undertake to correct FDA's 1988 Guidance position to specify that the pedigree must go back to the manufacturer. Instead, Congress left FDA's 1988 Guidance permitting pedigree to go back to an authorized distributor untouched and intact. Congressional failure to revise or repeal the Agency's 1988 interpretation is persuasive evidence that the interpretation is the one intended by Congress. *See Young v. Community Nutrition Inst.*, 476 U.S. 974, 983 (1986) (citations omitted); *see also United States v. Rutherford*, 442 U.S. 544, n. 10 ("once an agency's statutory construction has been 'fully brought to the attention of the public and the Congress," and the latter has not sought to alter that interpretation although it has amended the statute in other respects, then presumably the legislative intent has been correctly discerned.") (citations omitted).

Thus, contrary to the preamble to the proposed and final rule, the PDA of 1992 are in truth and in fact an affirmation of that part of the 1988 guidance that declared the pedigree could go back to an authorized distributor. FDA's unexplained and about-face determination that prior

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[7] As originally enacted, PDMA provided, in pertinent part:

> Each person who is engaged in the wholesale distribution of drugs subject to subsection (b) and who is not an authorized distributor of record of such drugs shall provide to each wholesale distributor of such drugs a statement identifying each sale of the drug (including the date of the sale) before the sale to such wholesale distributor.

Pub. Law 100-293, § 6(e)(1).

sales must be traced back to the manufacturer is inconsistent with the statute and its legislative history and cannot withstand judicial scrutiny.

(b) FDA's Interpretation Produces An Impermissibly Absurd Outcome

FDA's current interpretation of § 503(e)(1)(A) not only reads the final section of the provision in isolation without giving meaning to the remainder of the provision, but results in an impermissibly absurd outcome. Specifically, FDA's reading of the statute results in one of two equally nonsensical outcomes -- either: (a) § 503(e)(1)(A) would broadly and categorically exempt manufacturers and authorized distributors from the requirement to maintain and provide pedigree, and then as a practical matter, require those same authorized distributors of record to provide pedigrees; or alternatively, (b) it would impose a requirement on those wholesale distributors who are not authorized that is impossible to satisfy.

As FDA well knows, a literal reading of a statute which would lead to absurd results must be avoided when the statute can be given a reasonable application consistent with its words and with the legislative purpose. *Haggar Co. v. Helvering*, 308 U.S. 389, 394 (1940) (citations omitted); *see also Mova Pharm. Corp. v. Shalala,* 140 F.3d 1060, 1068 (D.C. Cir. 1998). "'It is a familiar rule, that a thing may be within the letter of the statute and yet not within the statute, because not within its spirit nor within the intention of its makers . . . If a literal construction of the words of a statute be absurd, the act must be so construed as to avoid the absurdity.'" *Mova Pharm.,* at 1068 (quoting *Holy Trinity Church v. United States*, 143 U.S. 457, 459-60 (1892)).

> In deciding whether a result is absurd, a court considers not only whether that result is contrary to common sense, but also whether it is inconsistent with the clear intentions of the statute's drafters – that is, whether the result is absurd when considered in the particular statutory context. If "'the literal application of a statute will produce a result demonstrably at odds with the intentions of its drafters,' . . . the intention of the drafters, rather than the strict language, controls.'"

Id. (quoting *United States v. Ron Pair Enterprises*, 489 U.S. 235, 242 (1989) and *Griffin v. Oceanic Contractors, Inc.,* 458 U.S. 564, 571 (1982)).

FDA has stated that under its final regulation,

> 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 § 203.50.

65 Fed. Reg. 56480, at 56481, n. 2 (Sept. 19, 2000). FDA also knows that authorized distributors of record will not for all practical purposes, provide the unauthorized distributors with the information that they would need to comply with § 203.50. Report to Congress, pp. V & 15. If the final rule is implemented as currently drafted, the economic impact is staggering: over 6,000 businesses, most of them small businesses, that are critical to the prescription drug

supply will be put out of business for lack of an ability to obtain and provide the required pedigree.

