



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305  
Docket # 88N-0258

Food and Drug Administration  
Rockville MD 20857

MAR 30 2004

Anthony L. Young, Esq.  
Kleinfeld, Kaplan & Becker LLP  
1140 19<sup>th</sup> Street, NW  
Suite 900  
Washington, DC 20036

Re: Docket Nos. 92N-0297/ PSA 4 and 88N-0258/ PSA 4

Dear Mr. Young:

This letter responds to your petition for stay of action dated December 1, 2003, requesting that the Food and Drug Administration (FDA) continue to stay the effective date of 21 CFR § 203.50 and 21 CFR § 203.3(u). In addition, your petition requested that FDA issue a draft guidance document regarding pharmaceutical distribution system integrity.

With regard to your first request, on February 23, 2004, FDA announced that it was further delaying the effective date of certain provisions of its regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA), including § 203.50 and § 203.3(u). As described in the enclosed *Federal Register* notice,<sup>1</sup> the further delay is intended to allow industry to continue to move toward implementing track and trace technologies. These technologies are expected to fulfill the pedigree requirements of the PDMA and obviate or resolve many of the concerns that have been raised regarding §§ 203.50 and 203.3(u) by ensuring that an electronic pedigree travels with a drug product at all times. It appears that industry will migrate to and implement electronic track and trace capability by 2007. Therefore, FDA delayed the effective date of §§ 203.50 and 203.3(u) until December 1, 2006. Prior to the effective date, we intend to evaluate the progress toward implementation of the electronic pedigree and its capacity to meet the intent of the PDMA, and will determine whether to further delay the effective date of the regulations or take other appropriate regulatory action. We believe FDA's delay of the effective date substantially grants your petition's first request.

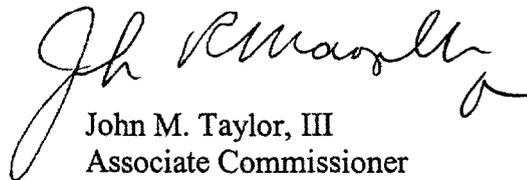
<sup>1</sup> The February 23, 2004, notice contained a few typographical errors. Those errors were corrected in a subsequent *Federal Register* notice on March 18, 2004. A copy of the corrective notice is also enclosed.

92N-0297

PAV1

With regard to your second request, we believe FDA's recently published Counterfeit Drug Final Report sufficiently explains FDA's current policy regarding pharmaceutical distribution system integrity. Therefore, we decline to issue a guidance document at this time. However, as discussed above, we intend to re-evaluate certain issues relating to pharmaceutical distribution system integrity prior to December 1, 2006, and you are welcome to resubmit this request and any other issues presented in your petition at that time. Also, as described in the Counterfeit Drug Final Report, the agency may issue guidance in the future, as necessary and appropriate, to address issues that may be raised by industry or state efforts to improve the integrity of the drug supply chain. You are welcome to resubmit this request or any other related issues at those times, as well.

Sincerely,

A handwritten signature in cursive script, appearing to read "John M. Taylor, III".

John M. Taylor, III  
Associate Commissioner  
for Regulatory Affairs

Enclosures

b. Bacteria, as follows:

- b.1. *Mycoplasma mycoides*;
- b.2. Reserved.

6. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Materials, Chemicals, “Microorganisms” & “Toxins,” ECCN 1C353 is amended by revising the List of Items Controlled to read as follows:

**1C353 Genetic elements and genetically modified organisms, as follows (see List of Items Controlled).**

\* \* \* \* \*

**List of Items Controlled**

*Unit:* \$ value.

*Related Controls:* Vaccines that contain genetic elements or genetically modified organisms identified in this entry are controlled by ECCN 1C991.

*Related Definitions:* N/A.

*Items:*

a. *Genetic elements, as follows:*

- a.1. Genetic elements that contain nucleic acid sequences associated with the pathogenicity of microorganisms controlled by 1C351.a. to .c, 1C352, or 1C354;
- a.2. Genetic elements that contain nucleic acid sequences coding for any of the “toxins” controlled by 1C351.d or “subunits of toxins” thereof.

*Technical Note:* 1. Genetic elements include, inter alia, chromosomes, genomes, plasmids, transposons, and vectors, whether genetically modified or unmodified.

2. This ECCN does not control nucleic acid sequences associated with the pathogenicity of enterohaemorrhagic *Escherichia coli*, serotype O157 and other verotoxin producing strains, except those nucleic acid sequences that contain coding for the verotoxin or its sub-units.

b. Genetically modified organisms, as follows:

- b.1. Genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of microorganisms controlled by 1C351.a. to .c, 1C352, or 1C354;
- b.2. Genetically modified organisms that contain nucleic acid sequences coding for any of the “toxins” controlled by 1C351.d or “subunits of toxins” thereof.

Dated: March 5, 2004.

**Peter Lichtenbaum,**

*Assistant Secretary for Export Administration.*

[FR Doc. 04–6111 Filed 3–17–04; 8:45 am]

BILLING CODE 3510–33–P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 203**

[Docket No. 1992N–0297]

RIN 0905–AC81

**Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; delay of effective date; correction.

**SUMMARY:** On February 23, 2004 (69 FR 8105), FDA published a delay of the effective date of certain requirements in a final rule published in the **Federal Register** of December 3, 1999 (64 FR 67720). FDA is correcting typographical errors in the **SUMMARY** and **SUPPLEMENTARY INFORMATION** sections of the February 23, 2004, document.

**FOR FURTHER INFORMATION CONTACT:** Aileen H. Ciampa, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

**SUPPLEMENTARY INFORMATION:** The **SUMMARY** and **SUPPLEMENTARY INFORMATION** sections of the document published on February 23, 2004 (69 FR 8105), are corrected as follows:

1. In the second paragraph of the **SUMMARY**, in the second from last sentence, the words “Therefore, it is necessary to delay the effective date of §§ 203.3(u) and 203.50 (21 CFR 203.3(u) and 203.50) until December 1, 2007 \* \* \*” is corrected to read “Therefore, it is necessary to delay the effective date of §§ 203.3(u) and 203.50 (21 CFR 203.3(u) and 203.50) until December 1, 2006 \* \* \*”.

2. In the **SUPPLEMENTARY INFORMATION** section in the ninth paragraph, the last sentence is corrected to read as follows: “The agency’s decision to delay the effective date of §§ 203.3(u) and 203.50 was based, in part, on comments received on FDA’s Counterfeit Drug Task Force’s Interim Report (Docket 03N–0361).”

3. In the **SUPPLEMENTARY INFORMATION** section, in the tenth paragraph, the second from last sentence is corrected to read as follows: “One comment suggested an interim solution of a “one forward, one back” pedigree for those drugs most likely to be counterfeited.”

4. In the **SUPPLEMENTARY INFORMATION** section, in the thirteenth paragraph, the first two sentences are corrected to read as follows: “Although FDA is further delaying the effective date of §§ 203.3(u) and 203.50, 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. The suggestion from the comments that there be a one-forward, one-back pedigree for those drugs most likely to be counterfeited until an electronic pedigree is uniformly adopted may have some merit.”

Dated: March 12, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

For the convenience of the reader, the text of the February 23, 2004, document as corrected, is reprinted as follows:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
21 CFR Part 203

[Docket No. 1992N–0297]

RIN 0905–AC81

Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date  
**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; delay of effective date.

**SUMMARY:** The Food and Drug Administration (FDA) is further delaying until December 1, 2006, the effective date of certain requirements of a final rule published in the **Federal Register** of December 3, 1999 (64 FR 67720). In the **Federal Register** of May 3, 2000 (65 FR 25639), the agency delayed until October 1, 2001, the effective date of certain requirements in the final rule relating to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record, and distribution of blood derivatives by entities that meet the definition of a “health care entity” in the final rule. The agency further delayed the effective date of these requirements in three subsequent **Federal Register** notices. Most recently, in the **Federal Register** of January 31, 2003 (68 FR 4912), FDA delayed the effective date until April 1, 2004. This action further delays the effective date of these requirements until December 1, 2006. The final rule implements the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA), and the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). The agency is taking this action to address concerns about the requirements in the final rule raised by affected parties.

As explained in the **SUPPLEMENTARY INFORMATION** section, FDA is working with stakeholders through its counterfeit drug initiative to facilitate widespread, voluntary adoption of track and trace technologies that

will generate a de facto electronic pedigree, including prior transaction history back to the original manufacturer, as a routine course of business. If this technology is widely adopted, it is expected to help fulfill the pedigree requirements of the PDMA and obviate or resolve many of the concerns that have been raised with respect to the final rule by ensuring that an electronic pedigree travels with a drug product at all times. Therefore, it is necessary to delay the effective date of §§ 203.3(u) and 203.50 (21 CFR 203.3(u) and 203.50) until December 1, 2006 to allow stakeholders time to continue to move toward this goal. In addition, the further delay of the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities is necessary to give the agency additional time to consider whether regulatory changes are appropriate and, if so, to initiate such changes.

**DATES:** The effective date for §§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities, added at 64 FR 67720, December 3, 1999, is delayed until December 1, 2006. Submit written or electronic comments by April 23, 2004.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Aileen H. Ciampa, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** PDMA (Public Law 100-293) was enacted on April 22, 1988, and was modified by the PDA (Public Law 102-353, 106 Stat. 941) on August 26, 1992. The PDMA, as modified by the PDA, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331, 333, 353, 381) to, among other things, establish requirements for the wholesale distribution of prescription drugs and for the distribution of blood derived prescription drug products by health care entities.

On December 3, 1999, the agency published final regulations in part 203 (21 CFR part 203) implementing PDMA (64 FR 67720) that were to take effect on December 4, 2000. After publication of the final rule, the agency received communications from industry, industry trade associations, and members of Congress objecting to the provisions in §§ 203.3(u) and 203.50. Respectively, these provisions define the phrase "ongoing relationship" as used in the definition of "authorized distributor of record" and set forth requirements regarding an "identifying statement" (commonly referred to as a "pedigree").

On March 29, 2000, the agency met with representatives from the wholesale drug industry and industry associations to discuss their concerns. In addition, FDA received a petition requesting that the relevant provisions of the final rule be stayed until

October 1, 2001. The agency also received a petition from the Small Business Administration requesting that FDA reconsider the final rule and suspend its effective date based on the severe economic impact it would have on more than 4,000 small businesses.

In addition to the communications regarding wholesale distribution by unauthorized distributors, the agency received several letters on, and held several meetings to discuss, the implications of the final regulations for blood centers that distribute blood derivative products and provide health care to hospitals and patients.

