

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK**

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RxUSA WHOLESALE, INC., ALDEN SURGICAL CO., INC., ATLANTIC BIOLOGICALS, INC., BELL MEDICAL SERVICES, INC., C.O. TRUXTON, INC., HYGEN PHARMACEUTICALS, INC., MEDEX MEDICAL, INC., MIKA PHARMACEUTICALS, INC. and STAT PHARMACEUTICALS, INC. : **Docket No. 06 CV 5086**
: **COMPLAINT**
: **FILED 9/20/2006**

Plaintiffs,

- against -

DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. FOOD AND DRUG ADMINISTRATION,

Defendant.

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Plaintiffs, by and through its attorneys, **The Law Firm of Michael Levine, P.C.**, complaining of the Defendant, respectfully alleges as follows, upon information and belief:

SUMMARY OF THE CASE

This complaint is filed and this action instituted seeking a declaratory judgment that either (i) the U.S. Food and Drug Administration's implementation of a rule (21 CFR 203.50) interpreting a certain section of the Prescription Drug Marketing Act of 1987 (21 USCS § 331, et. seq) is erroneous and unconstitutional, or (ii) that the statute itself is unconstitutional in that it violates the Equal Protection and Due Process provision of the U.S. Constitution.

Simply stated, 21 U.S.C. § 353 (e) provides that “each person who is engaged in the wholesale distribution of a drug ... and who is not the manufacturer or an authorized distributor of record of such drug shall, before each wholesale distribution of such drug ... provide to the person who receives the drug a statement ... identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction).” The statute, thus, requires that so-called “pedigree” information be transmitted with every wholesale distribution of pharmaceuticals. The statute, however, exempts so-called “authorized distributors” from the pedigree requirement. Thus, “authorized distributors” are permitted to sell pharmaceuticals without having to convey any accompanying pedigree information.

The Federal Drug Administration promulgated a Rule at 21 CFR 203.50(a), purportedly pursuant to the above-referenced statute, which Rule requires that all non-authorized distributors provide a pedigree statement with every resale of pharmaceuticals which sets forth, among other things, “the business name and address of all parties to each prior transaction involving the drug, *starting with the manufacturer.*” Thus, notwithstanding that Congress specifically exempted authorized distributors from having to transmit any pedigree information, wholesale purchasers of pharmaceuticals from those authorized distributors are, under the FDA Rule, required to transmit such information tracing the product all the way back to the manufacturer. Of course, that is physically impossible, since the wholesale purchasers can not possibly obtain that information from the authorized distributors (who are exempt from the requirement to convey such information under the statute).

Thus, an unauthorized wholesaler (i.e., a wholesaler who is not contained on a manufacturer's "list of authorized distributors of record") can not lawfully resell the goods it purchases from an authorized distributor because it can not convey pedigree information "starting with the manufacturer." Indeed, the best it can possibly do (which the FDA Rule renders illegal) is convey pedigree information "back to the exempted authorized distributor" from whom the product was obtained.

The net effect of this is that, under the FDA Rule, the entire secondary wholesale industry will be completely and immediately destroyed as soon as the FDA Rule becomes effective on December 1, 2006. Not a single secondary wholesaler can continue to lawfully operate because it can not compel the exempted authorized distributors to provide pedigree information, can not convey that information to any purchaser, and can not, therefore, lawfully resell pharmaceutical product to anyone.

Such destruction of the secondary wholesale industry violates the Fourteenth Amendment's Equal Protection clause because the disparate treatment between authorized distributors" and "unauthorized distributors" (i.e., non-authorized wholesalers) is not rationally related to the objective of the statute (and, indeed, is contrary to that objective). Moreover, such destruction is further unconstitutional in that it constitutes a taking of property (the business and assets of secondary wholesalers) without Due Process of Law.

JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction over the claims set forth herein pursuant to 28 U.S.C. § 1331 (in that this action is predicated upon a law of the United States), 28 U.S.C. § 1337 (in that the claims herein arise under an Act of Congress regulating commerce), and under 18 U.S.C. §§ 1964(a) and (b) (in that this action is predicated upon a law of the United States), and under 28 USCS § 2201 (in that this action seeks a declaration of the rights of interested parties).

