DEPARTMENT OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA

In re RAJARAM K. MATKARI 1304 Riverglen Way Berthoud, CO 80513	))))))	FDA Docket No. 98N-0562

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MEMORANDUM IN SUPPORT OF
PETITIONER'S MOTION FOR A SUMMARY DECISION

I. INTRODUCTION

Petitioner, the Center for Drug Evaluation and Research (CDER), files this Memorandum in Support of its Motion for Summary Decision, pursuant to 21 CFR § 17.17, seeking a finding that Respondent, Rajaram K. Matkari (Respondent or Matkari), is liable for a civil money penalty under the Federal Food, Drug, and Cosmetic Act (Act), as amended by the Generic Drug Enforcement Act of 1992 (GDEA), 21 U.S.C. §§ 335a and 335b. As Petitioner demonstrates through the Motion and this supporting Memorandum, and the Stipulations and Admissions of Fact and the Stipulated Record, Respondent provided services within the meaning of the GDEA to a person with a pending abbreviated new drug application, in direct contravention of his debarment. Because there is no genuine issue as to any material fact with respect to Respondent's liability for a civil money penalty, Petitioner is entitled to a summary decision on the issue of liability as a matter of law. 21 U.S.C. §§ 335a(c)(1)(C) and 335b; 21 CFR § 17.17.

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In addition, Petitioner believes that the Stipulations and Stipulated Record provide a sufficient basis for a summary decision finding that Respondent Matkari should be assessed the entire $250,000 permitted by statute. Consequently, Petitioner believes that there is sufficient basis for a summary decision both on the issue of liability as well as on the issue of the amount of the penalty.

II. BACKGROUND

A. Facts

Respondent Matkari was permanently debarred on October 20, 1993, from providing services, within the meaning of the GDEA, to a person with an approved or pending drug product application. 21 U.S.C. § 335a(a)(2)(A)and(B). See Stipulations and Admissions of Fact and Proposed Scheduling Order, filed October 27, 1999, (Stipulations) at ¶ 3(A); Stipulated Record (SR) at 13-15[1] (58 Fed. Reg. 54156 (Oct. 20, 1993))(Denial of Hearing and Final Debarment Order).

The debarment stemmed from Matkari's payment, while Vice-President for Regulatory Affairs at Pharmaceutical Basics, Inc., (PBI), of approximately $2000 to an official of the Food and Drug Administration (FDA) who was responsible for regulating PBI's products. SR at 13. Matkari pled guilty to violating 18 U.S.C.

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[1] A Bates-stamped copy of the Stipulated Record was filed on December 17, 1999. For convenience, a copy of the Stipulated Record accompanies this Motion and Memorandum.

§ 201(c)(1)(A), a felony conviction. SR at 3-8. As result of this felony conviction, Matkari was permanently debarred from "providing services in any capacity to a person with an approved or pending drug product application," as required by 21 U.S.C. § 335a(a)(2)(A) and (B). SR at 13-15.

Subsequently, Matkari became director of Napean Enterprises, Inc., (Napean), a Colorado corporation organized for the purpose of marketing wholesale pharmaceutical products. Stipulations at ¶ 3(B) and (C); SR at 17-22. Matkari is its sole director. Stipulations at ¶ 3(B). Napean, with Matkari at its helm, was at the center of an elaborate arrangement between several companies to manufacture and market an unapproved new drug called Menogen. Stipulations at ¶ 3(D),(E),(F), and (H).

In early March of 1996, Matkari on behalf of Napean, entered an agreement with Sage Pharmaceuticals (Sage), under which Sage manufactured for Napean the unapproved new drug, Menogen. SR at 90-93; (Breckenridge, Inc. v. Solvay Pharmaceuticals, Inc., No. 98-4604, 1999 WL 292667, at *5 (reproduced at SR 130-132)). The Menogen was then distributed by one or more other companies under arrangements that Matkari made. Stipulations at ¶ 3(C) and (H); SR at 49-52; 57-89; 101; see also Florida Breckenridge, Inc. v. Solvay Pharmaceuticals, Inc., et al., (Civ. No. 97-8417, S.D. Fla. March 18, 1998). Indeed, that arrangement has spawned a series of lawsuits, see Stipulations at ¶¶ 3(I) and 3(K), and, in

at least two of those cases, the court has recognized that Menogen is an unapproved new drug, marketed in violation of the Act. See Florida Breckenridge, Inc. v. Solvay Pharmaceuticals, Inc., No. 98-4604, 1999 WL 292667, at *5 (11th Cir. May 11, 1999) (reproduced at SR 130-132); United States v. Sage Pharmaceuticals, Inc., et al., Civ. No. 98-0718 (W.D. La. Sept. 22, 1998)(appeal pending on other issues).

Under the March 1996 agreement, Napean was responsible for all regulatory compliance matters pertaining to the marketing of Menogen. Stipulations at ¶ 3(F); SR at 91. This meant that Matkari was really responsible for all such compliance matters as he was the sole director of Napean. Stipulations at ¶ 3(B). Additionally, under that agreement, Napean assumed additional obligations which were pivotal to the manufacturing of the drug such as: furnishing the active raw materials; being responsible for all development costs; and paying invoices. SR at 90-93.

Sage had an abbreviated new drug application (ANDA) pending between February and June of 1997 for a product other than Menogen. SR at 46-47; Amendments to Stipulations and Admissions of Fact and Proposed Scheduling Order (Amended Stipulations) at ¶ 2. During the time that the Sage ANDA was pending, Matkari bought, paid for, and had delivered to Sage at least one shipment of the raw material used to manufacture the Menogen. SR 54-55; 46-47. Matkari arranged at least one such transaction, of a

particularly large amount of raw material, in March of 1997. SR at 54-55.

B. Statutory Background

The Act, 21 U.S.C. §§ 321 et seq., requires that all new drugs be reviewed and approved by FDA before being distributed in interstate commerce. 21 U.S.C. § 355(a). In 1984, Congress amended the Act to permit the submission and approval of ANDAs for generic copies of previously approved drugs. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (the 1984 Amendments). The 1984 Amendments permitted manufacturers of generic drugs, through ANDAs, to rely on FDA's prior determinations of safety and effectiveness regarding an innovator's drug. 21 U.S.C. § 355(j). However, drugs marketed under ANDAs must be demonstrated to be bioequivalent with the innovator, and any changes in manufacturing procedures or ingredients must be preapproved by FDA. 21 U.S.C. § 355(j)(2)(A). The manufacturer must also maintain the records necessary to ensure that the conditions for approval continue to be met. 21 U.S.C. § 355(k); 21 C.F.R. Parts 210, 211, and 314.

The GDEA, codified at 21 U.S.C. §§ 335a, 335b, and 335c, was enacted in response to findings of widespread fraud and corruption in the generic drug industry. The GDEA requires the

Secretary of the Department of Health and Human Services (HHS)[2] to debar individuals, corporations, partnerships, and associations, who have been convicted of certain felonies. 21 U.S.C. § 335a(a).

Under the GDEA, a debarred individual may not provide "services in any capacity" to a person with an approved or pending drug product application. 21 U.S.C. §§ 335a(a)(2)(A) and (B) and 335a(c). Any person that the Secretary finds -

* * * *

> (6) is a person that has an approved or pending drug product application and has knowingly -
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> (A) employed or retained as a consultant or contractor, or
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> (B) otherwise used in any capacity the services of, a person who was debarred ... or
>
> (7) is an individual debarred ... and, during the period of debarment, provided services in any capacity to a person that had an approved or pending drug product application,
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> shall be liable to the United States for a civil penalty for each such violation in an amount not to exceed $250,000 in the case of an individual.

21 U.S.C. § 335b(a).

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[2]The HHS Secretary has delegated certain authorities under the FDCA and related statutes (including the GDEA) to the Commissioner of Food and Drugs. See 21 C.F.R. § 5.10; 21 U.S.C. § 393(d).

III. ARGUMENT

A. Standard For Summary Decision

Under the relevant regulations, "a party may move, with or without supporting affidavits ..., for a summary decision on any issue in the hearing." 21 CFR § 17.17(a). The presiding officer "shall grant the motion if the pleadings, affidavits, and other material filed in the record, or matters officially noticed, show that there is no genuine issue as to any material fact and that the party is entitled to summary decision as a matter of law." 21 CFR § 17.17(b).

The general principles that govern summary judgment proceedings in the Federal courts apply to administrative proceedings under the Act. See John D. Copanos and Sons, Inc. v. FDA, 854 F.2d 510, 523 (D.C. Cir. 1988). Summary judgment is appropriate when there is no genuine issue of material fact and when the moving party is entitled to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). Summary judgment is "properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed 'to secure the just, speedy and inexpensive determination of every action.'" Id. at 327. Summary judgment is intended to "isolate and dispose of factually unsupported claims or defenses." Id. at 323-24.

To be entitled to a summary decision, the moving party must demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. at 323. Although the party opposing the motion will be afforded the benefit of reasonable factual inferences, a properly supported motion for summary judgment only will be defeated with specific facts showing that there is a genuine issue that warrants a hearing. That is, only a genuine dispute as to material fact or, in other words, a fact that "might affect the outcome of the suit under the governing law" will suffice to defeat this motion. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

Here, these proceedings are conducted to determine "whether the respondent is liable for a civil money penalty and, if so, the appropriate amount of any such civil money penalty considering any aggravating or mitigating factors." 21 C.F.R. § 17.33(a). To be entitled to a summary decision in this matter, Petitioner needs to demonstrate, by a preponderance of the evidence, that: (1) Respondent has been debarred under 21 U.S.C. § 335a; (2) during the period of debarment he provided services, within the meaning of the GDEA; and (3) the recipient of the services is a person that had an approved or pending drug product application. So long as Petitioner establishes these elements, the GDEA directs that Respondent shall be liable for - and the Secretary shall assess - a civil penalty "for each such

violation." 21 U.S.C. §§ 335a(c)(1)(C) and 335b(a); see also 21 C.F.R. § 17.33(b).

Given the Stipulations and Admissions of Fact, and the Stipulated Record in this case, there are no genuine issues of fact regarding any of these elements and there is ample basis for a summary decision that Respondent is liable for a civil money penalty because he has violated his debarment. In addition, there is sufficient basis for assessing the entire amount of $250,000 against Respondent for his violation.

B. There Is No Genuine Issue Concerning Respondent's Debarment

There can be no question but that Matkari was debarred pursuant to 21 U.S.C. § 335a. Matkari has stipulated to this fact. See Stipulations at § 3(A); SR at 13-15.

Matkari has stated that he may contest the validity of his conviction under United States v. Sun-Diamond Growers of California, 526 U.S. 398 (1999), and he suggests that such a possibility should have some influence on this proceeding. Matkari has not, however, provided any evidence that a challenge to the underlying conviction has been presented to the convicting court, let alone that his conviction has been reversed and, so long as the conviction stands, there is simply no issue concerning the validity of Matkari's debarment.

Moreover, even if Matkari were to successfully challenge his underlying conviction, that would not erase the violation that

led to this proceeding, for there is absolutely no question but that Matkari was debarred at the time he provided the services that led to this action. SR at 13-15; Stipulations at ¶ 3(A), 3(D) and Amended Stipulation ¶ 2.