There can be no question that Congress envisioned at least two things via the enactment of Section 503(e)(1)(A): first, that licensed manufacturers and licensed authorized distributors of record were exempt from pedigree requirements; and second, that licensed distributors, other than authorized distributors of record, could lawfully continue to operate in the prescription drug wholesale market. *See e.g.*, S. Rep. 100-303 (March 18, 1988), 1988 U.S.C.C.A.N 57, at 62 (describing the purpose of subsection 503(e) as "to restore accountability to the wholesale sector of the pharmaceutical market, and to regulate the [continued] wholesale distribution of prescription drug products."). When a literal reading of a statute would thwart the purposes of Congress -- as it would here by either imposing as a practical matter on authorized distributors of record the very requirements the section seeks to exempt them from, or by effectively forcing "other than" authorized distributors of record out of business -- "the agency may deviate no further from the statute than is needed to protect congressional intent." *Mova Pharm.*, 140 F.3d at 1068. The Agency did just that in its 1988 Guidance by imposing on "secondary" wholesale distributors an obligation to obtain pedigree back to the manufacturer *or authorized distributor of record*. In contrast, through the agency's final rule, the "FDA has embarked upon an adventurous transplant operation in response to blemishes in the statute that could have been alleviated with more modest corrective surgery." *Id.*, 1069. The more modest corrective surgery is of, course, the Agency's interpretation of the statute embodied in its 1988 Guidance.

C. The Agency's Final Rule Violates the APA

As demonstrated above, the Agency's final rule incorrectly and impermissibly interprets § 503(e)(1)(A). As such, it is arbitrary and capricious and otherwise not in accordance with law under the Administrative Procedure Act, 5 U.S.C. § 701 *et. seq.* ("APA").[8]

In addition, agency actions – including changes in policy – that lack a reasoned basis constitute arbitrary and capricious action in violation of the APA. *See* 5 U.S.C. § 706(2)(A); *see e.g., Greater Boston Tel. Corp., v. FCC,* 444 F.2d 841, 852 (D.C. Cir. 1970), *cert. denied*, 403 U.S. 923 (1971) ("[A]n agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored, and if an agency glosses over or swerves from prior precedents without discussion it may cross the line from the tolerably terse to the intolerably mute."). The radical change in policy between the issuance of the 1988 Guidance and the proposed and final rules occurred without the provision of any reasoned basis. Indeed, in its guidance to industry, FDA stated,

> [u]ntil these rules are finalized, the information in this letter may be relied upon with assurance of its acceptability to FDA. This letter, however, is not intended to bind FDA should events occur prior to the issuance of a rule that require a change in FDA's policy. Changes in FDA policy will be announced in future letters or notices.

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[8] A reviewing court "shall hold unlawful and set aside agency action" if the action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

Guidance, p. 1. As noted above, nothing in the passage of the PDA of 1992 requires the change implemented by the Agency – quite the opposite is true. To date, FDA has provided no reasoned articulation of the basis for the required change in policy as between the 1988 Guidance and the promulgation of the proposed and final rules. This shocking omission constitutes arbitrary and capricious action.

Agency action is also considered arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983), *cert. denied,* 480 U.S. 951 (1987). PDA respectfully submits that continuing to have a regulation in effect that forces over 6,000 licensed wholesale distributors out of business in the face of Congress' clear vision of a continuing secondary wholesale distribution market "fails to consider an important aspect of the problem."

IV. Conclusion

For the reasons stated above, there is no statutory or regulatory hurdle to the Agency reconsidering its final regulation set forth at 21 C.F.R. § 203.50(a)(6) and issuing, through proposed regulations under its formal notice and comment procedures, a revised regulation consistent with the Agency's prior guidance permitting pedigree to commence with a manufacturer or authorized distributor of record. The current version of 21 C.F.R. § 203.50(a)(6), if implemented, would not, for the reasons stated in this memorandum, withstand judicial review.

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