2. Venue properly lies in this district pursuant to 28 U.S.C. § 1391(c) (in that the defendant is an agency of the United States and the plaintiff resides in this District).

THE PARTIES

3. At all times relevant to this complaint, Plaintiff **RxUSA Wholesale, Inc.** (“Plaintiff”), formerly known as RxUSA International, Inc., was, and still is, a corporation, duly organized and existing under, and by virtue of, the laws of the State of New York.

4. At all times relevant to this complaint, Plaintiff **Alden Surgical Co., Inc.** was, and still is, a corporation, duly organized and existing under, and by virtue of, the laws of the State of New York.

5. At all times relevant to this complaint, Plaintiff **Atlantic Biologicals, Inc.** was, and still is, a corporation, duly organized and existing under, and by virtue of, the laws of the State of Florida.

6. At all times relevant to this complaint, Plaintiff **Bell Medical Services, Inc.**, was, and still is, a corporation, duly organized and existing under, and by virtue of, the laws of the State of New Jersey.

7. At all times relevant to this complaint, Plaintiff **C.O. Truxton, Inc.** was, and still is, a corporation, duly organized and existing under, and by virtue of, the laws of the State of New Jersey.

8. At all times relevant to this complaint, Plaintiff **Hygen Pharmaceuticals, Inc.**, was, and still is, a corporation, duly organized and existing under, and by virtue of, the laws of the State of Washington.

9. At all times relevant to this complaint, Plaintiff **Medex Medical, Inc.**, was, and still is, a corporation, duly organized and existing under, and by virtue of, the laws of the State of Tennessee.

10. At all times relevant to this complaint, Plaintiff **Mika Pharmaceuticals, Inc.**, was, and still is, a corporation, duly organized and existing under, and by virtue of, the laws of the State of New York.

11. At all times relevant to this complaint, Plaintiff **Stat Pharmaceuticals, Inc.**, was, and still is, a corporation, duly organized and existing under, and by virtue of, the laws of the State of California.

12. The Plaintiffs are all engaged in the wholesale sale of pharmaceutical products.

13. Each of the Plaintiffs deal only in legitimate and properly labeled pharmaceutical products.

14. Each of the Plaintiffs purchase pharmaceutical products for resale almost exclusively from authorized distributors and not directly from manufacturers because manufacturers typically refuse to sell product directly to the Plaintiffs. Therefore, Plaintiffs do not fall within the exempted category of “authorized distributors of record” for the purposes of 21 U.S.C. § 353 (e).

15. At all times relevant to this Complaint, the Defendant U.S. Food and Drug Administration (“FDA”) was, and still is, a part of the U.S. Department of Health and Human Services, and an agency of the United States responsible for ensuring the safety

and effectiveness of all drugs, biologics, vaccines, and medical devices in the United States.

FACTUAL BACKGROUND

16. The Prescription Drug Manufacturing Act of 1987 (21 USCS § 331, et. seq.) (the “PMDA”) was enacted on April 22, 1988 (Public Law 100-293) and was modified by the Prescription Drug Amendments of 1992 (“PDA”) on August 26, 1992 (Public Law 102-353, 106 Stat. 941).

17. The PDMA, as modified by the PDA, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the “FD&C Act,” 21 U.S.C. 331, 333, 353, 381) to, among other things, establish requirements for the wholesale distribution of prescription drugs by health care entities.

18. The new § 503(e)(1)(A) of the FD&C Act required 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 shall... provide to the person who receives the drug a statement...identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction)."

19. On August 1, 1988, the FDA issued a letter that provided guidance on the PDMA for the pharmaceutical industry on the PDMA pending the issuance of

implementing regulations (the “Guidance Letter”). The Guidance Letter stated that the above-referenced “pedigree requirement” could start with the “manufacturer or authorized distributor of record.”

20. Thus, under the FDA’s interpretation of the PDMA, a wholesaler of pharmaceutical products from an authorized distributor of the same was required to pass along pedigree information only as far back as the authorized distributor from which the products were purchased by the wholesaler.