Matkari suggests in the papers he filed earlier in this proceeding that he should be absolved of his obligation to comply with the terms of his debarment simply because he disagrees with it and in the future might choose to challenge it in the courts. This would be no different than a person convicted of murder, for example, arguing that he should be permitted to buy a gun even though such a purchase is prohibited for one convicted of such a crime, simply because he disagreed with the conviction and might pursue an appeal. Of course, this is not the law, and Matkari must abide by the statutory terms of his debarment for its duration. 21 U.S.C. § 335a(c)(1). See Lewis v. United States, 445 U.S. 55, 65 (1980)(felon prohibited from owning a gun even if predicate felony subject to challenge); see also Custis v. United States, 511 U.S. 485, 493, 497 (1994)(defendant could not challenge previous conviction during sentence enhancement proceedings).

C. There Is No Genuine Issue About Matkari, During The Period Of His Debarment, Providing Prohibited Services Within The Meaning Of The GDEA

1. The Prohibition On "Providing Services In Any Capacity"

The GDEA prohibits, among other things, an individual from "providing services in any capacity to a person that has an approved or pending drug product application." 21 U.S.C. § 335a(c)(1)(B). This prohibition has been construed broadly, in keeping with the purposes of the GDEA.

Under the GDEA, the exact nature or number of a debarred individual's interactions with a drug company that had a pending or approved drug product application are not at issue, for the debarred individual is prohibited from all such contact. The Court of Appeals for the District of Columbia Circuit has made this clear:

> we think it quite reasonable for the FDA to be concerned about any employment that might create an opportunity for regular and frequent contact between [the debarred individual] and the management of a drug company. The agency would find it very difficult, if not impossible, to assure itself and the public that [the debarred individual] is not, through that contact, actually selling advice or other services related to the circumvention of federal regulation.

DiCola v. Food and Drug Administration, 77 F.3d 504, 507 (D.C. Cir. 1996).

Here, the fact that Matkari held a position that provided an opportunity for contact with a drug company is sufficient to cause a violation of his debarment. The Stipulated Record and

Stipulations, however, confirm that Matkari's involvement was far greater and that he played a key role in arranging the manufacturing and marketing of an unapproved new drug and that he conducted this activity for more than one year. Stipulations at ¶ ¶ 3(B),(C), (D), (E), (F), (H); Amended Stipulations at ¶ 2; Stipulated Record at 41-44, 54-55, 57-93.

2. Matkari's Actions Were Prohibited By The GDEA

Matkari has stipulated that he is the sole director of Napean Enterprises Inc., a company organized to market wholesale pharmaceuticals. Stipulations at ¶ 3(B). Matkari also stipulated that he entered an agreement with Sage Pharmaceuticals, under which Sage manufactured a drug called Menogen for Matkari's company, Napean. Stipulations at ¶ 3(B),(C), and (D). Matkari purchased and arranged the delivery of the active ingredient raw materials for the Menogen Sage manufactured under that agreement. Stipulations at ¶ 3(E); SR at 25-26, 31, 54-55, 91. Matkari also identified customers for the finished drug product and arranged to have shipments of the finished drug distributed through other companies, including Florida companies by the name of Pegasus Laboratories and Breckenridge, Inc. Stipulations at 3(H); SR at 27, 33-36, 38-40,41-44, 49-89, 91 (numerous packing slips and shipping documents for Menogen, manufactured by Sage, distributed under

either a "Breckenridge" or "Sage" label, with Napean identified as the party responsible for the invoice).

Given Matkari's key role, through Napean, in orchestrating this entire drug manufacturing and distribution system, Matkari should not be heard to argue that he did not provide services within the meaning of the GDEA, in violation of his debarment. 21 U.S.C. § 335a(c)(1)(B). Indeed, it is difficult to imagine any interaction with a drug company that would go more to the core of such a company's functioning, as that provided by Matkari.

The Congressional intent in creating the debarment provision makes this clear. One Senator highlighted the "urgent" need to "reestablish generic drugs as credible market competitors. Crucial to this effort is an FDA that can refuse to deal with bad actors who have abused the system for drug approval and regulation." The debarment provision "gives FDA the tools that it needs to protect itself from such actors." 138 Cong. Rec. S5614 - S5616 (daily ed. April 10, 1992) (statement of Sen. Kennedy). Given this, it strains credulity to suggest that Matkari's activities are anything <u>but</u> those that Congress intended that he, as a debarred individual, avoid.

3. <u>The Prohibition Extends To All Services</u>

Matkari may argue that his services did not relate to the drug that was the subject of the Sage ANDA. Petitioner does not

dispute this point. Amended Stipulation at ¶ 1(B). However, it is irrelevant, for the GDEA's prohibition is much broader than such an argument would suggest. The plain wording of the statute makes crystal clear that the prohibition is on "services in any capacity," rather than a mere prohibition on work with particular drug applications. 21 U.S.C. § 335a(c)(1)(B). The D.C. Circuit has construed this prohibition to extend from the "board room" to the "cafeteria" and all places in between. DiCola v. Food and Drug Administration, 77 F.3d at 509.

Moreover, contrary to the argument Matkari suggests, the plain language of the GDEA mentions drug applications only in the context of identifying those persons for whom the debarred individual may not provide services, rather than in defining the services themselves. See 21 U.S.C. § 335a(c)(1)(B).

4. Matkari's Knowledge Of The Sage Application Is Irrelevant

Matkari also may argue that he did not know that Sage would file a drug application. This, too, is irrelevant, for Matkari got "close to the pharmaceutical industry at his peril." See DiCola v. Food and Drug Administration, 77 F.3d at 509. The plain wording of the GDEA makes clear that Congress held debarred individuals and those to whom they provide services to two different standards when setting liability for a violation of debarment. While the recipient of the debarred individual's services can only be held liable for a knowing violation,

Congress included no such element in establishing the offense of the debarred individual.[3]

"[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." Russello v. United States, 464 U.S. 16, 23 (1983).

Given that Congress included the knowledge element in establishing the violation of debarment for the recipients of the debarred person's services, but added no such element for a violation by a debarred individual, Congress clearly did not intend that the debarred individual only be held liable for "knowing" violations.

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[3]Moreover, even if knowledge were an element of the offense for a debarred individual, which it is not, Matkari would still be liable for violating his debarment because, for purposes of the GDEA, the terms "knowingly" and "knew" mean that -

> a person with respect to information-
>
> (1) has actual knowledge of the information, or
>
> (2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

21 U.S.C. § 321(cc).

Here, putting aside any question about Matkari's actual knowledge, even his allegations of a lack of knowledge demonstrate a reckless disregard for the truth, for a debarred individual cannot simply fail to mention his debarment in the hopes of continuing to work with the industry he abused while insulating himself from further enforcement efforts. The Stipulations demonstrate that Matkari tried to conceal the fact of his debarment even during his litigation with Sage, attempting to have the portion of Sage's complaint edited to avoid any mention of his debarment. Stipulations at ¶ 3(L).

D. There Is No Genuine Issue About Sage Having A Pending Abbreviated New Drug Application

There is no question but that the final statutory element for the imposition of civil money penalties, that the recipient of the services have an approved or pending drug product application, is met here. Matkari has stipulated that Sage had an ANDA pending between February and June of 1997, and the Stipulated Record demonstrates this point. Amended Stipulations at ¶ 2; SR at 46-47.

1. Matkari's Dealings With Sage Violated His Debarment

Matkari may argue that the Sage application was pending only for a portion of the year during which he provided services to Sage. This argument is unavailing, however, for the fact remains that Matkari arranged for the delivery and payment of at least one shipment of the raw materials in March of 1997, at which time the application was pending. Stipulations at ¶¶ 3(E) and Amended Stipulation ¶ 2.

There is no requirement in the GDEA that the recipient of the services hold the application for any specific length of time. Plainly, Congress intended a broad, prophylactic, "bright-line" prohibition on interaction with the pharmaceutical industry, whether or not the recipient of the services continued to hold an application.

As discussed above, it was Matkari's responsibility to ensure that he did not violate his debarment, and his claim of a

lack of knowledge of Sage's plans is simply irrelevant. See also 21 U.S.C. § 321(cc). See DiCola v. Food and Drug Administration, 77 F.3d at 509 (debarment puts debarred individual on notice that "he gets close to the pharmaceutical industry at his peril"); see also Bae v. Shalala, 44 F.3d 489, 495 (7th Cir. 1995):

> In enacting the GDEA, Congress adopted a bright-line rule excluding from the generic drug industry all individuals with prior felony convictions relating to the approval or regulation of any generic drug product. Although ... permanent debarment ... is undoubtedly harsh, it is not disproportionate ... to the magnitude of [the] wrongdoing.

Matkari clearly put himself in a position in which he was poised to violate his debarment, and that is exactly what Congress directed that he, as a debarred person, not do.

2. There Is No Credible Argument That The GDEA Permits Matkari's Dealings With Sage

Any claim of ignorance about Sage's application that Matkari might make is particularly inappropriate in this case, for Menogen, the product he arranged for Sage to manufacture, should have been the subject of an approval application, but was not. See Florida Breckenridge, Inc. v. Solvay Pharmaceuticals, Inc., No. 98-4604, 1999 WL 292667, at *5 (11th Cir. May 11, 1999)(recognizing that Menogen is an unapproved new drug) (SR at 132). Matkari seems to think that one violation of the law (causing the marketing of an unapproved new drug), excuses another (violating his debarment). Such an interpretation flies in the face of the Act, the GDEA, and the caselaw.

Congress made its purpose in establishing the debarment provisions quite clear in the preamble to the GDEA:

> The Congress finds that -
>
> (1) there is substantial evidence that significant corruption occurred in the Food and Drug Administration's process of approving drugs under abbreviated drug applications,
>
> (2) there is a need to establish procedures designed to restore and to ensure the integrity of the abbreviated drug application approval process and to protect the public health, and
>
> (3) there is a need to establish procedures to bar individuals who have been convicted of crimes pertaining to the regulation of drug products from working for companies that manufacture or distribute such products.

Section 1(c) of the GDEA, Pub. L. No. 102-282, 106 Stat. 149 (1992).

Given this, Matkari cannot credibly argue that Congress would permit him to provide services to the pharmaceutical industry, so long as he only dealt with companies that were ignoring their own obligations to obtain approval for their products.

Because Matkari has stipulated that he obtained raw materials for Sage, and that Sage had a pending application during part of that time, there can be no genuine issue of material fact about his violation of his debarment.

E. Matkari Should Be Assessed The Statutorily-Permitted Maximum Penalty of $250,000

1. There Is Sufficient Basis For Assessing The Full Penalty

As discussed above, based on the Stipulations and the Stipulated Record, there is ample basis for a summary decision that Matkari is liable for violating his debarment. While the government requests that its motion for summary decision be granted with respect to liability for this violation, it believes that the record would also support a summary decision on the amount of the penalty and that, in this case, the full amount of $250,000, authorized by the GDEA, should be imposed.

The GDEA states

> In determining the amount of a civil penalty ... the Secretary or the court shall take into account the nature, circumstances, extent, and gravity of the act subject to penalty, the person's ability to pay, the effect on the person's ability to continue to do business, any history of prior, similar acts, and such other matters as justice may require.

