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April 22, 2004

VIA HAND DELIVERY

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

Re: Docket No. 1992N-0297

Dear Sir or Madam:

The Pharmaceutical Distributors Association ("PDA") submits these comments on the Agency's Federal Register notice staying the effective date of 21 CFR §§ 203.3(u) and 203.50, regulations implementing the Prescription Drug Marketing Act ("PDMA"), from April 1, 2004 until December 1, 2006. 69 Fed. Reg. 8105 (February 23, 2004), *as corrected by* 69 Fed. Reg. 12792 (March 18, 2004).

The PDA's comments focus on the following sentence set forth in the notice:

[a]lthough FDA is further delaying the effective date of §§ 203.3(u) and 205.30, the agency encourages wholesalers to provide pedigree information that documents the prior history of the product, particularly for those drugs most likely to be counterfeited, even when such a pedigree is not required by the act.

69 Fed. Reg. 8107, *as corrected by* 69 Fed. Reg. 12792.

It is not clear to the PDA what this sentence means. The PDA believes that this sentence may reasonably be read in either of two ways. First, the term "wholesalers" may be read as applying to those licensed wholesalers who are not "authorized distributors of record." Licensed wholesalers who are not "authorized

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distributors of record” (often referred to as “secondary distributors”) are required, by PDMA, 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”). To PDA’s knowledge, this requirement has never been in dispute – the difficulties in implementing regulations under PDMA have heretofore focused on the scope of the pedigree to be provided – that is, how far back in the transactional history of the drug pedigree must go – in light of statutory exemptions granted to authorized distributors of record. Yet the Agency statement above says “such a pedigree is [at least at times] not required by the act.”

Although the Agency has delayed the effective date of these very regulations numerous times over the years, *see* 65 Fed. Reg. 25639 (May 3, 2000); 66 Fed. Reg. 12850 (March 1, 2001); 67 Fed. Reg. 6645 (February 13, 2002); 68 Fed. Reg. 4912 (January 31, 2003), it has never once in connection with those stays of effective date suggested that the pedigree is not a requirement that nonetheless applies, to the extent it can be complied with, to wholesalers who are not authorized distributors of record. Indeed, since shortly after PDMA’s passage, the industry has been operating under the guidance issued by the Agency in the form of an August 1, 1988 Letter to Regulated Industry and Other Interested Persons (“1988 Guidance”) which provides that a pedigree is required from distributors who are not authorized distributors of record, and which further provides that the pedigree so required may start with the manufacturer *or* the last authorized distributor of record. *See* 1988 Guidance, p. 12. The Agency has never formally revoked its 1988 Guidance, which has been relied upon by industry for nearly 16 years.

PDA has always and continues to support the Agency’s exploration of 21st century technological solutions to the problems inherent with the concept of paper pedigree under modern market conditions. Also, PDA has always and continues to support the Agency’s stay of the effective date of the details of the pedigree regulations pending resolution of these complex and important technological issues. However, the PDA respectfully submits that the Agency sends the wrong message by suggesting that there is no legal requirement for the provision of pedigree back to the manufacturer *or* authorized distributor of record by licensed wholesalers who are not authorized distributors of record.

The PDA and its members provide pedigree consistent with the 1988 Guidance, and the PDA and its members follow PDA Guidelines designed to assure the integrity of the sources of the prescription drugs they sell. To ensure

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that the Agency does not unintentionally send the wrong message, it should clarify the statement quoted above to make it clear that the PDMA's self-implementing requirement of a pedigree remains as stated in the Agency's 1988 Guidance.

The Agency should also consider whether to take additional actions to help ensure the integrity of the prescription drug supply. Primary among these would be the issuance of a guidance document embodying the Recommended Guidelines for Pharmaceutical Distribution System Integrity previously supplied to the Agency by PDA through its "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" submitted to this Docket and Docket No. 88N-0258 on December 1, 2003 ("Petition"). Although that portion of the PDA Petition seeking the continuation of stay of action and suspension of effective date was indeed addressed in part by the Agency's notice delaying the effective date of the pedigree regulations on February 23, 2004, PDA's separate request for issuance of the guidance document described above should still be considered. A copy of that portion of the Petition setting forth the Agency's authority to issue the guidance document and setting forth the proposed content of the guidance document is enclosed herewith as Attachment 1 for your convenience. In light of the Agency's suggestion that there is now no pedigree requirement for wholesale distributors who not authorized distributors of record, PDA believes it is important for the Agency to articulate through guidance minimum standards for ensuring the integrity of prescription drug wholesaling transactions to maximize the integrity of the prescription drug supply.

The language excerpted from the February 24th Federal Register notice delaying the effective date of the pedigree regulations is subject to several meanings. For the reasons set forth above, PDA believes that wholesalers other than "authorized distributors of record" are required to provide pedigree back to the manufacturer or the last authorized distributor of record. If the Agency's use of the word "wholesalers" was actually intended to refer to "authorized distributors of record," then perhaps the Agency meant to suggest that these statutorily exempt entities should nevertheless provide pedigree when they sell their products, as it said when it promulgated the PDMA regulations in 1999. If this was the actual intent, the agency should say so now. This reading would not be inconsistent with the rationale behind the Agency's position in its 1988 Guidance that PDMA is self-executing.

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Accordingly, the PDA respectfully requests that the Agency clarify the meaning of the sentence quoted above and that it reconsider PDA's request for issuance of an Agency guidance document setting forth the Recommended Guidelines For Pharmaceutical Distribution System Integrity.

Respectfully submitted,



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Enclosure

cc: Sal Ricciardi
President
Pharmaceutical Distributors Association