21. From the time of the issuance of the Guidance Letter until March 14, 2004, the industry operated in that manner, which became known as the “status quo.”

22. On December 3, 1999, however, the FDA published final regulations in part 203 (21 CFR part 203) implementing the provisions of the PDMA that were to take effect on December 4, 2000 (64 FR 67720). Specifically, 21 CFR 203.50 provided as follows, in relevant part (emphasis added):

(a) Identifying statement for sale by unauthorized distributors. Before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller shall provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug. This identifying statement shall include:

* * * * *

(6) The business name and address of all parties to each transaction involving the drug, *starting with the manufacturer.*

23. After publication of the final rule, the agency received communications from wholesalers, industry trade associations, and members of Congress objecting to the above-cited provision regarding the pedigree ``identifying statement."

24. On March 29, 2000, the agency met with representatives from the wholesale drug industry and industry associations to discuss their concerns regarding the regulations. As a result, the FDA delayed the effective date for those provisions until October 1, 2001 and reopened the administrative record (65 FR 25639). The rest of the regulations took effect on December 4, 2000.

25. 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.

26. 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).

27. On June 7, 2001, the FDA submitted its report to Congress. The report advised Congress, among other things, as follows (emphasis in original):

The PDMA pedigree exemption for authorized distributors not only puts unauthorized distributors at a disadvantage, but also has the effect of wiping the slate clean each time prescription drugs pass through an authorized distributor.

* * * * *

The [FDA] believes that, given today's prescription drug distribution system, the PDMA provision that exempts authorized distributors from having to maintain and pass on a pedigree undermines the purpose of the pedigree by allowing for potential gaps in the distribution history.

* * * * *

FDA does not have the authority to require authorized distributors to maintain and pass on a pedigree. Such a requirement would necessitate a statutory change.

28. After submitting its report to Congress, the FDA delayed the effective date of the provisions two more times, through 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).

29. Thereafter, and as part of its Counterfeit Drug Initiative, the FDA subsequently sought comment on the most effective ways to achieve the goals of PDMA. In particular, given recent or impending advances in technology, the FDA requested comment on the feasibility of using an electronic pedigree in lieu of a paper pedigree. The FDA reported that the majority of comments 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 Sec. 203.50.

30. As a result, the FDA further delayed, until December 1, 2006, the effective date of § 203.50, reporting that:

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.

31. The FDA further suggested that:

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 ... 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.

32. In concluding its report, the FDA stated as follows:

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 Sec. Sec. 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 ... When widely adopted, this technology would create a de facto universal e-pedigree that would document the movement of the drug from the place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, a universal e-pedigree could meet the statutory requirements in section 503(e) of the FD&C Act.

33. Electronic pedigree systems are presently available on an industry-wide basis in the wholesale pharmaceutical industry. If all wholesalers (authorized or otherwise) used the system, it would virtually eliminate any issue of counterfeit pharmaceuticals reaching the market and would (as confirmed by the FDA) effectively implement the statutory requirements in section 503(e) of the PDMA industry-wide.

34. Notwithstanding that, the FDA has announced that it will not further delay the implementation of its Rule (21 CFR 203.50) interpreting § 503(e)(1)(A) of the FD&C Act to requiring non-authorized wholesalers to provide pedigree information tracing products back to the manufacturer. The Rule will, therefore, be effective December 1, 2006.

35. Several of the plaintiffs in this action have already signed on to electronic pedigree systems, and the balance of them are willing to do so forthwith. They will, therefore, be in a position to be completely electronic-pedigree capable and to fully comply with the PDMA prior to December 1, 2006.

36. Notwithstanding the availability of functional electronic pedigree systems, however, almost all authorized wholesalers have, to date, either failed or refused to sign on to any of the electronic pedigree systems, since they are exempt from the pedigree requirements of the PDMA.

37. The exemption of authorized wholesalers from the pedigree requirements of the PDMA is irrational, is (as the FDA has found) not rationally related to the objectives of the PDMA (but rather is contrary thereto), and does not rest upon any reasonable basis.