21 U.S.C. § 335b(b)(2).

Here, there is sufficient basis to assess the full amount against Matkari. As discussed previously, not only did Matkari ignore his debarment, the services he provided were directed at manufacturing and distributing an unapproved product, an independent violation of the law. 21 U.S.C. § 355(a). Under the terms of the agreement Matkari reached with Sage, it was Matkari's responsibility to ensure that all approval requirements

were met for Menogen. Stipulations at ¶ 3(F); SR at 90-93. Moreover, this arrangement continued for over one year. SR at ¶¶ 49-93.

The severity of Matkari's violation warrants the full amount of the penalty. In DiCola, the Court of Appeals viewed with disfavor the suggestion that a debarred individual would continue to sell labels to drug companies because that type of employment permitted contact with - and the opportunity to influence - such companies. DiCola v. Food and Drug Administration, 77 F.3d 507. Here, Matkari was even more closely involved with the drug company than was DiCola: he played a key role in the scheme to manufacture and market an unapproved new drug. As the Stipulations and Stipulated Record demonstrate, in addition to ensuring regulatory compliance, Matkari was responsible for: obtaining the raw materials, locating the customers, making payments, arranging for distribution through other third-party companies, and ensuring that a minimum amount of the product was sold. Stipulations at ¶ 3(D),(E), (F), and (H); SR at ¶¶ 90-93 . In enacting the GDEA, Congress determined that the public deserves to be protected from people like Matkari, see Bae v. Shalala, 44 F.3d at 495, and, consequently, the penalty should send a strong message to Matkari, and those like him, that he is not free to disregard the law, nor will efforts to circumvent it be tolerated.

2. There Is No Basis For Decreasing The Penalty

Matkari has stipulated that he is able to pay the full amount of the penalty, so he should not be heard to argue that the penalty will cause him financial distress. Amended Stipulations at ¶ 1(A).

Matkari also may argue that he only violated his debarment a single time. Such an argument should not result in a reduction of the penalty for two reasons.

First, as discussed above, the Stipulations and Stipulated Record demonstrate that Matkari was a key part of a long-term scheme to manufacture and distribute a drug in violation of his debarment and the GDEA as well as the Act's approval requirements. The record in this case belies any contention that Matkari's involvement with Sage was limited in either scope or duration.

Second, the GDEA clearly contemplates the $250,000 to be charged "for each such violation." 21 U.S.C. § 335b(a)(emphasis added). Consequently, the violation established in this matter is an appropriate basis for awarding the $250,000. Additional violations would warrant an additional penalty, rather than provide further support for this one.

In light of the Act's purpose in protecting the public health, and Matkari's brazen disregard of the limitations imposed by his debarment which, in turn, resulted from his felony

conviction for abusing the drug approval process, as well as his continued disregard for the Act's approval requirements, the full civil money penalty amount of $250,000 is warranted. See generally, United States v. An Article of Drug...Bacto-Unidisk, 394 U.S. 784, 798 (1969)(Act to be construed broadly in keeping with its purpose of protecting the public health).

IV. CONCLUSION

Given that Matkari has stipulated to the facts establishing that he provided services to Sage in violation of his debarment, there is ample support for a summary decision that, at a minimum, finds Matkari liable for a civil penalty. Alternatively and in addition, given the Stipulations and the Stipulated Record, there is also ample basis for assessing the full amount of the statutorily-authorized penalty against Matkari.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on this 11th day of February 2000, I have caused a copy of the foregoing Motion For Summary Decision with supporting Memorandum and Stipulated Record and Proposed Findings of Fact and Conclusions and Order, to be served by overnight delivery on:

Mark London, Esq.
Christopher B. Mead, Esq.
London & Mead
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Annamarie Kempic

DEPARTMENT OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA

In re RAJARAM K. MATKARI 1304 Riverglen Way Berthoud, CO 80513	))))))	FDA Docket No. 98N-0562

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PETITIONER'S MOTION FOR SUMMARY DECISION

Petitioner, the Center for Drug Evaluation and Research, Food and Drug Administration, files this motion for a summary decision pursuant to 21 C.F.R. § 17.17. The grounds for this motion are that, based on the Stipulations and Stipulated Record, there is no genuine issue of material fact concerning Respondent Rajaram K. Matkari's provision of services to Sage Pharmaceuticals, a person with a pending drug product application, in violation of his debarment, 21 U.S.C. § 335b(a)(7), causing him to be liable for a civil money penalty under 21 U.S.C. § 335a(c)(1)(C) and 335b. In addition, the Stipulations and Stipulated Record support assessing the entire $250,000 penalty against Respondent.

A Memorandum of Law and the Stipulated Record are filed in support of this motion, and Proposed Findings of Fact and Conclusions and Order also are submitted.

DATED this 11th day of February, 2000.

Respectfully submitted,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA

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PROPOSED FINDINGS OF FACT AND CONCLUSIONS AND ORDER

The Stipulations and Admissions of Fact and Stipulated Record establish that Respondent Rajaram K. Matkari has violated 21 U.S.C. § 335a(c)(1)(B) and, pursuant to 21 U.S.C. §§ 335a(c)(1)(C) and 335b(a)(7), is liable for a civil money penalty, based on the following findings and conclusions.

1. Jurisdiction of this matter is vested in the Secretary of Health and Human Services pursuant to 21 U.S.C. § 335b(b)(1)(A).

2. The Secretary of Health and Human Services has delegated jurisdiction of this matter to the Food and Drug Administration under 21 CFR § 5.10(a)(1).

3. Under 5 U.S.C. § 3105 and 21 U.S.C.§ 335b and 21 CFR § 17.3, the authority to conduct a civil penalty hearing and assess a civil penalty is vested in this Administrative Law Judge.

4. Petitioner Food and Drug Administration is a component of the Department of Health and Human Services, an agency of the United States of America.

5. Respondent Rajaram K. Matkari (Respondent or Matkari) is a resident of the state of Colorado and the sole director of a Colorado corporation, Napean Enterprises, Inc. (Napean).

6. Napean was organized for the purpose of the wholesale distribution of pharmaceutical products.

7. Respondent Rajaram K. Matkari was permanently debarred by the Food and Drug Administration on October 20, 1993 (58 FR 54156 (Oct. 20, 1993)), pursuant to 21 U.S.C. § 335a(a)(2), because of his conviction of a federal felony.

8. As a debarred individual, Mr. Matkari is prohibited from providing services in any capacity to any person that had an approved or pending drug product application. 21 U.S.C. §§ 335a(a)(2) and 335a(c)(1)(B).

9. In March of 1996, Mr. Matkari, on behalf of Napean, entered an agreement with Sage Pharmaceuticals (Sage) to have Sage manufacture an unapproved new drug called Menogen.

10. Under that agreement, Matkari and Napean were responsible for all regulatory compliance matters pertaining to the marketing of Menogen, as well as furnishing the active raw materials, being responsible for all development costs, paying the invoices, and locating the customers.

11. Sage Pharmaceuticals had an abbreviated new drug application pending before the Food and Drug Administration between February and June of 1997.

12. Mr. Matkari provided to Sage services that are prohibited by 21 U.S.C. §§ 335a(a)(2) and 335a(c)(1)(B), on or about March 31, 1997, by obtaining the active raw materials Sage used to manufacture Menogen.

13. In providing such services, Mr. Matkari violated 21 U.S.C. §§ 335a(a)(2) and 335a(c)(1)(B), which set forth the provisions of his debarment.

14. Pursuant to 21 U.S.C. § 335b, Mr. Matkari is liable for a civil money penalty in an amount not to exceed $250,000 for each such violation.

15. Mr. Matkari is able to pay the full amount of $250,000 permitted to be assessed under 21 U.S.C. § 335b.

16. The appropriate amount of civil money penalty for which Mr. Matkari is liable, considering the nature, circumstances, extent, and gravity of his violation, Mr. Matkari's ability to pay, the effect on his ability to continue to do business, the history of prior, similar acts, and circumstances that mitigate or aggravate the violation, and such other matters as justice may require, is $250,000.

Accordingly, in consideration of the above findings and conclusions,

IT IS ORDERED that a civil money penalty in the amount of $250,000 is assessed against Rajaram K. Matkari, a debarred individual.

_____

Administrative Law Judge

cc:

Annamarie Kempic
U.S. Food and Drug Administration
5600 Fishers Lane(GCF-1), Room 6-64
Rockville, MD 20857
Telephone 301-827-1138
Fax: 301-443-0933

Mark London, Esq.
Christopher B. Mead, Esq.
London & Mead
1225 19th Street, N.W.
7th Floor
Washington, D.C. 20036
Telephone 202-331-3334
Fax: 202-785-4280

DEPARTMENT OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA

In re	)	
	)	
RAJARAM K. MATKARI	)	FDA Docket No. 98N-0562
1304 Riverglen Way	)	
Berthoud, CO 80513	)	
	)	

8715 '00 FEB 11 A11:48

STIPULATED RECORD

GPJ:fc (INFO0424)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA	*	
v.	*	CRIMINAL NO. HAR-99-0159
RAJ MATKARI	*	(Giving an Unlawful Gratuity, 18 U.S.C. § 201(c)(1)(A))
	*	

****

INFORMATION

The United States Attorney for the District of Maryland charges:

1. At all times pertinent to this Information:

a) The Division of Generic Drugs of the Food and Drug Administration (FDA) was responsible for reviewing applications submitted by pharmaceutical manufacturers seeking approval to market generic drugs to the public. The offices of the Division of Generic Drugs were located in Rockville, Maryland.

b) Charles Y. Chang was a public official, to wit: a Branch Chief in the Division of Generic Drugs. Mr. Chang was a resident of the State and District of Maryland. In his capacity as a Branch Chief, Charles Y. Chang supervised a group of chemists who reviewed applications submitted by various generic drug manufacturers.

c) Pharmaceutical Basics, Inc. (hereinafter PBI) was a manufacturer of generic drugs with its headquarters located

SEP-03-1999 09:50 FDA/CDER/RPS 301 827 5562 P.02

in Denver, Colorado. PBI regularly submitted drug applications for review and approval by the Division of Generic Drugs.

d) **RAJ MATKARI** was the Vice President for Regulatory Affairs and Product Development of PBI.

2. On or about August 19, 1987, in the State and District of Maryland,

RAJ MATKARI,

otherwise than as provided by law for the proper discharge of the official duties of a public official, did offer and give a thing of value, to wit: $2,000 in United States currency, to Charles Y. Chang, a public official, for and because of official acts that the said Charles Y. Chang had performed and was to perform.

18 U.S.C. § 201(c)(1)(A)

Date: 4/27/89

Breckinridge L. Willcox
Breckinridge L. Willcox
United States Attorney

SEP-03-1999 09:50 FDA/CDER/RPS 301 827 5562 P.03

U.S. Department of Justice

GPJ:fc (CRIME004)

United States Attorney
District of Maryland

United States Courthouse, Eighth Floor
101 West Lombard Street
Baltimore, Maryland 21201-2692

301/539-2940
FTS/962-4822

December 5, 1988

Hamilton P. Fox, III, Esquire
Dewey, Ballantine, Bushby,
Palmer & Wood
1775 Pennsylvania Avenue, N.W.
Washington, D.C. 20006

Re: Raj Matkari

Dear Mr. Fox:

This letter confirms the agreement between your client, Raj Matkari, and the United States Attorney's Office for the District of Maryland ("the government"). The terms of the agreement are as follows:

1. Mr. Matkari agrees to waive Indictment and plead guilty to a criminal Information charging him with one count of giving a gratuity to a public official in violation of 18 U.S.C. § 201(c)(1)(A). Mr. Matkari admits that he is, in fact, guilty of that offense and will so advise the Court.