Based on the concerns expressed by industry, industry associations, and Congress about implementing §§ 203.3(u) and 203.50 by the December 4, 2000, effective date, the agency delayed the effective date for those provisions until October 1, 2001 (65 FR 25639). FDA also delayed the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities until October 1, 2001, and reopened the administrative record to give interested persons until July 3, 2000, to submit written comments. The rest of the regulations took effect on December 4, 2000.

On May 16, 2000, the House Committee on Appropriations (the Committee) stated in its report accompanying the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2001 (H. Rept. 106-619), that it supported the "recent FDA action to delay the effective date for implementing certain requirements of the Prescription Drug Marketing Act until October 1, 2001, and reopen the administrative record in order to receive additional comments." The Committee further stated that it "believes the agency should thoroughly review the potential impact of the proposed provisions on the secondary wholesale pharmaceutical industry." The Committee directed the agency to provide a report to the Committee summarizing the comments and issues raised and agency plans to address the concerns.

On March 1, 2001, FDA again delayed the effective dates of the provisions to allow time for the agency to consider the comments and testimony received at an October 27, 2000, public hearing and to prepare its report to Congress (65 FR 56480). The agency's report, which was submitted to Congress on June 7, 2001, concluded that FDA could address some of the concerns raised by the secondary wholesale industry and the blood industry through regulatory changes. However, to make other changes requested by the secondary wholesale industry, Congress would have to amend section 503(e) of the act.

Since submitting its report to Congress, FDA has delayed the effective date of the provisions two more times, most recently until April 1, 2004. On both occasions, the effective date was delayed in order to give Congress additional time to determine whether legislative action was appropriate and to give the agency time to consider whether regulatory changes were warranted (67 FR 6645; 68 FR 4912).

Today, the agency is further delaying, until December 1, 2006, the effective date of

§§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities. The agency's decision to delay the effective date of §§ 203.3(u) and 203.50 was based, in part, on comments received on FDA's Counterfeit Drug Task Force's Interim Report (Docket 03N-0361).

As part of its Counterfeit Drug Initiative, FDA sought comment on the most effective ways to achieve the goals of PDMA. In particular, given recent or impending advances in technology, the agency requested comment on the feasibility of using an electronic pedigree in lieu of a paper pedigree. Although many comments received by the Task Force supported the use of paper pedigrees for their deterrent value and as a means to verify prior sales through due diligence, the majority of comments confirmed that significant concerns persist regarding the feasibility and limitations of full implementation of the PDMA pedigree requirements. Some comments suggested a risk-based approach to implementing PDMA, focusing on those drugs at high risk for counterfeiting. For example, some comments suggested that drugs at high risk for counterfeiting maintain a full pedigree that documents all sales and transactions back to the manufacturer. One comment suggested an interim solution of a "one forward, one back" pedigree for those drugs most likely to be counterfeited. The majority of comments, however, supported the eventual use of an electronic pedigree for all drug products in the supply chain and indicated that an electronic pedigree should be considered as a long-term solution to fulfilling the PDMA requirements codified at § 203.50.

In response to these comments, FDA is continuing to work closely with affected parties to identify and resolve concerns related to the implementation of the pedigree requirements of the PDMA. FDA is encouraged by the enthusiasm and interest that stakeholders in the U.S. drug supply chain have expressed toward the adoption of sophisticated track and trace technologies. Although there are technical, operational, and regulatory issues that have yet to be resolved, these are being considered and addressed by FDA and stakeholders. Currently, it appears that industry will migrate toward and implement electronic track and trace capability by 2007. If this capability is widely adopted, a de facto electronic pedigree will follow the product from the place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, this electronic pedigree could meet the statutory requirement in 21 U.S.C. 353(e)(1)(A) that "each person who is engaged in the wholesale distribution of a drug\*\*\* who is not the manufacturer or authorized distributor of record of such drug\*\*\* provide to 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.)" The permanent electronic pedigree would address the concerns that have been expressed by

wholesalers, particularly secondary wholesalers, regarding access to pedigrees because the required information would travel with the product at all times, regardless of whether a party to the transaction is an authorized distributor of record.

Until the electronic pedigree is in widespread use, FDA believes that the multi-layer strategies and measures discussed in the FDA's Counterfeit Drug Final Report (Final Report) can help reduce the likelihood that counterfeit drugs will be introduced into the U.S. drug distribution system. These measures, combined with implementation of Radio Frequency Identification (RFID) technology, could provide effective long-term protections to help minimize the number of counterfeit drug products in the U.S. distribution system. As discussed in greater detail in the Final Report, such long-term measures include the following: Use of authentication technologies in products and packaging and labeling, in particular, for drugs most likely to be counterfeited; adoption of secure business practices by stakeholders; adoption of the revised model rules for wholesale distributor licensure by States; stronger criminal penalties and enforcement at the State and national levels; and education and outreach to stakeholders, including greater communication through the counterfeit alert network.

Although FDA is further delaying the effective date of §§ 203.3(u) and 203.50, 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. The suggestion from the comments that there be a one-forward, one-back pedigree for those drugs most likely to be counterfeited until an electronic pedigree is uniformly adopted may have some merit. However, FDA believes legislative changes would be needed before it could adopt such a system.

To summarize, FDA has concluded that an electronic pedigree should accomplish and surpass the goals of PDMA and is potentially a more effective solution to tracing the movement of pharmaceuticals than a paper pedigree. As stated previously, it appears that industry will migrate toward and implement electronic track and trace capability by 2007. Therefore, to allow stakeholders to continue to move toward this goal, FDA has decided to delay the effective date of §§ 203.3(u) and 203.50 until December 1, 2006. Before the effective date, FDA intends to evaluate the progress toward implementation of the electronic pedigree and its capacity to meet the intent of PDMA, and determine whether to further delay the effective date of the regulations or take other appropriate regulatory action.

FDA is also further delaying the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities. This further delay is necessary to give FDA additional time to address concerns about the requirements raised by affected parties and consider whether regulatory changes are appropriate and, if so, initiate such changes.

FDA has examined the impacts of this delay of effective date under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this action is consistent with the regulatory philosophy and principles identified in the Executive order. This action will ease the burden on industry by delaying the effect of §§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities while FDA works with industry to resolve concerns about these provisions either with the implementation of technological solutions (§§ 203.3(u) and 203.50) or the consideration of possible regulatory changes (§ 203.3(q)). Thus, this action is not a significant action as defined by the Executive order.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. In addition, given the imminence of the current compliance date, seeking prior public comment on this delay is contrary to the public interest in the orderly issuance and implementation of regulations. Notice and comment procedures in this instance would create uncertainty, confusion, and undue financial hardship because, during the time that the agency would be proposing to extend the compliance date for the requirements identified below, those companies affected would have to be preparing to comply with the April 1, 2004, compliance date. In accordance with 21 CFR 10.40(c)(1), FDA is also providing an opportunity for comment on whether this delay should be modified or revoked.

This action is being taken under FDA's authority under 21 CFR 10.35(a). The Commissioner of Food and Drugs finds that this delay of the effective date is in the public interest.

Dated: February 17, 2004

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-6094 Filed 3-17-04; 8:45 am]

BILLING CODE 4160-01-5

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA-247F]

#### Schedules of Controlled Substances; Placement of 2,5-Dimethoxy-4-(n)-propylthiophenethylamine and N-Benzylpiperazine Into Schedule I of the Controlled Substances Act

**AGENCY:** Drug Enforcement Administration (DEA), Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** This final rulemaking is issued by the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) to place 2,5-dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7) and N-benzylpiperazine (BZP) into Schedule I of the Controlled Substances Act (CSA). This action by the DEA Acting Deputy Administrator is based on a scheduling recommendation by the Department of Health and Human Services (DHHS) and a DEA review indicating that 2C-T-7 and BZP meet the criteria for placement in Schedule I of the CSA. This final rule will continue to impose the regulatory controls and criminal sanctions of Schedule I substances on the manufacture, distribution, and possession of 2C-T-7 and BZP.

**EFFECTIVE DATE:** March 18, 2004.

**FOR FURTHER INFORMATION CONTACT:** Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7183.

**SUPPLEMENTARY INFORMATION:** On September 20, 2002, the Deputy Administrator of the DEA published two separate final rules in the **Federal Register** (67 FR 59161 and 67 FR 59163) amending § 1308.11(g) of Title 21 of the Code of Federal Regulations to temporarily place 2C-T-7, BZP and TFMPP (1-(3-trifluoromethylphenyl)piperazine into Schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). These final rules, which became effective on the date of publication, were based on findings by the Deputy Administrator that the temporary scheduling of BZP, TFMPP and 2C-T-7 was necessary to avoid an imminent hazard to the public safety. Section 201(h)(2) of the CSA (21 U.S.C. 811(h)(2)) requires that the temporary

**Required Actions**

(f) Locate the temperature control assembly, which is mounted on the fuel flow divider assembly and do the following:

(1) Read the SN of the temperature control assembly. The SN is located on the end cap of the temperature control assembly. The end cap has a one-inch hex flange and is threaded into the fuel flow divider body.

(2) If the SN is listed in 1.A.(3) of GE ASB No. CT58 S/B 73-A0081, Revision 2, dated August 7, 2003, or if the SN cannot be determined, remove the fuel flow divider assembly from service.

(g) After the effective date of this AD, do not install any fuel flow divider assembly P/N 4050T82G02 or 4067T04G02, that has a temperature control assembly with a SN listed in 1.A.(3) of GE ASB No. CT58 S/B 73-A0081, Revision 2, dated August 7, 2003.

**Alternative Methods of Compliance**

(h) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

**Material Incorporated by Reference**

(i) You must use GE ASB No. CT58 S/B 73-A0081, Revision 2, dated August 7, 2003 to identify by SN the affected temperature control assemblies. The Director of the Federal Register approved the incorporation by reference of this service bulletin in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You can get a copy from GE Aircraft Engines Customer Support Center, M/D 285, 1 Neumann Way, Evendale, OH 45215, telephone (513) 552-3272; fax (513) 552-3329, e-mail [GEAE.csc@ae.ge.com](mailto:GEAE.csc@ae.ge.com). You may review copies at the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA 01803-5299, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**Related Information**

(j) None.

Issued in Burlington, Massachusetts, on February 13, 2004.