38. Moreover, the effect of exempting authorized wholesalers from the pedigree requirements of the PDMA results in a complete inability on the part of the plaintiffs herein, and all other non-authorized wholesalers, to conduct any business *at all* because they are unable to obtain pedigree information from authorized wholesalers. Absent such information, non-authorized wholesalers can not lawfully resell any products and are, therefore, completely out-of-business.

AS AND FOR A FIRST COUNT:

**[DECLARATORY JUDGMENT THAT
THE FDA RULE AT 21 CFR 203.50
IS PARTIALLY UNENFORCEABLE BECAUSE IT
CONSTITUTES AN EQUAL PROTECTION VIOLATION]**

39. Plaintiffs repeat, reiterate and reallege each and every allegation heretofore set forth herein, with the same force and effect as though more fully set forth herein at length.

40. The interpretation of § 503(e)(1)(A) of the FD&C by the FDA, as set forth in the Rule contained in 21 CFR 203.50 is erroneous, contrary to the purpose of the

statute which it seeks to enforce, is arbitrary and capricious, and will result in the destruction of the entire non-authorized wholesale pharmaceutical industry.

41. The members of the non-authorized wholesale industry are in competition with the members of the authorized wholesale industry and there is no rational basis for favoring authorized wholesalers over non-authorized wholesalers.

42. That is especially true in the area of attempting to prevent counterfeit pharmaceutical products from entering the market because almost every reported case of a conviction (or compensatory penalty) for a reported pharmaceutical counterfeiting violation involved an *authorized* wholesalers.

43. Moreover, interpreting the pedigree statute to require a non-authorized wholesaler to provide pedigree information back to the manufacturer (while not requiring authorized wholesalers to provide such information), therefore resulting in the inability of non-authorized wholesalers to lawfully conduct business, will have a severe chilling effect on commerce, and result in the destruction of competition and consequential increased costs for pharmaceutical products.

44. The FDA requirement that a non-authorized wholesaler provide pedigree information tracing products back to the manufacturer (while not requiring authorized wholesalers to provide such information), therefore resulting in the inability of non-

authorized wholesalers to lawfully conduct business, is a violation of the Equal Protection Clause in the Fourteenth Amendment to the United States Constitution.

45. As such, the interpretation of § 503(e)(1)(A) of the FD&C by the FDA, as set forth in the Rule contained in 21 CFR 203.50, must be declared to be erroneous, unconstitutional, and unenforceable to the extent that it requires non-authorized wholesalers of pharmaceutical products to provide pedigree information tracing products back to the manufacturer, while exempting authorized wholesalers from the requirement to provide that information.

46. Moreover, the Court should issue a declaration that the correct interpretation of § 503(e)(1)(A) of the FD&C is that a non-exempt wholesaler who acquires pharmaceutical products from an authorized distributor is lawfully required to provide pedigree information on any subsequent sale tracing the product back only to the authorized distributor from which it was obtained.

AS AND FOR A SECOND COUNT:

**[DECLARATORY JUDGMENT THAT
THE FDA RULE AT 21 CFR 203.50
IS PARTIALLY UNENFORCEABLE BECAUSE IT
CONSTITUTES A DUE PROCESS VIOLATION]**

47. Plaintiffs repeat, reiterate and reallege each and every allegation heretofore set forth herein, with the same force and effect as though more fully set forth herein at length.

48. The Plaintiffs are entitled to Due Process of law prior to the taking of their businesses by act of the FDA.

49. Plaintiffs have not been afforded such Due Process in that the FDA has promulgated a regulation which irrationally interprets a statute and causes the destruction of Plaintiffs' businesses while having no rational relation to any legitimate state interest.

50. Indeed, the FDA's present "interpretation" of the statute is contrary to the FDA's original interpretation which established the status quo and upon which Plaintiff's reasonably relied.

51. As a result of the FDA's erroneous and irrational modified interpretation, the Plaintiffs have been denied Due Process of law.

