



Tom McPhillips
Vice President
U.S. Trade Group

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Sent Via Electronic Submission to Docket No. 2006D-0226

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments on Compliance Policy Guide 160.900 “Prescription Drug Marketing Act Pedigree Requirements Under 21 C.F.R. Part 203” (Docket Nos. 1992N-0297, 1998N-0258, 2006D-0226)

Dear Dockets Management:

Pfizer is a staunch supporter of federal efforts to combat counterfeiting. Hence, we support the FDA’s decision to lift the stay of the final PDMA regulations [21 C.F.R §§ 203.3(u) and 203.50] issued in 1999 and effective December 1, 2006. We recognize that the regulations will help provide additional protection against drug counterfeiting and diversion that currently threatens the nation’s drug supply. Although paper pedigrees are vulnerable to falsification and misuse, they will nevertheless aid in the enforcement of diligence in supply chain transactions pending comprehensive, interoperable technologies for anti-counterfeiting security measures, including electronic pedigree.

Specifically, Pfizer would like to offer the following comments on the draft CPG 160.900.

Pfizer Supports Expiration of the CPG Within One Year of Issuance

The final CPG sets out how FDA “intend[s] to prioritize [its] pedigree-related enforcement resources during the next year.” According to the draft, the prioritization is intended to provide “wholesale distributors [with] a better idea of where and how to focus their initial energies as they implement systems to come into complete compliance” with FDA’s pedigree regulations. To this end, the draft lists four “risk-based” factors that FDA will use to guide the Agency’s efforts.

Pfizer recognizes the initial need to use the risk-based approach proposed in the draft CPG. We are nevertheless concerned that counterfeiters and diverters may themselves use these factors as a roadmap to avoiding detection. In particular, rogue actors may “focus their energy” on activities that FDA has not identified as “risky.” Therefore, Pfizer supports the statement in the draft CPG that the CPG will expire within one year from the date of issuance. After such date, FDA should make clear that the Agency has phased out the risk-based approach and will focus all available enforcement efforts on all products in the drug supply chain.

Manufacturers Should Formally Designate Their “Authorized Distributors of Record”

The current regulation exempts authorized distributors of record (ADRs) from pedigree requirements. We request that the final CPG clarify that a drug wholesaler will not meet the PDMA’s definition of “authorized distributor of record” unless that wholesaler appears on the ADR list that manufacturers will be required to maintain under 21 C.F.R. 203.50(d).¹ This will help prevent rogue wholesalers from self-designating themselves as ADRS as a mechanism for slipping non-pedigreed counterfeits into the supply chain.

The “Identifying Information” on the Pedigree Should Include Lot Number Instead of “Lot or Control Number”

21 C.F.R. 203.50(a) sets forth the specific pedigree information that must be provided by the seller “[b]efore 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 “identifying information” must include: the proprietary and established name of the drug; dosage; container size; number of containers; drug’s lot or control number(s); business name and address of all parties to each prior transaction; and date of each previous transaction.

¹ 21 C.F.R. 203.50(d) provides:

“Each manufacturer shall maintain at the corporate offices a current written list of all authorized distributors of record.

(1) Each manufacturer's list of authorized distributors of record shall specify whether each distributor listed thereon is authorized to distribute the manufacturer's full product line or only particular, specified products.

(2) Each manufacturer shall update its list of authorized distributors of record on a continuing basis.

(3) Each manufacturer shall make its list of authorized distributors of record available on request to the public for inspection or copying. A manufacturer may impose reasonable copying charges for such requests from members of the public.”

Pfizer requests that the CPG clarify that the pedigree must contain the drug's **lot number only**. Lot numbers are required for all prescription packages and should be the preferred element that is included in the pedigree over a control number. Control numbers are not standardized identifiers and could be more easily subjected to counterfeiting activities. Thus, we request the more universally recognized lot number.

“Susceptible Drug List”

FDA has specifically asked for comments on the merit of the CPG providing a list of drugs that have been counterfeited in the past. We do not support the concept of a susceptible drug list. Our concern is that it is an approach that too narrowly focuses efforts, relies on the past and can suggest to counterfeiters other drugs that will be “fair game” to try and counterfeit. That is why Pfizer supports legislation that has been advanced in a growing number of states to require paper pedigrees for all medications that leave the normal distribution channel.

Additional Federal Legislation is Needed

On June 8, 2006, the Agency issued an “FDA Counterfeit Drug Task Force Report: 2006 Update” which, among other things, announced the Agency’s intent to publish the draft CPG for public comment before the stay on the pedigree regulations expires. Also in that Report, FDA indicated the Agency’s willingness to provide “technical assistance” if legislation related to electronic pedigrees is considered by Congress. We believe this would be a valuable contribution to the process of developing stronger federal legislation that intends to implement electronic pedigrees nationally.

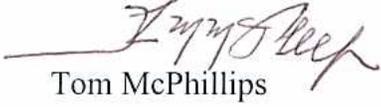
The current FDA regulations will go a long way in helping to shore up gaps in the national distribution system, particularly among states that have not passed their own pedigree legislation. However, the counterfeiting problem in the United States has evolved tremendously since the passage of the original Prescription Drug Marketing Act. In the ensuing years, numerous stakeholders have evaluated and supported appropriate anti-counterfeiting security measures and language. That is why we have and will continue to support state legislative and regulatory efforts to pursue even stronger pedigree rules that make entry of the distribution system by counterfeits even more difficult.

To that end, we strongly believe that federal legislation that embraces some of the principles in the state approaches would be beneficial in helping to protect our nation’s medication supply. For example, we are concerned that broad exemptions for ADRs from providing pedigrees as envisioned in the PDMA [21 C.F.R. §§ 203.3(u) and 203.50], is a flaw that should be corrected given the past history of counterfeits entering at the ADR level. We also recognize that electronic pedigrees and effective electronic track-and-trace technologies such as RFID will be far more effective than the PDMA’s paper pedigree system at ensuring the integrity of the pharmaceutical supply chain. Thus, efforts to tighten the overall controls will ultimately be valuable to patients.

In light of concerns about limitations in the existing federal pedigree law, we support amending the PDMA so that it is more fully aligned with the model pedigree legislation

discussed above. We are committed to working with the FDA in whatever manner possible to assist with current opportunities for tightening our distribution system, while we strive toward federal legislation that will help to thwart the efforts of counterfeiters once and for all.

Sincerely,


Tom McPhillips