2. The maximum sentence provided by statute for this charge is as follows: Mr. Matkari is subject to imprisonment for 2 years and a fine of $250,000. In addition, Mr. Matkari must pay $50.00 as a penalty assessment under 18 U.S.C. § 3013.

3. Mr. Matkari agrees to cooperate with the government on the following terms and conditions:

(a) Mr. Matkari shall fully and truthfully respond to all questions put to him by federal law enforcement authorities. He shall promptly turn over to such authorities any documents in his possession or under his control that are in any way relevant to their inquiries.

(b) Mr. Matkari shall cooperate completely with federal law enforcement authorities in any matter as to which his cooperation may be relevant. He shall comply with any and all reasonable instructions from such authorities with respect to the specific assistance that he shall provide.

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(c) Mr. Matkari shall testify fully and truthfully before grand juries and at all trials of cases at which his testimony may be relevant.

4. In return for the complete fulfillment by Mr. Matkari of all of his obligations under this agreement, the government agrees as follows:

(a) When he appears before the Court for sentencing for the offense to which he has agreed to plead guilty, the govenment will bring to the Court's attention and the Court will be entitled to consider (i) the nature and extent of his cooperation, and (ii) all other relevant information with respect to his background, character and conduct. Additionally, the government will be entitled to bring to the Court's attention and the Court will be entitled to consider any failure by Mr. Matkari to fulfill any of his obligations under this agreement.

(b) At Mr. Matkari's sentencing, the government will make no recommendation to the Court regarding sentencing. Mr. Matkari must understand that the Court is not a party to and is not bound by this agreement. In the federal criminal system, sentencing is a matter solely within the discretion of the Court, and the Court could impose any sentence it may deem appropriate up to and including the statutory maximum stated above in Paragraph 2.

5. If Mr. Matkari has failed or should fail in any way to fulfill completely each and every one of his obligations under this agreement, then the government will be released from its commitment to honor all of its obligations to him. Thus, for example, if at any time he should knowingly withhold material evidence from federal law enforcement authorities or otherwise not be completely truthful with such authorities or in his testimony before grand juries or at trials, the the government will be free (i) to prosecute him for perjury, false declaration, false statement and/or obstruction of justice; (ii) to charge him with other offenses, if any, that he has committed; (iii) to use against him in all of those prosecutions the information and documents that he himself has disclosed to federal law enforcement authorities during the course of his cooperation; and (iv) to recommend to the Court any sentence that the government considers appropriate, up to and including the maximum possible sentence.

6. Whether or not Mr. Matkari has completely fulfilled all of his obligations under this agreement shall be determined

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by the Court in an appropriate proceeding at which his disclosures and documents shall be admissible and at which the government shall be required to establish his breach by a preponderance of the evidence. Mr. Matkari understands and agrees that he shall not be relieved of his obligations under this agreement or permitted to withdraw his guilty plea solely because the government is relieved of any or all of its obligations.

7. Nothing in this agreement shall be construed to protect Mr. Matkari in any way from prosecution for perjury, false declaration or false statement in connection with this investigation, in violation of 18 U.S.C. §§ 1621, 1623 or 1001, or from prosecution for any other offense committed by him after the date of this letter. The information and documents that he discloses to the government pursuant to this agreement may be used against him in any such prosecution.

8. Mr. Matkari waives and agrees to waive any rights under the Speedy Trial Act and Local Rule 30, and he understands that his sentencing may be delayed until his cooperation has been completed so that at sentencing the Court will have the benefit of all relevant information.

9. This letter states the complete plea agreement in this case. There are no other agreements, promises, undertakings or understandings between Mr. Matkari and the government.

10. If Mr. Matkari fully accepts each and every term and condition of this letter, please sign and have Mr. Matkari sign the original and return it to me promptly. The enclosed copy is for your file.

Very truly yours,

Breckinridge L. Willcox
United States Attorney

By: _____
Gary P. Jordan
First Assistant U. S. Attorney

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I have read this agreement and carefully reviewed every part of it with my attorney. I understand it, and I voluntarily agree to it.

4/24/1989
Date

Raj Matkari

I am Mr. Matkari's attorney. I have carefully reviewed every part of this agreement with him. To my knowledge, his decision to enter into this agreement is an informed and voluntary one.

Date

Hamilton P. Fox, III, Esquire
Attorney for Raj Matkari

SEP-03-1999 09:51 FDA/CDER/RPS 301 827 5562 P.07

United States District Court

DISTRICT OF MARYLAND

UNITED STATES OF AMERICA

V.

RAJ MATKARI

(Name and Address of Defendant)

JUDGMENT IN A CRIMINAL CASE

Case Number: HAR-89-0159

Gary P. Jordan
Attorney for United States

Hamilton P. Fox, III
Attorney for Defendant

THE DEFENDANT ENTERED A PLEA OF:

[☒ guilty ☐ nolo contendere] as to count(s) One (1)
☐ not guilty as to count(s) _____.

✓ FILED ____ ENTERED ____ LODGED ____ RECEIVED ____. and

JUL 2 1989
AT BALTIMORE
CLERK U.S. DISTRICT COURT
DISTRICT OF MARYLAND
BY OFFICIAL DEPUTY

THERE WAS A:
[☐ finding ☐ verdict] of guilty as to count(s) _____.

THERE WAS A:
[☐ finding ☐ verdict] of not guilty as to count(s) _____.
☐ judgment of acquittal as to count(s) _____.
The defendant is acquitted and discharged as to this/these count(s).

THE DEFENDANT IS CONVICTED OF THE OFFENSE(S) OF: U.S.C., Title 18, Section 201(c)(1)(. Giving an Unlawful Gratuity.

IT IS THE JUDGMENT OF THIS COURT THAT: Imposition of sentence is suspended and, Defendant is placed on probation for Three (3) Years with 500 hours of community service. A Fine of $2,000.00 is imposed.

0007

In addition to any conditions of probation imposed above, IT IS ORDERED that the conditions of probation set out on the reverse of this judgment are imposed.

AO 245 (Reverse)

CONDITIONS OF PROBATION

Where probation has been ordered the defendant shall:

(1) refrain from violation of any law (federal, state, and local) and get in touch immediately with your probation officer if arrested or questioned by a law-enforcement officer;
(2) associate only with law-abiding persons and maintain reasonable hours;
(3) work regularly at a lawful occupation and support your legal dependents, if any, to the best of your ability. (When out of work notify your probation officer at once, and consult him prior to job changes);
(4) not leave the judicial district without permission of the probation officer;
(5) notify your probation officer immediately of any changes in your place of residence;
(6) follow the probation officer's instructions and report as directed.

The court may change the conditions of probation, reduce or extend the period of probation, and at any time during the probation period or within the maximum probation period of 5 years permitted by law, may issue a warrant and revoke probation for a violation occurring during the probation period.

IT IS FURTHER ORDERED that the defendant shall pay a total special assessment of $ 50.00 pursuant to Title 18, U.S.C. Section 3013 for count(s) One (1) . ~~as follows:~~

~~[illegible] are dismissed [illegible]~~

IT IS FURTHER ORDERED that the defendant shall pay to the United States attorney for this district any amount imposed as a fine, restitution or special assessment. The defendant shall pay to the clerk of the court any amount imposed as a cost of prosecution. Until all fines, restitution, special assessments and costs are fully paid, the defendant shall immediately notify the United States attorney for this district of any change in name and address.

IT IS FURTHER ORDERED that the clerk of the court deliver a certified copy of this judgment to the United States marshal of this district.

☐ The Court orders commitment to the custody of the Attorney General and recommends:

July 28, 1989
Date of Imposition of Sentence

Signature of Judicial Officer

JOHN R. HARGROVE, SR., UNITED STATES DISTRICT COURT JUDGE
Name and Title of Judicial Officer

7/28/89
Date

7/28/89

JOSEPH A. [illegible]
CLERK, U.S. DISTRICT COURT
DISTRICT OF MARYLAND
Karen A. Hoye
Deputy

RECEIVED
1989 JUL 31 AM 11:35
UNITED STATES ATTORNEY
BALTIMORE, MARYLAND

RETURN

I have executed this Judgment as follows:

Defendant delivered on _____ to _____ at
Date

_____, the institution designated by the Attorney General, with a certified copy of this Judgment in a Criminal Case.

United States Marshal

By _____
Deputy Marshal

0008

GPJ:fc (STMT0502)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA	*	
v.	*	CRIMINAL NO. HAR-89-0159
RAJ MATKARI	*	

****

STATEMENT OF FACTS

If this case had proceeded to trial, the government would have produced evidence to prove the following facts.

In August 1987, the defendant, Raj Matkari, was the Vice President for Regulatory Affairs and Product Development for Pharmaceutical Basics, Inc. (PBI). PBI is a generic drug manufacturer with headquarters in Denver, Colorado. PBI regularly submitted applications to the Division of Generic Drugs of the Food & Drug Administration for approval to market its products to the public. As Vice President for Regulatory Affairs, Mr. Matkari was directly responsible for monitoring the status of these applications.

Charles Y. Chang was Chief of a Branch of Review Chemists in the Division of Generic Drugs. In that capacity, Mr. Chang supervised his chemists' review of generic drug applications. As of August 1987, Mr. Chang and his chemists had reviewed and recommended approval for several applications submitted by PBI and there were a number of PBI applications pending in Mr. Chang's Branch.

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During the summer of 1987, Mr. Chang made known to Mr. Matkari that he was experiencing financial difficulties. Mr. Matkari cashed a check on or about August 7, 1987 and took $2,000 in United States currency from the proceeds with him when he travelled from Colorado to the Washington area on August 19, 1987. On that date, Mr. Matkari met Mr. Chang at the Bethesda Marriott Hotel in Bethesda, Maryland where he gave Mr. Chang an envelope containing $2,000 in currency.

In July, 1988, Charles Chang began cooperating with the government's investigation of corruption in the Division of Generic Drugs. On July 29, 1988, Mr. Chang placed a telephone call to Mr. Matkari which was monitored and recorded by an agent of the Office of the Inspector General of the Department of Health & Human Services. In this taped conversation, Mr. Matkari made statements admitting his payment of cash to Mr. Chang.

EXHIBITS

Exhibit 1.	October 20, 1993 Debarment Order, 58 FR 54156
Exhibit 2.	Articles of Incorporation of Napean Enterprises, Inc.
Exhibit 3.	Report of July 17, 23 and 29, 1997 Inspection of Sage Pharmaceuticals by Carolyn E. Barney, CSO, ORA SE NOL-DO SHR-LA , HFR-SE4555
Exhibit 4.	March 31, 1997 Invoice Number 14893 from Akzo Nobel (Diosynth, Inc.) to Napean Enterprises, shipped to Sage Pharmaceuticals, for Esterified Estrogens
Exhibit 5.	July 10, 14, 16, and 21, 1997 Handwritten Customer Lists and Shipping Instructions from Raj Matkari to Jack Antis, Pegasus Labs
Exhibit 6.	August 12, 1997 Memo from Joan S. Norton, CSO, to Keith Ehrlich, SI, Regarding August 7, 1997 Inspection of Pegasus Laboratories
Exhibit 7.	February 14, 1997 and May 2, 1997 Letters from Sage Pharmaceuticals to FDA Regarding Sage ANDA

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Exhibit 1.