52. The FDA requirement that a non-authorized wholesaler provide pedigree information tracing products back to the manufacturer (while not requiring authorized distributors to provide such information), therefore resulting in the inability of non-authorized wholesalers to lawfully conduct business, is a violation of the Due Process Clause in the Fourteenth Amendment to the United States Constitution.

53. As such, the interpretation of § 503(e)(1)(A) of the FD&C by the FDA, as set forth in the Rule contained in 21 CFR 203.50, must be declared to be erroneous, unconstitutional, and unenforceable to the extent that it requires non-authorized wholesalers of pharmaceutical products to provide pedigree information tracing products back to the manufacturer, while exempting authorized distributors from the requirement to provide that information.

54. Moreover, the Court should issue a declaration that the correct interpretation of § 503(e)(1)(A) of the FD&C is that a non-exempt wholesaler who acquires pharmaceutical products from an authorized distributor is lawfully required to provide pedigree information on any subsequent sale tracing the product back only to the authorized distributor from which it was obtained.

AS AND FOR A THIRD, ALTERNATIVE, COUNT:

**[DECLARATORY JUDGMENT THAT
§ 503(e)(1)(A) OF THE FD&C
IS PARTIALLY UNENFORCEABLE BECAUSE IT
CONSTITUTES AN EQUAL PROTECTION VIOLATION]**

55. Plaintiffs repeat, reiterate and reallege each and every allegation heretofore set forth herein, with the same force and effect as though more fully set forth herein at length.

56. If the FDA Rule contained in 21 CFR 203.50 correctly interprets and implements § 503(e)(1)(A) of the FD&C, then § 503(e)(1)(A) is unconstitutional in that it violates the Equal Protection Clause of the United States Constitution.

57. The requirement in § 503(e)(1)(A) of the FD&C that a non-authorized wholesaler provide pedigree information back to the manufacturer (while not requiring authorized distributors to provide such information), therefore resulting in the inability of non-authorized wholesalers to lawfully conduct business, is a violation of the Equal Protection Clause in the Fourteenth Amendment to the United States Constitution.

58. As such, § 503(e)(1)(A) of the FD&C must be declared to be unenforceable to the extent that it requires non-authorized wholesalers of pharmaceutical products to provide pedigree information back to the manufacturer, while exempting authorized distributors from the requirement to provide that information.

59. Moreover, the Court should issue a declaration either that (i) the exemption to authorized distributors in § 503(e)(1)(A) of the FD&C is unenforceable and authorized distributors must be required to provide pedigree information tracing the product back to the manufacturer, or (ii) the requirement in § 503(e)(1)(A) of the FD&C that a non-exempt wholesaler who acquires pharmaceutical products from an authorized distributor is lawfully required to provide pedigree information on any subsequent sale tracing the product back to the manufacturer is unenforceable and that providing pedigree information back to the authorized distributor from which the product was obtained is in full compliance with the statute.

AS AND FOR A FOURTH, ALTERNATIVE, COUNT:

**[DECLARATORY JUDGMENT THAT
§ 503(e)(1)(A) OF THE FD&C
IS PARTIALLY UNENFORCEABLE BECAUSE IT
CONSTITUTES A DUE PROCESS VIOLATION]**

60. Plaintiffs repeat, reiterate and reallege each and every allegation heretofore set forth herein, with the same force and effect as though more fully set forth herein at length.

61. If the FDA Rule contained in 21 CFR 203.50 correctly interprets and implements § 503(e)(1)(A) of the FD&C, then § 503(e)(1)(A) is unconstitutional in that it violates the Due Process Clause of the United States Constitution.

62. The requirement in § 503(e)(1)(A) of the FD&C that a non-authorized wholesaler provide pedigree information back to the manufacturer (while not requiring authorized distributors to provide such information), therefore resulting in the inability of non-authorized wholesalers to lawfully conduct business, is a violation of the Due Process Clause in the Fourteenth Amendment to the United States Constitution.

63. As such, § 503(e)(1)(A) of the FD&C must be declared to be unenforceable to the extent that it requires non-authorized wholesalers of pharmaceutical products to provide pedigree information back to the manufacturer, while exempting authorized distributors from the requirement to provide that information.