**Peter A. White,**

*Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.*

[FR Doc. 04-3680 Filed 2-20-04; 8:45 am]

BILLING CODE 4910-13-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 203**

[Docket No.1992N-0297]

RIN 0905-AC81

**Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; delay of effective date.

**SUMMARY:** The Food and Drug Administration (FDA) is further delaying, until December 1, 2006, the effective date of certain requirements of a final rule published in the **Federal Register** of December 3, 1999 (64 FR 67720). In the **Federal Register** of May 3, 2000 (65 FR 25639), the agency delayed until October 1, 2001, the effective date of certain requirements in the final rule relating to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record, and distribution of blood derivatives by entities that meet the definition of a "health care entity" in the final rule. The agency further delayed the effective date of these requirements in three subsequent **Federal Register** notices. Most recently, in the **Federal Register** of January 31, 2003 (68 FR 4912), FDA delayed the effective date until April 1, 2004. This action further delays the effective date of these requirements until December 1, 2006. The final rule implements the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA), and the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). The agency is taking this action to address concerns about the requirements in the final rule raised by affected parties.

As explained in the **SUPPLEMENTARY INFORMATION** section, FDA is working with stakeholders through its counterfeit drug initiative to facilitate widespread, voluntary adoption of track and trace technologies that will generate a de facto electronic pedigree, including prior transaction history back to the original manufacturer, as a routine course of business. If this technology is widely adopted, it is expected to help fulfill the pedigree requirements of the PDMA and obviate or resolve many of

the concerns that have been raised with respect to the final rule by ensuring that an electronic pedigree travels with a drug product at all times. Therefore, it is necessary to delay the effective date of §§ 203.3(u) and 203.50 (21 CFR 203.3(u) and 203.50) until December 1, 2007 to allow stakeholders time to continue to move toward this goal. In addition, the further delay of the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities is necessary to give the agency additional time to consider whether regulatory changes are appropriate and, if so, to initiate such changes.

**DATES:** The effective date for §§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities, added at 64 FR 67720, December 3, 1999, is delayed until December 1, 2006. Submit written or electronic comments by April 23, 2004.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Aileen H. Ciampa, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** PDMA (Public Law 100-293) was enacted on April 22, 1988, and was modified by the PDA (Public Law 102-353, 106 Stat. 941) on August 26, 1992. The PDMA, as modified by the PDA, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331, 333, 353, 381) to, among other things, establish requirements for the wholesale distribution of prescription drugs and for the distribution of blood derived prescription drug products by health care entities.

On December 3, 1999, the agency published final regulations in part 203 (21 CFR part 203) implementing PDMA (64 FR 67720) that were to take effect on December 4, 2000. After publication of the final rule, the agency received communications from industry, industry trade associations, and members of Congress objecting to the provisions in §§ 203.3(u) and 203.50. Respectively, these provisions define

the phrase "ongoing relationship" as used in the definition of "authorized distributor of record" and set forth requirements regarding an "identifying statement" (commonly referred to as a "pedigree").

On March 29, 2000, the agency met with representatives from the wholesale drug industry and industry associations to discuss their concerns. In addition, FDA received a petition requesting that the relevant provisions of the final rule be stayed until October 1, 2001. The agency also received a petition from the Small Business Administration requesting that FDA reconsider the final rule and suspend its effective date based on the severe economic impact it would have on more than 4,000 small businesses.

In addition to the communications regarding wholesale distribution by unauthorized distributors, the agency received several letters on, and held several meetings to discuss, the implications of the final regulations for blood centers that distribute blood derivative products and provide health care to hospitals and patients.

Based on the concerns expressed by industry, industry associations, and Congress about implementing §§ 203.3(u) and 203.50 by the December 4, 2000, effective date, the agency delayed the effective date for those provisions until October 1, 2001 (65 FR 25639). FDA also delayed the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities until October 1, 2001, and reopened the administrative record to give interested persons until July 3, 2000, to submit written comments. The rest of the regulations took effect on December 4, 2000.

On May 16, 2000, the House Committee on Appropriations (the Committee) stated in its report accompanying the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2001 (H. Rept. 106-619), that it supported the "recent FDA action to delay the effective date for implementing certain requirements of the Prescription Drug Marketing Act until October 1, 2001, and reopen the administrative record in order to receive additional comments." The Committee further stated that it "believes the agency should thoroughly review the potential impact of the proposed provisions on the secondary wholesale pharmaceutical industry." The Committee directed the agency to provide a report to the Committee summarizing the comments and issues raised and agency plans to address the concerns.

On March 1, 2001, FDA again delayed the effective dates of the provisions to allow time for the agency to consider the comments and testimony received at an October 27, 2000, public hearing and to prepare its report to Congress (65 FR 56480). The agency's report, which was submitted to Congress on June 7, 2001, concluded that FDA could address some of the concerns raised by the secondary wholesale industry and the blood industry through regulatory changes. However, to make other changes requested by the secondary wholesale industry, Congress would have to amend section 503(e) of the act.

Since submitting its report to Congress, FDA has delayed the effective date of the provisions two more times, most recently until April 1, 2004. On both occasions, the effective date was delayed in order to give Congress additional time to determine whether legislative action was appropriate and to give the agency time to consider whether regulatory changes were warranted (67 FR 6645; 68 FR 4912).

Today, the agency is further delaying, until December 1, 2006, the effective date of §§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities. The agency's decision to delay the effective date of §§ 203.3(u) and 203.50 was based, in part, on comments received on FDA's Counterfeit Drug Task Force's Interim Report (Docket 03N-0361).

As part of its Counterfeit Drug Initiative, FDA sought comment on the most effective ways to achieve the goals of PDMA. In particular, given recent or impending advances in technology, the agency requested comment on the feasibility of using an electronic pedigree in lieu of a paper pedigree. Although many comments received by the Task Force supported the use of paper pedigrees for their deterrent value and as a means to verify prior sales through due diligence, the majority of comments confirmed that significant concerns persist regarding the feasibility and limitations of full implementation of the PDMA pedigree requirements. Some comments suggested a risk-based approach to implementing PDMA, focusing on those drugs that are at high-risk of being counterfeited. For example, some comments suggested that drugs at high risk for counterfeiting maintain a full pedigree that documents all sales and transactions back to the manufacturer. One comment suggested an interim solution of "one forward, one back" pedigree for most likely to be counterfeited. The majority of comments, however, supported the eventual use of an electronic pedigree

for all drug products in the supply chain and indicated that an electronic pedigree should be considered as a long-term solution to fulfilling the PDMA requirements codified at § 203.50.

In response to these comments, FDA is continuing to work closely with affected parties to identify and resolve concerns related to the implementation of the pedigree requirements of the PDMA. FDA is encouraged by the enthusiasm and interest that stakeholders in the U.S. drug supply chain have expressed toward the adoption of sophisticated track and trace technologies. Although there are technical, operational, and regulatory issues that have yet to be resolved, these are being considered and addressed by FDA and stakeholders. Currently, it appears that industry will migrate toward and implement electronic track and trace capability by 2007. If this capability is widely adopted, a de facto electronic pedigree will follow the product from the place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, this electronic pedigree could meet the statutory requirement in 21 U.S.C. 353(e)(1)(A) that "each person who is engaged in the wholesale distribution of a drug\*\*\* who is not the manufacturer or authorized distributor of record of such drug\*\*\* provide to 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.)" The permanent electronic pedigree would address the concerns that have been expressed by wholesalers, particularly secondary wholesalers, regarding access to pedigrees because the required information would travel with the product at all times, regardless of whether a party to the transaction is an authorized distributor of record.

Until the electronic pedigree is in widespread use, FDA believes that the multi-layer strategies and measures discussed in the FDA's Counterfeit Drug Final Report (Final Report) can help reduce the likelihood that counterfeit drugs will be introduced into the U.S. drug distribution system. These measures, combined with implementation of Radio Frequency Identification (RFID) technology, could provide effective long-term protections to help minimize the number of counterfeit drug products in the U.S. distribution system. As discussed in greater detail in the Final Report, such long-term measures include the

following: Use of authentication technologies in products and packaging and labeling, in particular, for drugs most likely to be counterfeited; adoption of secure business practices by stakeholders; adoption of the revised model rules for wholesale distributor licensure by States; stronger criminal penalties and enforcement at the State and national levels; and education and outreach to stakeholders, including greater communication through the counterfeit alert network.

Although 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 most likely to be counterfeited, even when such a pedigree is not required by the act. The suggestion from the comments that there be a one-forward, one-back pedigree for high-risk drugs until an electronic pedigree is uniformly adopted may have some merit. However, FDA believes legislative changes would be needed before it could adopt such a system.

To summarize, FDA has concluded that an electronic pedigree should accomplish and surpass the goals of PDMA and is potentially a more effective solution to tracing the movement of pharmaceuticals than a paper pedigree. As stated previously, it appears that industry will migrate toward and implement electronic track and trace capability by 2007. Therefore, to allow stakeholders to continue to move toward this goal, FDA has decided to delay the effective date of §§ 203.3(u) and 203.50 until December 1, 2006. Before the effective date, FDA intends to evaluate the progress toward implementation of the electronic pedigree and its capacity to meet the intent of PDMA, and determine whether to further delay the effective date of the regulations or take other appropriate regulatory action.

FDA is also further delaying the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities. This further delay is necessary to give FDA additional time to address concerns about the requirements raised by affected parties and consider whether regulatory changes are appropriate and, if so, initiate such changes.

FDA has examined the impacts of this delay of effective date under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic,

environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this action is consistent with the regulatory philosophy and principles identified in the Executive order. This action will ease the burden on industry by delaying the effect of §§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities while FDA works with industry to resolve concerns about these provisions either with the implementation of technological solutions (§§ 203.3(u) and 203.50) or the consideration of possible regulatory changes (§ 203.3(q)). Thus, this action is not a significant action as defined by the Executive order.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the *Federal Register*, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. In addition, given the imminence of the current compliance date, seeking prior public comment on this delay is contrary to the public interest in the orderly issuance and implementation of regulations. Notice and comment procedures in this instance would create uncertainty, confusion, and undue financial hardship because, during the time that the agency would be proposing to extend the compliance date for the requirements identified below, those companies affected would have to be preparing to comply with the April 1, 2004, compliance date. In accordance with 21 CFR 10.40(c)(1), FDA is also providing an opportunity for comment on whether this delay should be modified or revoked.

This action is being taken under FDA's authority under 21 CFR 10.35(a). The Commissioner of Food and Drugs finds that this delay of the effective date is in the public interest.

Dated: February 17, 2004.