:ES: Copies of this information
n may be obtained from Steven
of the Office of Information
Management, ACF, by calling
-8946.
n comments and questions
g this information collection
e sent directly to: Laura Oliven,
sk Officer for ACF, OMB
Management Branch, New
e Office Building, room 3002,
Street NW., Washington, DC
202) 395-7316.

tion on Document

Child Care and Development
ant Second Annual Report to
gress: An Interim Report on
Services and Expenditures
CF-700).
No.: 0980-0241.
ption: The Child Care and
ment Block Grant Act
es the Secretary of the
ent of Health and Human
to award grants to States,
es, Indian Tribes, and Tribal
tions to increase the
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e. Section 658K of the Child
Development Block Grant Act
5082 of the Omnibus Budget
iation Act of 1990, Pub. L. 101-
45 CFR 98.70 and 98.71
rantees to prepare and submit
l report on the program. The
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h the first interim report, the
terim report will consist of
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expended funds, the extent to
e affordability and availability
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ecretary. The requirements for
nt annual reports will identify
ional information which
must submit as it is available,
g: the number of children being
by CCDBG and other Federal
e and pre-school programs; the
number of child care programs,
e providers, caregivers, and
personnel in the grantee's
rea; salaries and other
ation paid to full- and part-time
e service providers; and
to encourage public-private
ips that promote business
ent in meeting child care

ta collected in this second
eport are necessary for the
on of the required annual
Congress, as specified in
section 658L of the Act. This information will also assist in program evaluation, management, and monitoring. In addition, grantees must submit information on their review of licensing and regulatory requirements, as well as describe the standards and health and safety requirements applicable to child care providers in their area, if such information was not submitted with the first interim report that was due December 31, 1992.

Annual Number of Respondents: 260.

Annual Frequency: 1.

Average Burden Hours Per Response: 50.

Total Burden Hours: 13,000.

Dated: October 7, 1993.

Larry Guerrero,

Deputy Director, Office of Information Systems Management.

[FR Doc. 93-25693 Filed 10-19-93; 8:45 am]

BILLING CODE 4184-01-M

Third Meeting of the Advisory Committee on Head Start Quality and Expansion

AGENCY: Administration for Children and Families, DHHS.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given, pursuant to Public Law 92-463, the Federal Advisory Committee Act, that the Advisory Committee on Head Start Quality and Expansion will hold its third meeting on Tuesday, November 2, 1993 at the Grand Hyatt Hotel, 1000 H Street, NW., Washington, DC.

The meeting shall be open to the public. The proposed final agenda will include a discussion of the draft report of the Advisory Committee.

Records shall be kept of all Committee proceedings and shall be available for public inspection at 370 L'Enfant promenade, SW., Aerospace Building, suite 500, Washington, DC 20447.

If a sign language interpreter is needed, contact David Siegel at the address and telephone below.

FOR FURTHER INFORMATION CONTACT: David Siegel, 7th floor, Aerospace Building, 370 L'Enfant Promenade, SW., Washington, DC 20047 (202) 401-9215.

Dated: October 15, 1993.

Lawrence J. Love,

Deputy Assistant Secretary for Program Operations.

[FR Doc. 93-25638 Filed 10-18-93; 11:22 am]

BILLING CODE 4184-01-M

Food and Drug Administration

[Docket No. 92N-0412]

Raj Matkari; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Deputy Commissioner for Operations of the Food and Drug Administration (FDA) denies a hearing for and issues a final order permanently debarring Mr. Raj Matkari, 1304 Riverglen Way, Berthoud, CO 80513, under section 306(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 335a(a)). The Deputy Commissioner bases this order on her finding that Mr. Matkari was convicted of a Federal felony for conduct relating to the development or approval, including the process for development or approval of a drug product; and relating to the regulation of a drug product under the act.

EFFECTIVE DATE: October 20, 1993.

ADDRESSES: Application for termination of debarment to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Megan L. Foster, Center for Drug Evaluation and Research (HFD-366), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

Mr. Raj Matkari, the former Vice President for Regulatory Affairs and Product Development of Pharmaceutical Basics, Inc. (PBI), pled guilty and was sentenced on July 28, 1989, for giving an unlawful gratuity, a felony offense under 18 U.S.C. 201(c)(1)(A). The basis for this conviction was Mr. Matkari's payment of approximately $2,000 to an FDA chemistry review branch chief who was involved in the regulation of PBI's drug products and who was specifically responsible for supervising the chemists who reviewed PBI's applications to determine whether these applications met certain statutory standards for approval.

In a certified letter received by Mr. Matkari on November 25, 1992, the Deputy Commissioner for Operations offered Mr. Matkari an opportunity for a hearing on a proposal to issue an order under section 306(a) of the act debarring Mr. Matkari from providing services in any capacity to a person that has an

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approved or pending drug product application. FDA based the proposal to debar Mr. Matkari on its finding that he was convicted of a felony under Federal law for conduct relating to the development, approval, and regulation of PBI's drug products.

The certified letter also informed Mr. Matkari that his request for a hearing could not rest upon mere allegations or denials but must present specific facts showing that there was a genuine and substantial issue of fact requiring a hearing. The letter also noted that if it conclusively appeared from the face of the information and factual analyses in his request for a hearing that there was no genuine and substantial issue of fact which precluded the order of debarment, FDA would enter summary judgment against him, making findings and conclusions, and denying his request for a hearing.

Mr. Matkari responded to the proposal to debar in a letter filed by FDA on January 2, 1993, in which he requested a hearing. Mr. Matkari also submitted a brief argument in support of his hearing request in a letter filed by FDA on February 4, 1993.

The Deputy Commissioner has considered Mr. Matkari's arguments and concludes that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing. Mr. Matkari's arguments and the agency's responses follow.

II. Mr. Matkari's Arguments in Support of a Hearing

Mr. Matkari first argues that his conduct does not fall within the provisions for mandatory debarment but instead falls within those for permissive debarment. Mr. Matkari fails to support this statement with an explanation or further argument.

Paragraphs (a)(2)(A) and (a)(2)(B) of section 306 of the act require FDA to debar an individual if the Secretary finds that the individual has been convicted of a felony under Federal law for conduct: (1) Relating to the development or approval, including the process for development or approval, of any drug product; or (2) otherwise relating to the regulation of any drug product under the act.

These mandatory debarment provisions apply to Mr. Matkari's conviction for payment of an illegal gratuity. While this crime is listed in the permissive debarment provisions, section 306(b)(2)(B)(ii), an individual convicted of this crime will be considered to be a candidate for permissive debarment only if FDA finds that the conduct giving rise to the conviction did not relate to the development or approval or the regulation of any drug product. Because FDA finds that Mr. Matkari's conduct leading to his conviction did relate to the development and approval and the regulation of his corporation's drug products, the mandatory provisions, rather than the permissive provisions, are applicable in this case. Mr. Matkari has not disputed FDA's finding that his conduct leading to his conviction relates to the development and approval and the regulation of his corporation's drug products. Therefore, Mr. Matkari's claim fails to raise a genuine and substantial issue of fact.

In his second and final argument, Mr. Matkari claims that the debarment provisions do not apply retroactively to convictions that predate the enactment of the statute. He does not support this claim with further argument.

The provision of the act which applies to Mr. Matkari, section 306(a)(2), is clearly retroactive. This is evidenced in section 306(a) of the act, which treats mandatory debarment of corporations differently with respect to retroactivity from mandatory debarment of individuals. Mandatory debarment of corporations under 306(a)(1) of the act is not retroactive because it only applies to convictions "after the date of enactment of this section." However, section 306(a)(2) of the act, which pertains to mandatory debarment of individuals, does not contain this limiting language. Therefore, if Congress had intended for section 306(a)(2) of the act not to be retroactive, it would have included the language "after the date of enactment of this section."

Section 306(l)(2) of the act, which sets out the effective dates for each provision of the act, also indicates that section 306(a)(2) is retroactive. The only limitation section 306(l)(2) sets on section 306(a) of the act is that section 306(a) shall not apply to a conviction which occurred more than 5 years before the initiation of an agency action. This language indicates that any applicable conviction may be used as the basis for debarment, so long as it occurred no more than 5 years prior to the initiation of debarment proceedings. Certain other provisions covered in section 306(l) of the act are further limited by the statement that the section shall not apply to an action which occurred before June 1, 1992. Thus, when Congress intended that a certain section not be retroactive, it set a specific effective date or used specific limiting language as in section 306(a)(1) of the act. Congress' intentional omission of an effective date for section 306(a)(2) of the act indicates its intent that this section be retroactive.

Mr. Matkari acknowledges that he was convicted of a felony as alleged by the agency in its proposal to debar him but has failed to demonstrate that his conviction does not relate to the development, approval, or regulation of any drug product. In addition, Mr. Matkari's legal arguments do not create a basis for a hearing and, in any event, are unpersuasive. Therefore, Mr. Matkari has failed to raise a genuine and substantial issue of fact regarding this conviction. Accordingly, the Deputy Commissioner for Operations denies Mr. Matkari's request for a hearing.

III. Findings and Order

Therefore, the Deputy Commissioner for Operations, under section 306(a) of the act, finds that Mr. Raj Matkari has been convicted of a felony under Federal law for conduct (1) Relating to the development or approval, including the process for development or approval, of a drug product (21 U.S.C. 335a(a)(2)(A)); and (2) relating to the regulation of a drug product (21 U.S.C. 335a(a)(2)(B)).

As a result of the foregoing findings, Mr. Raj Matkari is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective October 20, 1993 (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(ee)). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Matkari in any capacity, during his period of debarment, will be subject to civil money penalties (21 U.S.C. 335b(a)(6)). If Mr. Matkari, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (21 U.S.C. 335b(a)(7)). In addition, FDA will not accept or review any abbreviated new drug application or abbreviated antibiotic drug application submitted by or with the assistance of Mr. Matkari during his period of debarment.

Mr. Matkari may file an application to attempt to terminate his debarment pursuant to section 306(d)(4)(A) of the act. Any such application would be reviewed under the criteria and processes set forth in section 306(d)(4)(C) and (d)(4)(D) of the act. Such an application should be identified with Docket No. 92N-0412 and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four

copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 27, 1993.

Jane E. Henney,

Deputy Commissioner for Operations.