64. Moreover, the Court should issue a declaration either that (i) the exemption to authorized distributors in § 503(e)(1)(A) of the FD&C is unenforceable and authorized distributors must be required to provide pedigree information tracing the product back to the manufacturer, or (ii) the requirement in § 503(e)(1)(A) of the FD&C that a non-exempt wholesaler who acquires pharmaceutical products from an authorized distributor is lawfully required to provide pedigree information on any subsequent sale tracing the product back to the manufacturer is unenforceable and that providing pedigree information back to the authorized distributor from which the product was obtained is in full compliance with the statute.

WHEREFORE, it is respectfully prayed that this Court issue an Order as follows:

1. Upon the First Count above, declaring that the interpretation of § 503(e)(1)(A) of the FD&C by the FDA, as set forth in the Rule contained in 21 CFR 203.50, is erroneous, violative of the Equal Protection Clause of the United States Constitution, and unenforceable to the extent that it requires non-authorized wholesalers of pharmaceutical products to provide pedigree information back to the manufacturer, while exempting authorized distributors from the requirement to provide that information, and further declaring that the correct interpretation of § 503(e)(1)(A) of the FD&C is that a non-exempt wholesaler who acquires pharmaceutical products from an authorized distributor is lawfully required to provide pedigree information on any subsequent sale tracing the product back only to the authorized distributor from which it was obtained..

2. Upon the Second Count above, declaring that the interpretation of § 503(e)(1)(A) of the FD&C by the FDA, as set forth in the Rule contained in 21 CFR 203.50, is erroneous, violative of the Due Process Clause of the United States Constitution, and unenforceable to the extent that it requires non-authorized wholesalers of pharmaceutical products to provide pedigree information back to the manufacturer, while exempting authorized distributors from the requirement to provide that information, and further declaring that the correct interpretation of § 503(e)(1)(A) of the FD&C is that a non-exempt wholesaler who acquires pharmaceutical products from an authorized

distributor is lawfully required to provide pedigree information on any subsequent sale tracing the product back only to the authorized distributor from which it was obtained..

3. Alternatively (and only in the event that relief is not awarded on either Count 1 or Count 2 herein), declaring that § 503(e)(1)(A) of the FD&C is not rationally related to its purpose, does not rest upon any reasonable basis, is violative of the Equal Protection Clause of the United States Constitution, and is unenforceable to the extent that it requires non-authorized wholesalers of pharmaceutical products to provide pedigree information back to the manufacturer, while exempting authorized distributors from the requirement to provide that information, and further declaring either that (i) the exemption to authorized distributors therein is unenforceable and authorized distributors must be required to provide pedigree information tracing the product back to the manufacturer, or (ii) the requirement that a non-exempt wholesaler who acquires pharmaceutical products from an authorized distributor provide pedigree information on any subsequent sale tracing the product back to the manufacturer is unenforceable, and that providing pedigree information tracing the product back to the authorized distributor from which the product was obtained is in full compliance with the statute.

4. Alternatively (and only in the event that relief is not awarded on either Count 1 or Count 2 herein), declaring that § 503(e)(1)(A) of the FD&C is not rationally related to its purpose, does not rest upon any reasonable basis, is violative of the Due Process Clause of the United States Constitution, and is unenforceable to the extent that it requires non-authorized wholesalers of pharmaceutical products to provide pedigree

information back to the manufacturer, while exempting authorized distributors from the requirement to provide that information, and further declaring either that (i) the exemption to authorized distributors therein is unenforceable and authorized distributors must be required to provide pedigree information tracing the product back to the manufacturer, or (ii) the requirement that a non-exempt wholesaler who acquires pharmaceutical products from an authorized distributor provide pedigree information on any subsequent sale tracing the product back to the manufacturer is unenforceable, and that providing pedigree information tracing the product back to the authorized distributor from which the product was obtained is in full compliance with the statute.

5. Awarding to Plaintiffs such other, further and different relief as to the Court may seem just, proper and equitable in the premises.

Dated: September 20, 2006

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