Jeffrey Shuren,

*Assistant Commissioner for Policy.*

[FR Doc. 04-3856 Filed 2-18-04; 4:04 pm]

BILLING CODE 4160-01-S

## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

#### 30 CFR Part 75

#### Self-Contained Self-Rescuers (SCSRs); Updating a Reference for Locating SCSRs More Than 25 Feet From a Miner

**AGENCY:** Mine Safety and Health Administration (MSHA), Labor.

**ACTION:** Technical amendment.

**SUMMARY:** This technical amendment updates the reference in 30 CFR 75.1714-2(e) (Self-rescue devices; use and location requirements) from 30 CFR 75.1101-23 (Program of instruction; location and use of fire fighting equipment; location of escapeways, exits and routes of travel; evacuation procedures; fire drills) to 30 CFR 75.1502 (Mine emergency evacuation and firefighting program of instruction). This action is necessary to amend the outdated reference in § 75.1714-2(e).

**DATES:** Effective February 23, 2004.

**FOR FURTHER INFORMATION CONTACT:**

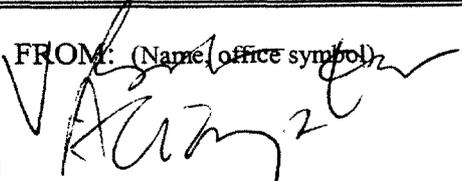
Marvin W. Nichols, Jr., Director, Office of Standards, Regulations, and Variances, MSHA, 1100 Wilson Blvd., Room 2350, Arlington, Virginia 22209-3939, *Nichols.Marvin@dol.gov*, (202) 693-9440 (telephone), or (202) 693-9441 (facsimile).

**SUPPLEMENTARY INFORMATION:**

#### Background

On September 9, 2003, we published the Emergency Evacuations final rule (68 FR 53037 Sept. 9, 2003). Among other things, the rule removed § 75.1101-23 (Program of instruction; location and use of fire fighting equipment; location of escapeways, exits and routes of travel; evacuation procedures; fire drills) and replaced it with § 75.1502 (Mine emergency evacuation and firefighting program of instruction). The Emergency Evacuations final rule was effective upon publication in the *Federal Register*.

In issuing the Emergency Evacuations rule we inadvertently omitted updating the reference in § 75.1714-2(e). Section 75.1714-2(e) references another section of 30 CFR which provides the mechanism for mine operators to apply to the District Manager for permission to place SCSRs more than 25 feet away from a miner. The reference to § 75.1101-23 in § 75.1714-2(e) should have been renumbered to correspond with the change in the numbering in the Emergency Evacuations rule. This technical amendment updates the

CDER Office of Regulatory Policy Routing Slip		Date January 23, 2004	
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D. Horowitz (HFD-300)	(see attached)		
D. Autor (HFD-300)/FYI			
P. O'Rourke (HFD-316)/FYI			
2. (HFD-7)			
3. M. Goldberger (HFD-1)		MJG	2/6/04
4. S. Galson (HFD-1)			2/6
5. (HFD-7)			
6. Concurrent: S. Ray (GCF-1)			
W. McConagha (GCF-1)		cleared	OCC
7. (HFD-7)			
8. J. Taylor (HFC-1)		gar	3/25
9. (HFD-7)/for distribution			
REVIEW DRAFT		X	FINAL CLEARANCE
REMARKS			
<u>Petition for Stay of Action Response</u> (92N-0297 PSA 4 and 88N-0258/ PSA 4)		<b>EXPEDITE</b>	
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.			
NOTE: Please expedite. We intend to issue this document concurrently with the Counterfeit Drug Task Force report (which is targeted to publish in early February). Thank you.			
COMIS#: 6030			
FROM: (Name, office symbol)  Aileen H. Ciampa (HFD-7)		Room No. - Bldg. 1101 - RKW 2 ----- Phone No. 594-2041	

CDER Office of Regulatory Policy Routing Slip	Date January 23, 2004
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TO: (Name, office symbol)	Reply By (optional)	Initials	Date
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D. Horowitz (HFD-300)	<i>(see attached)</i>		
D. Autor (HFD-300)/FYI			
P. O'Rourke (HFD-316)/FYI			
2. <del>(HFD-7)</del>			
3. M. Goldberger (HFD-1)		<i>MJG</i>	<i>2/6/04</i>
4. S. Galson (HFD-1)		<i>SG</i>	<i>2/6</i>
5. <del>(HFD-7)</del>			
6. Concurrent: S. Ray (GCF-1)			
W. McConagha (GCF-1)		<i>W</i>	<i>2/17/04</i>
7. <del>(HFD-7)</del>			
8. J. Taylor (HFC-1)			
9. <del>(HFD-7)</del> /Hold for Public. of PDMA; Delay of Effec. Date			

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REMARKS

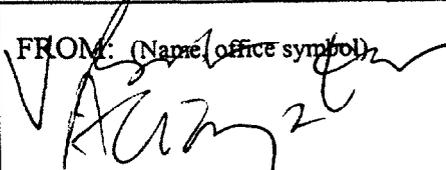
EXPEDITE

Petition for Stay of Action Response  
(92N-0297 PSA 4 and 88N-0258/ PSA 4)

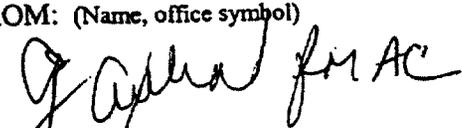
Petition for Continuation of Stay of Action and Suspension of Effective Date and for Issuance of a Draft Agency Guidance Document Setting Forth the Recommended Guidelines for Pharmaceutical Distribution System Integrity.

NOTE: Please expedite. We intend to issue this document concurrently with the Counterfeit Drug Task Force report (which is targeted to publish in early February). Thank you.

COMIS#: 6030

FROM: (Name, office symbol)  Aileen H. Ciampa (HFD-7)	Room No. - Bldg. 1101 - RKW 2 <hr style="border: none; border-top: 1px dashed black;"/> Phone No. 594-2041
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DES

CDER Office of Regulatory Policy Routing Slip		Date January 23, 2004	
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D. Autor (HFD-300)/FYI			
P. O'Rourke (HFD-316)/FYI			
2. (HFD-7)			
3. M. Goldberger (HFD-104)			
4. S. Galson (HFD-1)			
5. (HFD-7)			
6. Concurrent: S. Ray (GCF-1)			
W. McConagha (GCF-1)		WMM	2/12/04
7. (HFD-7)/Hold for Public. of PDMA; Delay of Effec. Date			
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<b>FROM: (Name, office symbol)</b>  Aileen H. Ciampa (HFD-7)		Room No. - Bldg. 1101 - RKW 2 <hr/> Phone No. 594-2041	

CDER Office of Regulatory Policy Routing Slip		Date January 23, 2004	
TO: (Name, office symbol)	Reply By (optional)	Initials	Date
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P. O'Rourke (HFD-316)/FYI			
2. (HFD-7)			
3. M. Goldberger (HFD-104)			
4. S. Galson (HFD-1)			
5. (HFD-7)			
6. Concurrent: S. Ray (GCF-1)			
W. McConagha (GCF-1)			
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<b>REMARKS</b> <p><b>EXPEDITE</b></p> <p><u>Petition for Stay of Action Response</u> (92N-0297 PSA 4 and 92N-0238/PSA 4)</p> <p><u>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.</u></p> <p>NOTE: Please expedite. We intend to issue this document concurrently with the Counterfeit Drug Task Force report (which is targeted to publish in early February). Thank you.</p> <p>COMIS#: 6030</p>			
FROM: (Name, office symbol)		Room No. - Bldg. 1101 - RKW 2	
Aileen H. Ciampa (HFD-7)		Phone No. 594-2041	

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CDER Office of Regulatory Policy Routing Slip		Date January 23, 2004	
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P. O'Rourke (HFD-316)/FYI			
2. (HFD-7)			
3. M. Goldberger (HFD-104)			
4. S. Galson (HFD-1)			
5. (HFD-7)			
6. Concurrent: S. Ray (GCF-1)			
W. McConagha (GCF-1)			
7. (HFD-7)/Hold for Public. of PDMA; Delay of Effec. Date			
<input type="checkbox"/> REVIEW DRAFT	<input checked="" type="checkbox"/> X	<input type="checkbox"/> FINAL CLEARANCE	
<p>REMARKS</p> <p style="text-align: right;"><b>EXPEDITE</b></p> <p><u>Petition for Stay of Action Response</u> (92N-0297 PSA 4 and 88N-0258/ PSA 4)</p> <p>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.</p> <p>NOTE: Please expedite. We intend to issue this document concurrently with the Counterfeit Drug Task Force report (which is targeted to publish in early February). Thank you.</p> <p>COMIS#: 6030</p>			
FROM: (Name, office symbol)		Room No. - Bldg.	
<i>Aileen H. Ciampa for AC</i>		1101 - RKW 2	
Aileen H. Ciampa (HFD-7)		Phone No. 594-2041	

**Docket Nos. 92N-0297  
88N-0258**

**BEFORE  
THE UNITED STATES OF AMERICA  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

**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**

**BY THE  
PHARMACEUTICAL DISTRIBUTORS ASSOCIATION**

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

**December 1, 2003**

Pursuant to 21 C.F.R. § 10.35, the Pharmaceutical Distributors Association ("PDA"), a trade association of state-licensed wholesale distributors of prescription drugs, requests that the Commissioner of Food and Drugs continue the stay and suspend the effective date of 21 C.F.R. § 203.50 and 21 C.F.R. § 203.3(u), which are presently scheduled to go into effect on April 1, 2004. 68 Fed. Reg. 4912 (January 31, 2003).

In connection with a stay and suspension of the effective date for these regulations, the PDA also petitions the Commissioner of Food and Drugs to publish a draft Agency guidance document setting forth the Recommended Guidelines for Pharmaceutical Distribution System Integrity ("Guidelines," attached hereto as Appendix A) for public comment under 21 C.F.R. § 10.1150.

I. **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 of record ("ADRs"), 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, indicate that the only indicia of an ongoing relationship (a prerequisite to ADR status) is the existence of a written agreement between a wholesaler and manufacturer. 21 C.F.R. § 203.3(u).

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 1, 2001. 65 Fed. Reg. 25639. Further stays of the effective date to April 1, 2002, April 1, 2003, and April 1, 2004 were promulgated on March 1, 2001, February 13, 2002, and January 31, 2003, respectively. 66 Fed. Reg. 12850 (March 1, 2001); 67 Fed. Reg. 6645 (February 13, 2002); 68 Fed. Reg. 4912 (January 31, 2003).

## **II. ACTION REQUESTED**

The PDA requests the regulations noted above be stayed and suspended until one year after the FDA issues reconsidered final regulations implementing the PDMA.