[FR Doc. 93–25672 Filed 10–19–93; 8:45 am]

BILLING CODE 4160–01–P

[Docket No. 93N–0368]

Drug Export; Antihemophilic Factor (Human), Affinity Chromatography Purified, Solvent Detergent/Heat Treated, Method C

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Alpha Therapeutic Corp. has filed an application requesting approval for the export of the biological product Antihemophilic Factor (Human), Affinity Chromatography Purified, Solvent Detergent/Heat Treated, Method C to the United Kingdom.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human biological products under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Frederick W. Blumenschein, Center for Biologics Evaluation and Research (HFM–560), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–1070.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of biological products that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the Federal Register within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Alpha Therapeutic Corp., 5555 Valley Blvd., Los Angeles, CA 90032, has filed an application requesting approval for the export of the biological product Antihemophilic Factor (Human), Affinity Chromatography Purified, Solvent Detergent/Heat Treated, Method C to the United Kingdom. The Antihemophilic Factor (Human), Affinity Chromatography Purified, Solvent Detergent/Heat Treated, Method C is indicated solely for the prevention and control of bleeding in patients with moderate or severe Factor VIII deficiency due to hemophilia A or acquired Factor VIII deficiency. The application was received and filed in the Center for Biologics Evaluation and Research on August 30, 1993, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by November 1, 1993, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Biologics Evaluation and Research (21 CFR 5.44).

Dated: October 1, 1993.

P. Michael Dubinsky,

Deputy Director, Office of Compliance, Center for Biologics Evaluation and Research.

[FR Doc. 93–25677 Filed 10–19–93; 8:45 am]

BILLING CODE 4160–01–P

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

MEETING: The following advisory committee meeting is announced:

Veterinary Medicine Advisory Committee

Date, time, and place. November 9, 1993, 8:30 a.m., and November 10, 1993, 8 a.m., Goshen Room, Holiday Inn-Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open committee discussion, November 9, 1993, 8:30 a.m. to 10 a.m.; open public hearing, 10 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 2:15 p.m.; open public hearing, 2:15 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 4:30 p.m.; closed committee deliberations, November 10, 1993, 8 a.m. to 5 p.m.; Gary E. Stefan, Center for Veterinary Medicine (HFV–244), 7500 Standish Pl., Rockville, MD 20855, 301–594–1769.

General function of the committee. The committee reviews and evaluates available data concerning safety and effectiveness of marketed and investigational new animal drugs, feeds, and devices for use in the treatment, prevention of animal disease and increased animal production.

Agenda—Open public hearing. Any interested persons requesting to present data, information, or views, orally or in writing, on issues pending before the committee should communicate with the contact person.

Open committee discussion. The committee will discuss flexible labeling for approved new animal drugs, and FDA's Compliance Policy Guide on Proper Drug Use and Residue Avoidance by Non-Veterinarians.

Closed committee deliberations. The committee will review and discuss trade secret and/or confidential commercial information relevant to a new animal drug application. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b (c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee

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Exhibit 2.

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ARTICLES OF INCORPORATION
OF
NAPEAN ENTERPRISES, INC.

The undersigned entity hereby establishes a corporation pursuant to the Colorado Business Corporation Act as amended and adopts the following Articles of Incorporation:

951150966 $50.00
SECRETARY OF STATE
12-11-95 16:00

ARTICLE I
NAME

The name of the corporation is: Napean Enterprises, Inc.

ARTICLE II
PURPOSE

The corporation shall have and may exercise all of the rights, powers and privileges now or hereafter conferred upon corporations organized under the laws of Colorado. In addition, the corporation may do everything necessary, suitable or proper for the accomplishment of any of its corporate purposes. The corporation may conduct part or all of its business in any part of Colorado, the United States or the world and may hold, purchase, mortgage, lease and convey real and personal property in any of such places. More specifically, the corporation is organized for the purpose of the wholesale distribution of pharmaceutical products.

ARTICLE III
STOCK AND RIGHTS OF SHAREHOLDERS

3.1 The aggregate number of shares which the corporation shall have authority to issue is 100,000 shares of common stock. The shares of this class of common stock shall have unlimited voting rights and shall constitute the sole voting group of the corporation, except to the extent any additional voting group or groups may hereafter be established in accordance with the Colorado Business Corporation Act. The shares of this class shall also be entitled to receive the net assets of the corporation upon dissolution.

3.2 Each shareholder of record shall have one vote for each share of stock standing in his name on the books of the corporation and entitled to vote. Cumulative voting shall not be permitted in the election of directors or otherwise.

3.3 Unless otherwise ordered by a court of competent jurisdiction, at all meetings of shareholders, a majority of the shares of a voting group entitled to vote at such meeting, represented in person or by proxy, shall constitute a quorum of that voting group.

3.4 Shareholders shall have pre-emptive rights.

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ARTICLE IV
DIRECTORS

The number of directors of the corporation shall be fixed by the by-laws. One Director shall constitute the initial board of directors. The following persons are elected to serve as the corporation's initial directors until the first annual meeting of shareholders or until their successors are duly elected and qualified:

NAME	ADDRESS
Rajaram K. Matkari	120 Bunyan Street, Suite D Berthoud, Colorado 80513

ARTICLE V
REGISTERED OFFICE AND AGENT

The street address of the initial registered office of the corporation is 3025 South Parker Road, Suite 200, Aurora, Colorado 80014. The name of the initial registered agent of the corporation at such address is: Beck and Cassinis, P.C.

ARTICLE VI
PRINCIPAL OFFICE

The address of the initial principal office of the corporation is: 120 Bunyan Street, Suite D, Berthoud, Colorado 80513.

ARTICLE VII
LIABILITY OF OFFICERS AND DIRECTORS

The following provisions are inserted for the management of the business and for the conduct of the affairs of the corporation, and same are in furtherance of and not in limitation or exclusion of the powers conferred by law.

7.1 Conflicting Interest Transactions. As used in this paragraph, "conflicting interest transaction" means any of the following: (a) a loan or other assistance by the corporation to a director of the corporation or to an entity in which a director of the corporation is a director or officer, or has a financial interest; (b) a guaranty by the corporation of an obligation of a director of the corporation or of an obligation of an entity in which a director of the corporation is a director or officer, or as a financial interest; or (c) a contract or transaction between the corporation and a director of the corporation or between the corporation and an entity in which a director of the corporation is

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a director or officer, or has a financial interest. No conflicting interest transaction shall be void or voidable, be enjoined, be set aside or give rise to an award of damages or other sanctions in a proceeding by a shareholder or by or in the right of the corporation, solely because the conflicting interest transaction involves a director of the corporation or an entity in which a director of the corporation is a director or officer, or has a financial interest, or solely because the director is present at or participates in the meeting of the corporation's board of directors or of the committee of the board of directors which authorizes, approves or ratifies a conflicting interest transaction or solely because the director's vote is counted for such purpose if: (i) the material facts as to the director's relationship or interest as to the conflicting interest transaction are disclosed or are known to the board of directors or the committee and the board of directors or committee in good faith authorizes, approves or ratifies the conflicting interest transaction by the affirmative vote of a majority of the disinterested directors, even though the disinterested directors are less than a quorum; or (ii) the material facts as to the director's relationship or interest and as to the conflicting interest transaction are disclosed or are known to the shareholders entitled to vote thereon and the conflicting interest transaction is specifically authorized, approved or ratified in good faith by a vote of the shareholders; or (iii) a conflicting interest transaction is fair as to the corporation as of the time it is authorized, approved or ratified by the board of directors, a committee thereof or the shareholders. Common or interested directors may be counted in determining the presence of a quorum at a meeting of the board of directors or of a committee which authorizes, approves or ratifies the conflicting interest transaction.

7.2 Loans and Guaranties for the Benefit of Directors. Neither the board of directors nor any committee thereof shall authorize a loan by the corporation to a director of the corporation or to any entity in which a director of the corporation is a director or officer, or has a financial interest, or a guaranty by the corporation of an obligation of a director of the corporation or of an obligation of an entity in which a director of the corporation is a director or officer, or has a financial interest, until at least ten (10) days after written notice of the proposed authorization of the loan or guaranty has been given to the shareholders who would be entitled to vote thereon if the issue of the loan or guaranty were submitted to a vote of the shareholders. The requirements of this paragraph 7.2 are in addition to, and not in substitution for, the provisions of paragraph 7.1 of Article VII.

7.3 Indemnification. The corporation shall indemnify, to the maximum extent permitted by law, any person who is or was a director, officer, agent, fiduciary or employee of the corporation against any claim, liability or expense arising against or incurred by such person made party to a proceeding because he is or was a

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director, officer, agent, fiduciary or employee of the corporation or because he is or was serving another entity as a director, officer, partner, trustee, employee fiduciary or agent at the corporation's request. The corporation shall further have the authority, to the maximum extent permitted by law, to purchase and maintain insurance providing such indemnification.

7.4 Limitation on Director's Liability. No director of this corporation shall have any personal liability for monetary damages to the corporation or its shareholders for breach of his fiduciary duty as a director, except that this provision shall not eliminate or limit the personal liability of a director to the corporation or its shareholders for monetary damages for: (a) any breach of the director's duty or loyalty to the corporation or its shareholders; (b) acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; (c) voting for or assenting to a distribution in violation of Colorado Revised Statutes § 7-106-401 or the Articles of Incorporation if it is established that the director did not perform his duties in compliance with Colorado Revised Statutes § 7-108-401, provided that the personal liability of a director in this circumstance shall be limited to the amount of the distribution which exceeds what could have been distributed without violation of Colorado Revised Statutes § 7-106-401 or the Articles of Incorporation; or (d) any transaction from which the director directly or indirectly derives an improper personal benefit. Nothing contained herein will be construed to deprive any director of his right to all defenses ordinarily available to a director nor will anything herein be construed to deprive any director of any right he may have for contribution from any other director or person.

7.5 Negation of Equitable Interests in Shares or Rights. Unless a person is recognized as a shareholder through the procedures established by the corporation pursuant to Colorado Revised Statutes § 7-107-204 or any similar law, the corporation shall be entitled to treat the registered holder of any shares of the corporation as the owner thereof for all purposes permitted by the Colorado Business Corporation Act, including, without limitation, all rights deriving from such shares, and the corporation shall not be bound to recognize any equitable or other claim to, or interest in, such shares or rights deriving from such shares on the part of any other person, including, without limitation, a purchaser, assignee or transferee of such shares, unless and until such other person becomes the registered holder of such shares or is recognized as such, whether or not the corporation shall have either actual or constructive notice of the claimed interest of such other person. By way of example and not limitation, until such other person has become the registered holder of such shares or is recognized pursuant to Colorado Revised Statutes § 7-107-204 or any similar applicable law, he shall not be entitled: (a) to receive notice of the meetings of the shareholders; (b) to vote at such meetings; (c) to examine a list

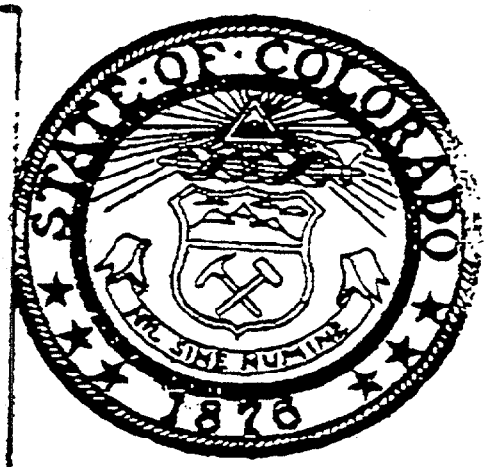
STATE OF COLORADO
DEPARTMENT OF STATE

I hereby certify that this is a true and complete copy of the document filed in this office and admitted to record in file 19951150966

DATED August 1 1997

Victoria Buckley
Secretary of State

By Jackie S. Scott



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of the shareholders; (d) to be paid dividends or other distributions payable to shareholders; or (e) to own, enjoy and exercise any other rights deriving from such shares against the corporation. Nothing contained herein will be construed to deprive any beneficial shareholder, as defined by Colorado Revised Statutes § 7-113-101(1), of any right he may have pursuant to Article 113 of the Colorado Business Corporation Act or any subsequent law.