## **III. STATEMENT OF GROUNDS**

### **A. Background**

The controversy pertaining to the regulations at issue has been on-going since FDA issued its about-face final regulation in December 1999. Specifically, since December 1999, the following has occurred:

- PDA and a delegation of 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 ("SBA") seeking reconsideration of the final rule and suspension of its effective date based on the severe economic impact it would have on more than 4,000 small businesses.
- In a Notice discussing the meeting, FDA noted that petitions and other communications were 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 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. PDA and other trade associations participated in that hearing. Written comments were received through November 20, 2000.

- FDA issued an additional stay of the final rule until April 1, 2002 on March 1, 2001. 66 Fed. Reg. 12850 (March 1, 2001). FDA granted the extension of the effective date 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. 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.
- The FDA's Congressional Report on the Prescription Drug Marketing Act, House Report 106-619 ("PDMA Report to Congress"), was signed and sent to the Congress on June 5, 2001.
- FDA issued additional stays of the final rule on February 13, 2002, and January 31, 2003, such that the final rule is currently stayed until April 1, 2004. 67 Fed. Reg. 6645 (Feb. 13, 2002); 68 Fed. Reg. 4912 (January 31, 2003). In the January 31, 2003 notice announcing the stay until April 1, 2004, FDA concluded that:

In its report to Congress, the agency concluded that it could address some, but not all, of the concerns raised by the secondary wholesale industry and the blood industry through regulatory changes. However, Congress would have to act to amend Section 503(e) of the act to make the types of changes requested by the secondary wholesale industry. As a result, on February 13, 2002, FDA further delayed the effective date of the relevant provisions of the final rule until April 1, 2003, in part to give Congress time to consider the information and conclusions contained in the agency's report and to determine if legislative action was

appropriate. Based on a recent petition submitted by affected parties, FDA understands that members of Congress are, in fact, considering the issues presented in the agency's report. Due to competing legislative priorities, however, the issues have not yet been resolved. Therefore, to give Congress additional time to determine if legislative actions appropriate, the agency is further delaying the effective date for Sections 203.3(u) and 203.50 . . . . The further delay of the effective date until April 1, 2004, will also give the agency additional time to consider whether regulatory changes are warranted. [68 Fed. Reg. at 4913.

- In July 2003, the PDA filed with FDA a Memorandum of Law outlining the FDA's current authority to revisit and revise the final regulation set forth at 21 C.F.R. § 203.50(a)(6) and to issue, through proposed regulations under its formal notice and comment procedures, a revised regulation consistent with the Agency's 1988 Guidance permitting pedigree to commence with a manufacturer or authorized distributor of record. A copy of that Memorandum is attached hereto as Appendix B.
- In July 2003, the Commissioner of FDA established the Counterfeit Drug Task Force ("CDTF"), charging it with developing recommendations for achieving four fundamental goals: (1) preventing the introduction of counterfeit drugs; (2) facilitating the identification of counterfeit drugs, (3) minimizing the risk and exposure to consumers to counterfeit drugs; and (4) avoiding the addition of unnecessary costs on the prescription drug distribution system, or unnecessary restrictions on lower-cost sources of drugs. CDTF Interim Report, p. 1.
- On October 2, 2003, the CDTF issued an Interim Report setting forth a multi-pronged approach to the goals set by the Commissioner. In its Interim Report, the CDTF concluded: (1) there is no single "magic bullet" against the growing number of sophisticated counterfeiters; rather, a multi-pronged strategy to secure

the drug supply could be much more difficult for counterfeiters to overcome; (2) there are many new technologies and approaches that have the potential to prevent and contain counterfeit drug threats; (3) because many of these new technologies have

not been fully developed, broad public comment was warranted to guide the CDTF's further work in connection with achieving the most-cost effective manner to keep drugs in America secure. *Id.*, pp. 1-2.

- In its Interim Report, the CDTF emphasized the following factors, among other things: (1) the value and importance of continued availability of discounted drug pricing;<sup>1</sup> (2) weaknesses in PDMA and its implementing regulations with regard to the paper pedigree requirement;<sup>2</sup> (3) the need to implement cost-effective technologies in place of paper pedigree requirements to maximize authentication and to minimize burdens placed on participants in the distribution system;<sup>3</sup> (4) the need to increase the due diligence and secure business practices by all purchasers in the system (identifying as a potential option to improve prescription drug security, "issuance of an FDA guidance document concerning physical site security and supply chain integrity")<sup>4</sup>; and (5) the need to maximize criminal penalties for drug counterfeiting.<sup>5</sup>
- The CDTF held a public meeting and technology forum on October 15, 2003 to collect testimony regarding the problem of counterfeit drugs and to learn more about specific anti-counterfeiting technologies. The President of PDA, Mr. Sal Ricciardi, presented testimony at that public meeting.
- In its Interim Report, the CDTF sought public comment on no less than 45 questions. *See id.*, pp. 29-34. Public comments were due on the CDTF on

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1 *See e.g., id.*, pp. 7, 10.

2 *See e.g., id.*, pp. 14-15.

3 *Id.*

4 *Id.*, p. 26.

5 *See e.g., id.*, p. 16.

November 3, 2003. The PDA filed comments in response to numerous questions posed by the Interim Report, including therewith a copy of the Guidelines attached hereto as Appendix A.

- The CDTF is in the process of reviewing the information presented at the public meeting and in the comments submitted, and anticipates releasing a final report in January 2004. See *id.*, p. 6.

**B. The Definition of Ongoing Relationship In The Final Rule Must Continue to Be Stayed**

In the 1988 Guidance, FDA provided that an “ongoing relationship”

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.

1988 Guidance. In March 1994, FDA proposed the following definition for “ongoing relationship”:

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 sell the manufacturer’s products for a period of time or for a number of shipments, at least one sale is made under that agreement, and the name of the authorized distributor of record is entered on the manufacturer’s list of authorized distributors of record.

59 Fed. Reg 11842, 11863 (March 14, 1994).

In final rules promulgated by the FDA in 1999, FDA defined an “ongoing relationship” for the 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 the manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.

64 Fed. Reg. 67757 (December 3, 1999).

Thus, under the final rules FDA requires the existence of a written agreement as the sole objective criteria by which to attain ADR status. The final rule's narrowing of the definition of ongoing relationship and ADR status from that set forth in the 1988 Guidance has raised concerns not only among industry, but even with FDA since the final rules were promulgated.

Indeed, in FDA's PDMA Report to Congress, the Agency 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.* PDA agrees.

The PDA has provided FDA with extensive comments on the anticompetitive impact of § 203.3(u) as it is presently drafted. Those comments concluded that two transactions in the previous twenty-four month period should be sufficient evidence of the on-going relationship required by PDMA. Moreover, in its 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.

In its comments filed in response to the CDTF Interim Report, the PDA emphasized the need for a single, federal definition for ADR, and recommended that the definition of ADR be modified from that set forth in the 1988 Guidance to include additional objective criteria as evidence of an ongoing relationship as follows:

1. The distributor appears on the manufacturer's list of ADR's, or
2. The distributor has a written agreement currently in effect with the manufacturer,  
or
3. The distributor has a verifiable account number with the manufacturer (by phone check or invoices with account numbers), and a minimal transactional or volume requirement as follows:
  - 5000 sales units (unit is the manufacturer unit of sale, e.g., bottle of 100 100 mg. tablets) within 12 months, or
  - 12 purchases (invoices) from the manufacturer within 12 months.

PDA Comments on Selected Goals, Plans And Questions Posed By The Food And Drug Administration's Counterfeit Drug Task Force Interim Report (November 3, 2003). This revised definition is more stringent than that provided in the 1988 Guidance, but removes control over ADR status from the hands of manufacturers and provides objective verifiable criteria for ADR status.<sup>6</sup>

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<sup>6</sup> Below, the PDA separately requests that the FDA issue a revised definition of ongoing relationship through promulgation of an Agency Guidance document.

Given that there appears to be agreement between industry and the FDA on the anticompetitive impact of §203.3(u) in its present form, implementation of this provision should be stayed and its effective date suspended until one year after the FDA issues a reconsidered regulation.

**C. The Scope of the Pedigree Requirement Must Continue to Be Stayed**

As is evidenced by the long history of the controversies surrounding the scope of the pedigree requirement set forth in Section III.A above, PDA and other trade associations have diligently attempted to achieve a legislative solution, although these efforts have not been successful. The legislative discussions initiated on these subjects by FDA and by PDA and others were not frivolous and were pursued in good faith.

The issues presented by the FDA's PDMA Report to Congress and by PDA to the Congress are serious ones regarding the effect of FDA regulation on a significant number of businesses, most of them small businesses. Indeed, the SBA filed a petition on this point – a petition that remains pending. In July 2003, the PDA filed with FDA a Memorandum of Law outlining the FDA's current authority to revisit and revise the final regulation set forth at 21 C.F.R. § 203.50(a)(6) and to issue, through proposed regulations under its formal notice and comment procedures, a revised regulation consistent with the Agency's 1988 Guidance permitting pedigree to commence with a manufacturer or authorized distributor of record.

In light of the fact that FDA is faced with resolving these outstanding issues, as well as numerous legitimate questions raised by the CDTF in its Interim Report that strike at the heart of whether a paper pedigree requirement remains sensible at all, a continued stay and suspension of the effective date is clearly warranted. This is

particularly so because 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, 2000 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, 2004 effective date.

PDA then sought a decision by FDA that the final rule not apply to prescription drugs already in distribution as of any new effective date so that those safe and effective approved drugs could continue to be distributed. Although FDA has granted extensions of the effective date, it has not yet interpreted the effective date to apply only to drugs first entering commerce on that date as PDA has requested. PDA herein reiterates its request that in granting a stay of the regulation, FDA issue an interpretation which states 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's request regarding the effective date is not an unusual or controversial request and it is common and usual for the FDA to make its regulations effective in this fashion. Doing so allows predictability and stability in commerce and business and assures that inventories of valuable safe and effective pharmaceuticals are not lost to the technicalities of a recordkeeping regulatory initiative. FDA's failure to grant this request in the past has had no reasoned basis.

There is also 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 since its publication, mergers have reduced that number to three. See *e.g.*, CDTF Interim Report, p. 7 ("There are three large wholesalers who account for about 90% of the primary wholesale market"). The public policy against market concentration will be advanced if the relief requested herein is granted.

The stay requested herein and the resulting delay in the implementation date of these portions of the final rule are not outweighed by public health or other public interests. FDA and the prescription drug wholesale industry have operated under the 1988 Guidance for fifteen years. And FDA has already stayed the effective date of the final rule from December 4, 2000 to April 1, 2004. Continuing to operate under the 1988 Guidance, until the efforts of PDA, other trade associations, and FDA to continue to work through the issues presented by the PDMA Report To Congress and the CDTF Interim Report, to analyze FDA's current authority to implement technological solutions as an alternative to paper pedigree requirements, and/or to seek a more comprehensive

solution to perceived weaknesses in PDMA in Congress does not disserve the public interest.