ARTICLE VIII
INCORPORATOR

The name and address of the incorporator is:

Name	Address
Beck and Cassinis, P.C.	Suite 200 3025 South Parker Road Aurora, Colorado 80014

DATED this 11th day of December, 1995.

Beck and Cassinis, P.C.

By: _____
William J. Graveley

Beck and Cassinis, P.C. hereby consents to the appointment as the initial registered agent for Napean Enterprises, Inc.

Beck and Cassinis, P.C.

By: _____
William J. Graveley

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Exhibit 3.

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SUMMARY OF FINDINGS/COMPLETE REPORT

This directed inspection was conducted as a follow-up to Assignment #287 to determine if Sage has applied for an ANDA or NDA for the product, Menogen, and to collect samples of the Menogen products. This inspection was conducted in accordance with C.P. 7356.002, Drug Process Inspection.

The previous inspection, conducted on 11/19-27/96 found that the firm had significant GMP deficiencies including: no validation of the manufacturing and packaging processes for seven products; tablet sample weights not recorded for four products during validation; no stability data available for five products; an additional 110 grams of dextramethorphan hydrobromide dispensed above the validated formula for PanMist DM; screen sizes to PanMist changed without being evaluated and approved by QC; PanMist stability not evaluated after changing the screen size during production; validated mixing times not specified for Profen LA tablets; identity tests not performed on all components: no procedures for retention periods of active ingredients and reserve samples; no final product report completed for 6 of 9 complaints; and no annual review conducted of PanMist S, Palgic D, and Capsin tablets. The inspection was classified AA.

On 7/17/97, I showed my credentials and presented the FDA-482, Notice of Inspection, to Dr. Jivn Ren Chen, President. I also presented my credentials to Mr. William J. Roche, Quality Assurance Manager.

Sage continues to manufacture oral generic pharmaceutical products in solid or liquid dosage forms; topical products in either spray, lotion, or gel dosage forms; and topical wound dressings which are medical devices. Sage manufacturers four drug profile classes as follows: liquids (LIQ); tablets, prompt release (TCM); tablets, extended release (TTR); and non-sterile ointments (OIN). The firm markets its products through generic distributors, major retail pharmacy chains, drug wholesalers, and hospitals. The firm has not applied for and does not hold any approved NDAs or ANDAs.

The firm's corporate officers are Mr. Tony (NMI) Yeh - Chairman of Board and Mr. Jivn Ren Chen, Ph.D. - President. The Chairman, Mr. Tony Yeh, maintains an office and receives mail at Yung Yeou Trading Co. Ltd.; 6F., No.5, 6 Alley Sec.2; Chien Kuo N. Rd.; Taipei-10409, Taiwan, ROC.

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The firm's managing officials include Dr. Jivn Ren Chen, Ph.D.- President; William J. Roche - Manager of Quality Assurance; and Jason J. Jagneaux, Assistant General Manager. Mr. Roche reports to Dr. Chen who answers directly to Mr. Tony (NMI) Yeh, Chairman of the Board. Mr. Jagneaux reports to Mr. Roche. Dr. Chen, Mr. Roche and Mr. Jagneaux maintain offices and receive mail at this firm's address.

Dr. Chen is the most responsible person at this facility and is in control of all activities. He is also responsible for initiating a committee to formulate new products for research and development, and he is the person customers contact for new products. Dr. Chin is responsible for the firm's financial transactions and approves all new Master Formula Records.

MENOGEN and MENOGEN H.S. PRODUCTS:

During the inspection, Dr. Chin informed me of the following: Sage is a contract manufacturer of Menogen and Menogen H.S. prescription products for Napean Enterprises, Inc. in Colorado. This contract developed after three or four meetings and several phone calls with Raj Matkari who owns Napean Enterprises, Inc. These meetings took place at this facility located at 5408 Interstate Dr. in Shreveport, LA and included Dr. Chin, William J. Roche, Raj Matkari, and one member of his staff. Sage performed the research and development for the Menogen and Menogen H.S. products. Neither Raj Matkari with Napean Enterprises, Inc. nor Breckenridge Pharmaceutical, Inc. gave Sage the formulas for these two products.

Dr. Chin also stated he did not know for sure if there was an NDA or ANDA for this product, however, he conveyed that Raj Matkari had admitted to him that there was no NDA or ANDA for this product since it was "grandfathered in" and, therefore, did not need an NDA. Dr. Chin said that he checked the Approved Drug Products 17th Edition, 1997 and researched the pre 1962 Physician Desk References and did not find it listed. He also reviewed the FDA Compliance Policy Guides, and thought that Sage was covered by the Policy Guideline Exemption #4 listed on page 136 of the August 1996 Edition. He related that he had not checked with the Center for Drug Evaluation and Research (CDER) since he believed Napean Enterprises, Inc. would be responsible for securing the NDA or ANDA if one was needed.

Dr. Chin remarked that Menogen and Menogen H.S. are the only products Sage manufactures for Napean Enterprises. Per Raj Matkari's request, sage uses either a Sage or Breckenridge label on the Menogen and the Menogen H.S. products for a total of four different Menogen product labels. One label, which the firm called

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the Breckenridge label, states the product is Distributed by Breckenridge Pharmaceutical, Inc., Boca Raton, FL. This label also identifies Sage Pharmaceuticals, Inc., Shreveport, LA, as the manufacturer. The other label, called the Sage label, does not have the Distributed by Breckenridge statement.

The Menogen (full-strength) label stating that the product contains 1.25 mg of Esterified Estrogens and 2.5 mg Methyltestosterone is shown in Exhibit 1 for the Breckenridge label and in Exhibit 2 for the Sage label. The Menogen H.S. (half-strength) label stating that the product contains 0.625 mg Esterified Estrogens and 1.25 mg Methyltestosterone, is shown in Exhibit 3 for the Breckenridge label and Exhibit 4 for the Sage label. Each 100 tablet bottle is packaged in a white cardboard box that contains one physician insert and three identical patient inserts. The physician insert is shown in Exhibit 5; the patient insert is shown in Exhibit 6.

Dr. Chin also related that Napean Enterprises provided a customer list to Sage and requested that Sage ship Menogen and Menogen H.S. to those customers on the list. Sage did not sell or receive any money from the shipments of Menogen products; instead, Napean Enterprises paid Sage directly for all Menogen products produced and shipped by Sage. Napean Enterprises also ordered and provided the raw ingredients such as Esterified Estrogens which was manufactured in Holland.

According to Dr. Chin, no products were shipped to Breckenridge for distribution by Breckenridge Pharmaceuticals, Inc. of Boca Raton, Florida, and that there was no connection between Breckenridge and Sage. Sage has not manufactured any other products for Napean Enterprises and has not placed any Distributed by Breckenridge labels on any other products besides Menogen.

The above statements by Dr. Chin regarding Sage's involvement with Menogen were placed in the attached Affidavit. However, Mr. Roche during the closeout discussion, stated that the firm's lawyers had advised that no member of the firm read or sign an affidavit. Both Mr. Roche and Mr. Jagneaux declined to read or sign affidavits prepared for them, and Mr. Roche declined on Dr. Chin's behalf since Dr. Chin was not present at the final discussion with management.

During this inspection, Dr. Chin informed me that the firm is not currently manufacturing Menogen and Menogen H.S. products. Part of the last manufactured lot of Menogen H.S., S7059, was shipped to Pegasus Laboratories in Pensacola, FL. The batch records for this lot of product are attached as Exhibits 7.1-.23. The Analytical Methodology for assaying Menogen is shown in Exhibits 8.1-.12. This lot was sampled as C/R DOC 97-653-214 which may be referenced for additional batch records.

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FIRM'S CURRENT PRODUCTS:

The firm's tableted products include:
Menogen, Menogen H.S. - Esterified Estrogens, Methyltestosterone
Palgic D - Carbinoxamine Maleate 8 mg, Pseudoephedrine Hcl 120 mg
ColdLoc LA, Despec S.R., SA-VENT S.R.), - Phenylpropanolamine Hcl 75 mg, Guaifenesin 600 mg
Flextra DS, - Acetaminophen 500 mg, Phenyltoloxamine 50 mg

The firm's liquid products include:
PanMist S - Pseudoephedrine Hcl 45 mg, Guaifenesin 200 mg.
Palgic DS, - Carbinoxamine Maleate 2 mg, Pseudoephedrine Hcl 30 mg
ColdLoc, Depec SF/AF, SA-TUSS Liquid, - Guaifenesin 100 mg, Phenylpropanolamine Hcl 20 mg, Phenylephrine Hcl 5 mg.

Additional products include:
Redutemp 500-, Acetaminophen 500 mg - suspension product
Capsin - Capsaicin 0.025% - topical analgesic
Capsin Extra Potency - Capsaicin 0.075% - topical analgesic
Vitamin A & D Ointment - topical first aid antiseptic ointment
Moisture Care - topical first aid antiseptic ointment
Septicare - Benzethonium Cl, 0.2% - germicidal wound cleaner
Clinseptic Gel - Benzalkonium Cl, 0.13% - germicidal wound cleaner
Clinswound, Saline, Surfactants - wound irrigate
DermaBath/Dermaclin - bathing solutions
Dermaclin S - bathing solutions
PeriFoam - bathing solutions
Skin Seal - Skin Sealants
PanoPlex - Medical Device Wound Dressing

During the current inspection, the following was collected and submitted to NOL-DO for regulatory consideration since Menogen was being manufactured without a NDA or ANDA. The physical samples has been sent to San Juan District Laboratory for potency analysis:

a. 6/100 tablet bottles Menogen, lot #S7054, - C/R 97-653-212
b. 6/100 tablet bottles Menogen H.S., lot #S7057 - C/R 97-653-213
c. DOC sample, DOC 97-653-214, Menogen H.S. lot #S7059. Part of Lot S7059 was shipped to Pegasus Laboratories in Pensacola, FL.

At the conclusion of the inspection, Dr. Chin was not available; however, Mr. Roche and Mr. Jagneaux were present. I had prepared Affidavits for Dr. Chin, Mr. Roche, and Mr. Jagneaux. During this closeout meeting, Mr. Roche stated that on advice of the firm's attorney, affidavits could not be read or signed by any member of the firm. During this closeout interview, I also stated that since Sage was manufacturing Menogen without a NDA or ANDA, this situation would be reviewed further through New Orleans Compliance and CDER in Washington. No FDA-483 was issued.