Accordingly, implementation of 21 CFR § 203.50 in its present form should be stayed and its effective date suspended until one year after FDA issues a reconsidered final regulations regarding the scope of the pedigree requirement under PDMA.

**D. FDA Has The Authority To Issue An Agency Guidance Document Setting Forth the Guidelines For Public Comment**

This petition separately requests that the Commissioner of FDA issue a draft Agency guidance document for public comment under 21 C.F.R. § 10.115 that incorporates the Guidelines attached hereto in the form of a Guidance Document Submission as Appendix A.7

The Guidelines do essentially two things, both of which FDA has the authority to implement through issuance of a draft guidance document for public comment. First, through their definition of ADR, they propose an interpretation of PDMA's definition of "ongoing relationship." Second, they propose a system of due diligence checks, which, if followed, will help ensure the integrity of the drug supply.

FDA has ample authority to issue a draft Guidance for public comment as requested herein. As an initial matter, it is clear that an Agency guidance document need not originate with the Agency. Under 21 C.F.R. § 10.115(f), the public can suggest areas for guidance document development and can submit drafts of proposed guidance for FDA to consider. 21 C.F.R. §§ (f)(1)-(2).

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7      These Guidelines (with slightly different definitions) have also been adopted by HDMA.

It is equally clear that FDA may issue a guidance document for the purposes of describing the agency's interpretation of or policy on a regulatory issue. 21 C.F.R. § 1-115(b)(1). Indeed, FDA does this routinely. See e.g., Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of The Federal, Food & Cosmetic Act (Sept. 1999) (setting forth guidance, including various definitions, on qualifying for pediatric exclusivity under Section 505A of the FFDCA while final regulations on that subject are not yet in place).

By implementing the definition section of the proposed Guidelines, FDA would be doing no more than it has routinely done before: it would be providing a slightly revised and more stringent (from the 1988 Guidance) interpretation of "ongoing relationship" pending finalization of the regulations. It is clear that the Agency is authorized to do this in the form of a Guidance document because it did so in 1988. See also 21 C.F.R. § 10.115(c)(1) (explaining that a "Level 1" guidance document as including those that set forth initial interpretations of statutory or regulatory requirements; set forth changes in interpretation or policy that are of more than a minor nature; or cover highly controversial issues).<sup>8</sup>

The balance of the Guidelines essentially sets forth a series of due diligence voluntary mechanisms through which those in the prescription drug distribution chain may help ensure the integrity of the drug products that they buy and sell, i.e., that these drug products are not being bought from wholesalers who might be wholesalers of drug

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<sup>8</sup> The PDA notes that this definition could alternatively be implemented by the Agency through formal rulemaking procedures. The PDA has elected to request that the Agency issue these definitions in the form of a draft Guidance for public comment as PDA believes that this is a more efficient method for getting the definition in place.

products that are adulterated or misbranded. The CDTF, in their Interim Report, flagged this very issue as one that needed to be addressed. The CDTF stated that:

lack of high level of diligence by members of the U.S. drug distribution chain can facilitate the introduction of counterfeit drugs into the U.S. drug supply. Investigations performed by Federal and State authorities have repeatedly shown the existence of illicit nationwide networks designed to capitalize on the inadequate due diligence performed by members of the drug distribution system in order to introduce potentially unsafe diverted and counterfeit drugs into the distribution system.

CDTF Interim Report, p. 10.

Not only is it clear through the CDTF Interim Report that FDA should be interested in maximizing industry standards for due diligence, it is also crystal clear that the CDTF believes that FDA has the authority to issue guidance on it. In its Interim Report, the CDTF envisioned “[i]ssuance of a guidance document concerning physical site security and supply chain integrity.” CDTF Interim Report, p. 26. Surely this would not have been an option on the table if the CDTF believed such an activity to be beyond the authority of FDA. In fact, nothing in the Agency’s Good Guidance Practices regulation precludes issuance of an agency guidance document on such topics.<sup>9</sup>

The Good Guidance Practices regulation expressly permits issuance of guidance on FDA’s “inspection and enforcement policies.” 21 C.F.R. § 10.115(b)(2). Indeed, FDA’s Office of Regulatory Affairs routinely publishes such guidance in the form of Compliance Policy Guides (“CPGs”). See e.g., Compliance Policy Guidance for FDA

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<sup>9</sup> By regulation, the only items that may not be issued in the form of Guidance documents are: documents relating to internal FDA procedures, agency reports, general information documents provided to consumers or health professionals, speeches, journal articles and editorials, media interviews, press materials, warning letters, memoranda of understanding, or other communications directed to individual persons or firms. 21 C.F.R. § 10.115(b)(2). The Guidelines cannot reasonably be characterized as falling into any of the prohibited categories of guidance.

Staff and Industry: Pharmacy Compounding, Section 460.200 (setting forth guidance on what types of compounding might be subject to enforcement action under the current law, and outlining therein the factors that FDA will consider with regard to its determination whether or not to take enforcement actions under the new drug, adulteration, or misbranding provisions of the FDCA).

It is PDA's view that the Guidelines could also form the basis of an Agency enforcement policy that creates a "safe harbor" from any strict criminal liability that might attach under FDCA § 301 with respect to the unknowing, unintentional and non-negligent commerce in counterfeit or otherwise unlawful prescription drugs.

Finally, as a policy matter, putting the Guidelines in place now through issuance of a draft Guidance document for public comment makes sense. FDA is continuing to analyze 21<sup>st</sup> Century technology and the other information it received in response to the CDTF Interim Report to determine whether it currently has the authority to do more vis-à-vis anti-counterfeiting efforts, or whether it will need to approach Congress with a more comprehensive plan. If the history of these regulations tells us anything, it tells us that this effort will take time. Given that this is the case, and given that counterfeiters are not going to stop their bad behavior, it only serves the public interest to issue voluntarily guidelines that the trade believes will help ensure the integrity of the products reaching the American consumer.

#### **IV. CONCLUSION**

For the reasons set forth above, the PDA respectfully requests FDA continue the stay and to suspend the effective date of 21 C.F.R. § 203.50 and 21 C.F.R. § 203.3(u),

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which are presently scheduled to go into effect on April 1, 2004, and that in connection  
with

that stay, to issue a draft Agency guidance document for comment under 21 C.F.R. § 10.115 setting forth the Guidelines attached hereto as Appendix A.

Respectfully submitted,

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## **APPENDIX A**

### ***Guidance Document Submission***

### **Recommended Guidelines for Pharmaceutical Distribution System Integrity**

#### **Preamble**

Prescription drug wholesalers, like all nongovernmental entities, do not have the investigative powers and resources to guarantee that certain products are not counterfeit. But they are uniquely situated to perform due diligence in order to protect the integrity of the pharmaceutical distribution system. Even with due diligence, in today's fast paced, just-in-time market, it is not always possible to determine the authenticity of specific prescription drugs being offered for sale. But rigorous due diligence can establish whether the sources of those prescription drugs meet certain criteria which provide a greater level of assurance that those sources are legitimate and present no reasonable probability of distributing counterfeit prescription drugs.

Experience with counterfeit drug distributors indicates that they are distinctly different from legitimate prescription drug wholesalers. Therefore, the first step in defining due diligence criteria is to identify the pertinent characteristics shared by legitimate prescription drug wholesalers. Once identified, these pertinent characteristics are the basis for the due diligence requirements contained herein. The logical nexus between the characteristics of legitimate prescription drug wholesaler and the due diligence criteria is an important safeguard to help assure the integrity of the prescription drug distribution system without disadvantaging law abiding wholesalers.

Legitimate prescription drug wholesalers share the following pertinent characteristics:

1. Their business is structured as a "going concern"
2. They demonstrate appropriate financial responsibility
3. They have robust operational standards
4. They have rigorous compliance systems
5. They can demonstrate their corporate and compliance history

An entity that does not display these characteristics may be identified as a suspect source of prescription drugs, or a source that may present an unreasonable risk to the integrity of the pharmaceutical distribution system and the public health.

The due diligence criteria and due diligence best practices in this guideline have been designed to identify facts and information about an entity that would demonstrate whether that entity displays the characteristics of a legitimate prescription drug wholesaler or, in the alternative, is reasonably likely to be a suspect source of prescription drugs. It is recommended that a prescription drug wholesaler:

1. Independently apply these Guidelines when evaluating proposed purchases from prescription drug wholesaler;
2. Use the due diligence best practices to determine whether the source of the prescription drugs meets the due diligence criteria; and
3. Purchase prescription drugs from sources that substantially demonstrate the characteristics of a legitimate prescription drug wholesaler in accordance with 2, above.

These Guidelines, therefore, outline best practices for the exercise of due diligence by prescription drug wholesalers to enhance the detection and elimination of illegitimate sources which market counterfeit products.

The public interest in drug product safety and efficacy is well served by this industry effort to detect and prevent counterfeit products from entering the prescription drug distribution pipeline in the United States.

## **I. Initial Information Request**

When a prescription drug wholesaler is considering making purchases from another prescription drug wholesaler for the first time, it is recommended that a completed information request be obtained from the prospective selling wholesaler prior to the purchase. The information request should include the following information and it is recommended that this information request be updated annually:

1. A listing of states the company is domiciled in and shipping into and copies of all current state/federal regulatory licenses/registrations including license/registration number(s). (Note: purchaser is advised to check to ensure expiration dates have not passed);
2. The company's most recent site inspection(s) dates and inspection reports or resolutions (both state and federal inspections);
3. The minimum liability insurance limits the company maintains including general as well as product liability insurance;
4. All other "doing business as" (d/b/a's) names, and formerly known as (f/k/a's), including all affiliated businesses;
5. A complete list of all corporate officers;
6. A complete list of all owners of greater than 10 percent of the business unless it is a publicly-held company;
7. A list of all disciplinary actions by state/federal agencies against the company as well as principals, owners or officers over the last ten years, or since the company was first licensed, or any of the listed individuals were first in the prescription drug wholesale business;
8. The number of employees at the facility and screening procedures for hiring;
9. A full description of each facility/warehouse. Include all locations utilized for drug storage and/or distribution), including:
  - a. Square footage;
  - b. Security and alarm system description;
  - c. Terms of lease/own;
  - d. Address; and
  - e. Temperature and humidity controls.
10. A description of prescription drug import/export activities, including:
  - a. A listing of all countries importing from and exporting to;
  - b. A listing of what products are being imported/exported from each country identified in 10a;
  - c. The nature of the company's import/export activities pertaining to prescription drugs (i.e., repackaging, re-labeling, etc.); and
  - d. How are products designated for import/export separated from domestic inventory?
11. A description of the process the company uses to validate and certify its suppliers and purchases including the supplier's ADR status, (particularly if the process differs from the Recommended Guidelines for Pharmaceutical Distribution System Integrity).
12. A list of the classes of trade (e.g., manufacturer, wholesale, retail, hospital, institutional, clinics, etc.) the seller is purchasing from or selling his/her product from or to.
13. Available financial statements or SEC filings.
14. Systems and procedures in place for prompt reporting of any suspected counterfeit, stolen or otherwise unlawful prescription drug products or buyers or

sellers of same to the appropriate state and federal authorities and manufacturer(s) of the product(s).

## **II. Certification of ADR Status**

If the selling prescription drug wholesaler claims to be an ADR, it is recommended that the purchaser obtain a written statement from the seller stating that it is an ADR and on what basis. It is also recommended that the purchaser independently verify the seller's ADR status on the initial purchase and then at least annually thereafter.

## **III. Background Check**

It is recommended that the purchaser conduct a background check of any prescription drug wholesaler it conducts business with prior to the initial transaction. This background check should include:

1. Subject to the requirements of the Fair Credit Reporting Act:
  - a. A criminal background and criminal and civil litigation check of all company officers, key management, principals and owners with 10 percent or greater interest in the company (the latter applying to non-publicly held companies only);
  - b. A driver's license and social security verification of all company officers, key management and owners;
  - c. Before completing a background check on the referenced individuals in 1a and 1b above, the purchaser must obtain the written consent of each such individual, clearly indicating how the information will be used. If the purchaser decides not to purchase from the prescription drug wholesaler based on the background information obtained, the purchaser must notify the individual (orally or in writing) in accordance with the notice requirements of the Fair Credit Reporting Act, 15 U.S.C. §1681(a);
2. A credit history maintained by an independent third party credit evaluation organization;
3. A check of the national database of licensed prescription drug wholesalers (if such a database is created);
4. A check to determine if civil/criminal litigation exists against the company; and
5. Verification of the date of incorporation and years in business, place of incorporation and form of entity.

## **IV. Physical Site Inspection**

It is recommended, prior to an initial purchase, that a purchaser conduct a physical site inspection(s) of any prescription drug wholesaler seller it intends to do business with to ensure that the company's facility(ies) is/are in compliance with appropriate storage and operational conditions and practices. These inspections should be conducted on a biannual basis. A third party, so long as not a prescription drug wholesaler, may be used to conduct the inspections on behalf of the purchaser. A standard checklist for site inspections should be utilized and incorporate the following:

#### Administrative/Management

It is recommended that the purchaser:

1. Establish the authority, training, and experience of each individual providing the required information to them on behalf of the seller and each individual who controls and is responsible for the direct supervision of all persons who inspect, handle or have access to prescription drug products;
2. Request and examine the seller's organizational chart to identify key management and structure of the company; and
3. Verify the number of employees at the facility.

#### Building (size, physical conditions, etc.)

It is recommended that the purchaser check the

1. Structural appearance and general integrity based on a visual inspection;
2. Square footage;
3. Year of construction;
4. General security and alarm system;
5. Climate control; and
6. Surrounding area (e.g., zoning)

It is recommended that the purchaser examine the following:

1. Documentation of PDMA compliance status including receipt and provision of "identifying statements," ADR status, requirements for PDMA compliance guarantees, recordkeeping and compliance with state and federal laws relating to the purchase and sale of prescription drugs.
2. Procedures for stock rotation;
3. Policies and procedures for conducting inspections of samples of product purchases;
4. Visually inspect a sample of the seller's product;
5. Temperature monitoring program and documentation;
6. Systems/procedures for detecting adulterated/misbranded product, including systems and procedures to verify that manufacturer-identified anti-tampering devices are intact;
7. Systems/procedures for validating Identifying Statements;

8. Condition of medical product inventory in the warehouse;
9. Compliance with 21 CFR 1304.22 DEA recordkeeping requirements; and
10. Form of payment the seller uses to purchase product.

## **V. Seller Qualification**

Once the site inspection has been completed, the results should be discussed with those employees or representatives of purchaser who are responsible for approving new suppliers. If the seller's background check, the completed information request, and the site inspection are determined to be satisfactory and the purchaser obtains the appropriate internal approval of the new supplier, the seller should execute signed agreements or contract provisions with language specific to PDMA compliance and compliance with all state and federal laws relating to the purchase and sale of pharmaceuticals and that the purchaser will be notified if the seller receives information that the integrity or legal status of prescription drugs sold to purchaser has been called into question by the manufacturer, retailers, wholesalers, or state or federal authorities. The signed agreements should include language stating that the seller agrees to notify the purchaser of any changes in its information request within 30 days.

## **VI. Ongoing PDMA Compliance Review**

It is recommended that the purchaser conduct ongoing compliance reviews and document all findings. These reviews should include:

1. Verifying that the seller is meeting the requirements for obtaining an "Identifying Statement", and that the "Identifying Statements" contain the required information;

2. Verifying that the seller has an effective process in place to authenticate the accuracy and integrity of the "Identifying Statement."
3. Performing appropriate supplemental review actions when:
  - a. The "Identifying Statement" has more than three entities on it; or
  - b. The price of the product being sold is substantially less than the prevailing market prices.

## **VII. Additional Purchaser Responsibilities**

In addition to all the previous steps, it is also recommended that the purchaser:

1. Maintain an internal company list of non-complying/at risk companies that are not reputable, or otherwise suspect, whose products prescription drug wholesaler would not purchase, based upon prior experience or other criteria;
2. Maintain an internal list of non-complying/at risk products (i.e. biologics, previously counterfeited drugs) that the prescription drug wholesaler would not purchase from a non-manufacturing vendor (NMV) or non-ADR;
3. Have systems and procedures in place for prompt reporting of any suspected counterfeit, stolen or otherwise unlawful prescription drug products or buyers or sellers of same to the appropriate state and federal authorities and manufacturer(s) of the product(s).
4. Cooperate with state and federal regulatory authorities by promptly providing copies of requested records and other information relevant to administrative, civil and criminal investigations related to prescription drug products.

### **Definition of Authorized Distributor of Record**

1. The distributor appears on the manufacturer's list of ADR's, or
2. The distributor has a written agreement currently in effect with the manufacturer, or
3. The distributor has a verifiable account number with the manufacturer (by phone check or invoices with account numbers), and a minimal transactional or volume requirement as follows:
  - a. 5000 sales units (unit is the manufacturer unit of sale, e.g., bottle of 100 100 mg. tablets) within 12 months, or
  - b. 12 purchases (invoices) from the manufacturer within 12 months



## APPENDIX B

### MEMORANDUM

TO: The Food and Drug Administration

FROM: The Pharmaceutical Distributors Association

DATE: July 23, 2003

SUBJECT: Authority Under the Federal Food, Drug, and Cosmetic Act to Strengthen Minimum Requirements for State Licensure of Prescription Drug Wholesalers and to Require Anti-Counterfeiting Technologies in the Manufacture of Prescription Drugs

#### I. Introduction

The Pharmaceutical Distributors Association ("PDA") is a trade association of licensed prescription drug wholesalers. This is one of two memoranda that the PDA is providing to the Food and Drug Administration in support of PDA's position that FDA has the legal authority to implement the Prescription Drug Marketing Act, as amended,<sup>10</sup> in a fashion that will preserve the businesses of small licensed prescription drug wholesalers and provide 21<sup>st</sup> century protections to the prescription drug supply.

In this memorandum, PDA describes examples of various regulatory measures that the FDA is currently authorized to implement in its effort to combat counterfeiting of prescription drug products and distribution of adulterated drugs. Specifically, for the reasons set forth below, it is PDA's position that FDA is authorized under existing law to tighten the minimum standards for state prescription drug wholesaler licensure to significantly reduce the likelihood that felons or other unqualified individuals are licensed to wholesale prescription drugs. FDA is also currently authorized to require manufacturers of new prescription drugs to use anti-counterfeiting and anti-tampering technologies to significantly increase industries' and the Agency's ability to protect against counterfeiting, tampering, and adulteration.

PDA understands that FDA launched a major initiative to more aggressively protect consumers from counterfeit drugs on July 16, 2003. The PDA strongly supports efforts to effectively and practically protect the prescription drug supply against counterfeit, adulterated or misbranded products. That effort should allow licensed legitimate businesses, large and small, to continue to distribute prescription drugs so that prescription drugs remain available at competitive prices. PDA supports FDA's creation

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<sup>10</sup> Pub. L. 100-293, as amended by the Prescription Drug Amendments of 1992, Pub. L. 102-353.

of an internal Counterfeit Drug Task Force to explore the use of modern technologies and other measures to make it more difficult to counterfeit drugs and to distribute them. The PDA provided information to FDA's contractor with respect to the Agency's June 2001 Report to Congress on the PDMA, and stands ready and willing to provide the Task Force with any additional information that it or its members may have that would be useful to the Task Force.

## II. FDA Has The Authority To Strengthen The Minimum Standards For State Licensing of Prescription Drug Wholesalers

PDA worked cooperatively with State of Florida authorities in their successful effort to pass legislation to strengthen wholesale distributor licensing requirements. FDA should exercise its existing authority to propose and promulgate regulations to strengthen the minimum standards for state licensing.

The PDMA amended the Federal Food, Drug & Cosmetic Act ("FFDCA") by providing, in pertinent part, that:

(A) No person may engage in the wholesale distribution in interstate commerce of drugs subject to subsection (b) in a State unless such person is licensed by the State in accordance with the guidelines issued under subparagraph (B) . . . .

(B) The Secretary shall by regulation issue guidelines establishing minimum standards, terms, and conditions for the licensing of persons to make wholesale distributions in interstate commerce of drugs subject to subsection (b). Such guidelines shall prescribe requirements for the storage and handling of such drugs and for the establishment and maintenance of records of the distributions of such drugs.

FFDCA, § 503(e)(2).

Thus, FDA was directed in 1988 to issue guidelines establishing minimum requirements for licensing. These guidelines were also required to prescribe requirements for drug storage/handling, and maintenance of drug distribution records. FDA did this via final regulations set forth in 21 CFR Part 205. 55 Fed. Reg. 38012 (September 14, 1990). In the final rule, FDA made clear that States are free to adopt standards that exceed the FDA-established minimum requirements. *See e.g., id.* at 38013.

The minimum qualifications for licensing are currently set forth at 21 CFR § 205.6. In that section, FDA sets forth a list of non-exclusive factors that the State must consider when assessing a wholesale prescription drug license application, including the applicant's: past convictions (including felonies); past experience in the manufacture or distribution of prescription drugs; furnishing of false or fraudulent material in any application made in connection with drug manufacturing or distribution; compliance history under previously granted licenses (including consideration of any suspension or revocation thereof and compliance history with regard to maintenance of required

records). 21 CFR § 205.6(a)(1)-(7). The state licensing authority is also free to consider other factors it considers relevant to and consistent with the public health and safety. 21 CFR § 205.6(a)(8). A state may deny a license to an applicant if it "determines that the granting of such a license would not be in the public interest." 21 CFR § 205.6(b).

In its summary of § 205.6 in the preamble to the final rule, FDA stated,

[t]he agency believes that careful screening of applicants is necessary and prudent in reducing the opportunities for diversion of prescription drugs. State authorities must consider an applicant's history, which may reflect upon the applicant's ability to prevent drug diversion. Where granting a license would not be in the public interest, State authorities may deny a license to an applicant.

55 Fed. Reg. 38012, 38012 (Sept. 14, 1990). In the Preamble to the final rule, FDA specifically "declined" to set a federal standard for what was meant by "not in the public interest." *Id.* at 38018.

FDA is authorized by PDMA to do more than it has done with regard to establishing minimum standards for state licensure while leaving the states vested with, and primarily responsible for, licensure. For example, FDA could, consistent with the mandate of FFDCFA § 503(e)(2)(A) & (B), affirmatively require the state licensing authority to investigate an applicant's prior violations relating to the handling of prescription drugs, *and affirmatively preclude that authority from granting a license to an applicant with any such history.* Stated differently, FDA can and should by regulation identify a non-exclusive, categorical, list of prescription drug-related or fraud-related activities that are "not in the public interest" and accordingly require the states to deny licenses for individuals with criminal records in these activities. FDA likewise has the authority under § 503(e)(2)(A) & (B) to determine that certain other minimum protective measures must be in place before a wholesale distributor license can issue, such as a requirement that the licensee carry a bond and/or carry product liability insurance.

Using the authority of existing law to promulgate stronger minimum requirements for state licensure in light of new information and threats to the integrity of the prescription drug supply raises no legal issues and should not be controversial. Where the FDA is authorized to establish minimum requirements, as it is undoubtedly the case here, and where more is needed to adequately implement congressional concerns about the integrity of prescription drugs, FDA has the authority to revisit its regulations and to strengthen them to better effectuate the intent of Congress.

There can be little question that more stringent state licensure requirements are warranted. Notwithstanding the current statutory and regulatory scheme, drug counterfeiting and the adulteration of drugs in the wholesale distribution system is on the rise. In response to these continuing problems, at least one state -- Florida -- has enacted wholesale distribution licensing legislation that is significantly more stringent than the standards promulgated by FDA under PDMA. *See Florida Prescription Drug Protection Act, S.B. 2312.* The Florida Prescription Drug Protection Act tightened the prescription

drug wholesale distribution application process by requiring extensive sworn background information, fingerprints, and a statewide and national criminal background check. In addition, applicants for a prescription drug wholesaler permit must submit a bond of \$100,000 (or other equivalent means of security) to the Florida Department of Health. The Department of Health is authorized to deny an application for a permit for no less than eighteen separate reasons, including the following:

- management, officers, or directors of the applicant or any affiliated party are incompetent or untrustworthy
- lack of experience in distribution of prescription drugs
- lack of experience in managing a wholesale distributor as to make the issuance of the proposed permit hazardous to the public health, or to jeopardize the reasonable promise of successful operation;
- past experience in manufacturing or distributing prescription drugs that indicates that the applicant poses a public health risk;
- affiliation (directly or indirectly) with any person or persons whose business operations are or have been detrimental to the public health;
- guilty finding or plea, or nolo contendere plea by applicant or affiliated party to any felony or crime punishable by imprisonment for 1 year or more under the laws of the United States, any state, or any other country;
- applicant or affiliates are currently charged with a felony;
- applicant has submitted false information to Florida or any other state in connection with obtaining a distribution permit
- any distribution permit previously granted to applicant or affiliated party by any federal, state, or local authority has been disciplined, suspended, or revoked
- lack of financial and physical resources to operate in compliance with the permit
- receipt of financial support/assistance by applicant or any affiliated party by a person whose permit was subject to discipline, suspended, or revoked
- receipt of financial support/assistance by applicant or any affiliated party from a person found guilty of any violation of Florida drug laws or regulations, or any federal or state drug law, or any felony where the underlying facts relate to drugs
- failure to comply with requirements for distribution of prescription drugs under Florida laws, similar federal laws, similar laws in other states, or regulations adopted under such laws.

These are the kinds of factors that should be considered by FDA in proposing stronger requirements for state licensure.

### III. FDA Has The Authority To Require Manufacturers of New Drugs to use Anti-Counterfeiting Technologies

FDA likewise has the current authority to require use of anti-counterfeiting/anti-tampering technology to protect the integrity of prescription drugs and their packaging.

Although FDA has recently stated that, "PDMA does not envision the use of modern technologies that can assist with tracking or verifying the authenticity of legitimate prescription drugs,"<sup>11</sup> nothing in PDMA limits its use. Indeed, FDA appears to have already determined – both through the materials provided in connection with its announcement of its recent Anti-Counterfeiting initiative, and through comments it has made about these technologies elsewhere, that imposing a requirement to utilize these technologies is within the ambit of FDA's authority. In FDA's view, the new drug regulatory provisions of the FDCA, as amended, provide ample authority to require the use of such technology.

Specifically, in the Agency's recent proposed rule to require certain drug product and biological product labels to carry bar codes, FDA contemplated requiring use of non-linear technologies, such as radio frequency identification ("RFID"). In describing these non-linear technologies, FDA stated,

We realize that other technologies may be able to encode more data or be more versatile compared to linear bar codes. For example. . . RFID's ability to track individual items could help drug companies and public health agencies identify and eliminate counterfeit drug products.

68 Fed. Reg. 12499, 12509 (March 13, 2003). Although FDA declined to specify the use of nonlinear technologies in the bar code proposal due to concerns about costs, it solicited comments about the use of other technologies and formats as part of the on-going rule making process. *Id.* at 12509-10.

FDA's recent announcement regarding its Anti-Counterfeiting initiative makes clear that FDA has determined that it possesses the authority under the FDCA to require use of these modern technologies to protect the integrity of the prescription drug supply. Thus, FDA states that its new Task Force will explore:

**Technology.** The task force will examine currently available and potential, future, low-cost technologies that can be used to assure product and package integrity and track legitimate products through the distribution chain. Known technologies include those visible to the naked eye, such as inks and watermarks. These features could be used with existing packaging and the existence of such a mark would help consumers and pharmacists identify counterfeit drugs. In some cases covert features may be used to authenticate products when used with special equipment (e.g., magnifying lens, special lamps). However, one limitation of packaging technologies is that, if they are not linked inextricably to particular drug product (e.g., using marks on "blister packs" or similar technology), it is possible that counterfeiters would repackage illegitimate drugs in legitimate packaging. Moreover, it may be costly and time-intensive to use the tools required to authenticate such

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11 [www.fda.gov/oc/initiatives/counterfeit/backgrounder.html](http://www.fda.gov/oc/initiatives/counterfeit/backgrounder.html) (July 16, 2003).

printed package labels. In addition, incorporation of one or more substances into the drug product itself, (e.g., taggants) may also be useful in distinguishing legitimate from counterfeit drugs. Technologies are being developed to track products through the distribution chain. These include bar coding and radio frequency chips. These technologies are able to transmit a great deal of very specific information about the product and can enable distributors and retailers to track products through the entire distribution network. Although many of these technologies are not now mature and have limitations, and further cost-benefit analysis is needed, they offer great promise as counter-measures to make legitimate prescription drugs more secure from counterfeiters.<sup>12</sup>

As FDA determined was the case with its proposed bar-coding requirements, various provisions of the FFDCA authorize FDA to issue regulations requiring use of technology to assure that new drugs are not adulterated or misbranded while in interstate commerce or held for sale. In particular:

- Section 502(a) of the FFDCA prohibits false or misleading labeling of drugs. This prohibition includes, under section 201(n) of the act, failure to reveal material facts relating to potential consequences under customary conditions of use. Information that could be readily accessed through the use of these technologies, such as the authentic nature of the drug, is material with respect to consequences which might result from use of the drug under customary conditions of use.
- The premarket approval provisions of the FFDCA authorize FDA to require that prescription drug labeling provide the practitioner with adequate information to permit safe and effective use of the drug product. Under section 505 of the act, FDA approves a new drug application (“NDA”) only if the drug is shown to be safe and effective for its intended use under the conditions set forth in the drug's labeling. Use of anti-counterfeiting/anti-tampering technologies will ensure the safe and effective use of drugs by reducing the incidence of ingestion of fake, subpotent, or contaminated products. Such technology could allow those in the distribution system to verify that an authentic product is being provided.
- Section 505(b)(1)(D) requires an NDA to contain a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug. The same requirement exists for abbreviated new drug applications (see section 505(j)(2)(A)(vi) of the FFDCA). Anti-counterfeiting technology would confirm that the facilities and controls used to manufacture the product are those that are authorized by the NDA or the ANDA.
- Requiring use of anti-counterfeiting technologies would permit the efficient enforcement of the adulteration provisions of the FFDCA. A regulation requiring their use should avert unintentional mix up and mislabeling of drugs during

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12 [www.fda.gov/oc/initiatives/counterfeit/backgrounder.html](http://www.fda.gov/oc/initiatives/counterfeit/backgrounder.html) (July 16, 2003)

labeling, packaging, relabeling, and repackaging. Anti-counterfeiting technologies therefore prevent adulteration under section 501(a)(2)(B) of the act. It is a manufacturing method or control necessary to ensure that a drug product has the identity and strength its labeling represents it to have, and meets the quality and purity characteristics which the drug purports or is represented to possess.

Thus, use of anti-counterfeiting/anti-tampering technology in packaging for drugs would permit the efficient enforcement of the adulteration provisions of Section 501, the misbranding provisions in section 502(a), the safety and effectiveness provisions of section 505 of the FFDCA, as amended.

#### IV. Conclusion

FDA has ample authority to strengthen the minimum standards for state licensure and to require use of 21<sup>st</sup> Century technology to protect the integrity of the prescription drug supply.