SEP-03-1999 09:57 FDA/CDER/RPS 301 827 5562 P.28

Sage Pharmaceuticals, Inc., 5408 Interstate Dr., Shreveport, S
LA 71109 (CFN 2319121) 7/17,23,29/97 CEB

ATTACHMENTS:

Assignment # 281
FDA-482, Notice of Inspection
Affidavit for Dr. Jivn-Ren Chin
(Affidavit for Mr. Roche is attached to lead C/R 97-653-212 and
Affidavit for Mr. Jagneaux is attached to DOC 97-653-214)

EXHIBITS:

1.1	Menogen Label, Breckenridge
2.1	Menogen Label, Sage
3.1	Menogen H.S. Label, Breckenridge
4.1	Menogen H.S. Label, Sage
5.1	Physician insert
6.1	Patient insert
7.1-.23	Menogen H.S., S7059, batch records
8.1-.12	Analytical Methology for assaying Menogen

Carolyn E. Barney

Carolyn E. Barney
Investigator SHV-RP

0028

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NO.
4298 Elysian Fields Ave.
New Orleans, LA 70122
(504) 589-6344

2. NAME AND TITLE OF INDIVIDUAL
Jiyn-Ren Chen, Ph.D., President

3. DATE
7/17/97

4. FIRM NAME
Sage Pharmaceuticals, Inc.

5. HOURS a.m.

6. NUMBER AND STREET
5408 Interstate Dr.

p.m.

7. CITY AND STATE & ZIP CODE
Shreveport, LA 71109

8. PHONE # & AREA CODE
318-635-1594

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

9. SIGNATURE *(Food and Drug Administration Employee(s))*
Carolyn E. Barney

10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))*
Carolyn E. Barney, CSO

Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

[1]Sec. 704. (a)(1) For purposes of enforcement of this Chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein *(including records, files, papers, processes, controls, and facilities)* bearing on whether prescription drugs or restricted devices which are adulterated or misbranded within the meaning of this Chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Chapter. No inspection authorized by the preceding sentence or by paragraph (2) shall extend to financial data, sales data other than shipment data, pricing data, personnel data *(other than data as to qualifications of technical and professional personnel performing functions subject to this Act)*, and research data *(other than data relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 507(d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(k) of the title.* A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2]Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F - Licensing — Biological Products and Clinical Laboratories and******

Sec. 351(c) "Any officer, agent, or employee of the Department of Health & Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F — ******Control of Radiation.

Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests *(or testing programs)* required by section 358 (h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records *(including testing records)*, make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

******

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information.

FORM FDA 482 (5/85) PREVIOUS EDITION IS OBSOLETE

0029

NOTICE OF INSPECTION

SEP-05-1999 09:58 FDA/CDER/RPS 301 827 5562 P.20

Exhibit 4.

SEP-03-1999 09:58 FDA/CDER/RPS 301 827 5562 P.31

AKZO NOBEL

Diosynth Inc.
Tax I.D. No. 36-2821730

Tel. (773) 235-7500
Fax (773) 235-7504
(800) 621-1509

Invoice

DIOSYNTH

PLEASE REMIT TO:
DIOSYNTH, INC.
P.O. BOX 70372
CHICAGO, IL 60673-0372

Sold To:
NAPEAN ENTERPRISES
P.O. BOX 1530

BERTHOUD CO 80513
USA
ATTN: ACCOUNTS PAYABLE

Shipped To:
SAOH PHARMACEUTICALS
RECEIVING CENTER
5408 INTERSTATE AVE
SHREVEPORT LA 71109
USA
ATTN: RECEIVING CENTER

Invoice Number	Invoice Date	Customer P.O. Number	Delivery	Terms
14893	31-MAR-97	031497		NET 30 DAYS

Carrier	Customer Reference No.	Our Order No.
FEDERAL EXPRESS	58033	10781

Product	Batch Number	Quantity	Unit	Unit Price	Total
ESTERIFIED ESTROGENS TYPE CC	10176	2,848.000	GMA	$40.0000	$113,920.0

CONFIDENTIAL

SUBTOTAL $113,920.0
INVOICE TOTAL (US DOLLARS) $113,920.0

Attachment # 3
7/17/97
95-83-212
CDER

SEP-03-1999 09:58 FDA/CDER/RPS 301 827 5562 P.32

0031

FAA

Exhibit 5.

SEP-03-1999 09:59 FDA/CDER/RPS 301 827 5562 P.33

TO: JACK ANTIS, LYNN (PEGASUS LABS)

FROM: RAJ MATKARI

Attachment 5
page 1 of 4
8/12/97

RE: MENOGEN H.S. TABLETS – LOT. S7058
– SHIPMENT OF 15 ORDERS BY UPS
(A TOTAL OF 2,436 X100)
ON 7/11/97

– PLEASE SHIP THE FIFTEEN ORDERS FOR MENOGEN H.S. TABLETS, LOT. S7058 (BRECKENRIDGE LABEL) – A TOTAL OF 2,436 X100 USING THE FIFTEEN (15) PACKING SLIPS WHICH WE ARE FAXING WITH THIS MEMO.

7/11/97

– THE LOT NUMBER, QUANTITY AND THE SHIPPING ADDRESS IS TYPED ON EACH ONE OF THE PACKING SLIPS. STAMP THE DATE AT THE TOP OF THE PACKING SLIPS.

– ALL THE 15 SHIPMENTS SHOULD BE SHIPPED BY UPS TOMORROW (FRIDAY THE JULY 11TH)

– USE THE CARTONS (OF 24X100'S) OR THE MASTER SHIPPERS (6X24X100 OR 144X100) FOR SHIPPING THE ORDERS.

– USE PEGASUS' LABEL FOR THE SHIPPING ADDRESSES AND INCLUDE A COPY OF THE PACKING SLIP WITH EACH SHIPMENT.

0033

TO: JACK ANTI (PEGASUS LABS)

Attachment 5
page 2 of 4
8/12/97

7-14-97

FROM: RAJ MATKARI

RE: MENOGEN H.S. TABLETS, LOT. S705 8 (BRECKENRIDGE Label)

— SHIPMENT OF FIVE (5) ORDERS BY UPS ON 7/15

(A TOTAL OF 216 X 100)

— Please ship these five (5) orders for MENOGEN H.S. Tablets, LOT. S705 8 (A TOTAL OF 216 X 100) using the five packing slips which we are faxing with this memo.

— All the required information is on the packing slips except the date of shipping.

— Please ship by UPS tomorrow, if possible and use a copy of each packing slip with the shipment.

— Fax the copies of packing slips (with date of shipping) to our Colorado fax number.

0034

7/16/97

TO: JACK ANTIS (PEGASUS Labs)

FROM: RAJ MATKARI

Attachment 5
page 3 of 4
8/12/97 JSN

Re – MENOGEN H.S. Tablets, LOT. 57058
(Breckenridge Label)
— SHIPMENTS – A TOTAL OF 48 X 100
On Thursday (7-17)

Please ship the accompanying two orders for Menogen H.S. Tablets (Breckenridge Label) by UPS and include the dates on the packing slips.

Please fax the copies of packing slips to US in Colorado Friday morning.

Thanks – RM

0035

7-21-9

TO: JACK A[illegible]TIS (Pegasus Labs)

FROM: RAJ MATKARI

Attachment 5
page 4 of 4
8/12/97 JSN

RE: MENOGEN H.S. Tablets, LOT. 57059
(Breckenridge Label)

— SHIPMENTS ON Tuesday (7/22) by UPS.
(A TOTAL OF 372 X100)

Please ship the accompanying five (5) Orders for MENOGEN H.S. Tablets LOT. No. 57059 by UPS on Tuesday (7/22)

Please include the Date of Shipping on each one of the five Packing Slip and Fax back to me (to our Colorado Fax only) on Wednesday (7/23)

I would appreciate it if you can use the slightly damaged carton (24 X100) of Menogen H.S. Tablets since this is the end of

SEP-03-1999 10:02 FDA/CDER/RPS 301 827 5562 P.07

Exhibit 6.

SEP-03-1999 10:05 FDA/CDER/RPS 301 827 5562 P.08

Department of Health & Human Services Public Health Service

MEMORANDUM

Date: August 12, 1997

From: Joan S. Norton, CSO

Subject: Attempted Sample Collection of Menogen H.S.

To: Keith S. Ehrlich, SI

Firms: Pegasus Laboratories
8809 Ely Road
Pensacola, FL 32514
CFN: 1038896

Breckenridge, Inc.
1515 N. Federal Hwy.
Boca Raton, FL 33432

Napean, Inc. a.k.a.
Pharmaceutical Consultants
120 Bunyan Ave., Ste. D
Berthoud, CO 80513

In a 8/7/97 telecommunication, CO Jimmy Walthal, FLA-DO Compliance Branch, requested a visit to Pegasus Laboratories for the purpose of collecting physical samples of Menogen H.S. which is manufactured by Sage Pharmaceuticals, 5408 Interstate Ave., Shreveport, LA 71109. This drug was reportedly shipped in interstate commerce without an approved ANDA. Photocopies of labeling, package inserts, and shipping documents were provided via Facsimile.(Attachment 1).

To: J. Walthal, FLA-DO Compliance Branch

The above investigator's memo reports information obtained during a visit to Pegasus Laboratories. No samples were available for collection. Based on Attachment 5, which could be a hand written note by Mr. Raj Matkari of Napean, Inc., we believe that Matkari maybe in violation of his debarment.

Paul L. Figarole
Paul L. Figarole
Acting Supervisory Investigator

DIST: O: FLA-DO/CB w/att
cc: TLH-RP w/att
cc: BCR-RP

SEP-03-1999 10:03 FDA/CDER/RPS 301 827 5562 P.09

On 8/7/97, I visited the firm and met with Mr. Jack D. Antis, President and owner of Pegasus Laboratories. Credentials were shown to him. I explained the purpose of my visit was to collect samples of Menogen. Mr. Antis stated that Sage Pharmaceuticals (Sage) had drop shipped Menogen H.S. to Pegasus, but his firm had already shipped all the drugs to various outside businesses. He said that the drugs were received as finished product and Pegasus did not repack or relabel any of the product. Since no product and/or labeling was available for sampling, this investigation focused on obtaining distribution records and individual responsibility.

Mr. Antis provided photocopies of the following records to document the receipt of Menogen from Sage (Attachment 2):

Sage packing slip dated 7/3/97, with a handwritten notation showing the drugs were received on 7/8/97.

Overnite Transportation Company freight bill number 704 891 036 dated 7/8/97.

A review of the packing slip and freight bill found the records to be the same as that provided with this assignment. Mr. Antis provided a copy of a computer generated inventory/distribution record which shows the date and quantity of units (100 tablet bottles) his firm shipped to outside business, along with the name of the company, city and state (Attachment 3). A review of the computer inventory record found that Pegasus had shipped Menogen H.S. to thirty three (33) companies. Mr. Antis stated that all drugs were shipped via United Parcel Service between 7/10/97 and 7/22/95. Upon request, he provided UPS Shipping Records covering the shipment of drugs to the 33 business (Attachment 4).

I asked to review invoices covering the purchase of the drugs. Mr. Antis stated that he did not purchase the drugs from Sage. He said the drugs were drop shipped to Pegasus upon an oral agreement with the owners of Breckenridge, Inc. and Pharmaceuticals Consultants (a.k.a. Napean, Inc). He reported that Pegasus only drop shipped the drugs to various other firms. Mr. Antis claimed no knowledge as to why Breckenridge and Pharmaceuticals Consultants did not handle the distribution themselves; however, he reported that he has had previous dealings with the owners of both firms. He provided the following information on these two firms:

Mr. Larry Runsdorf is the owner of Breckenridge, Inc. The firm operates as a distributor of drug products. Mr. Runsdorf also acts as a sales representative for Pharmaceuticals Consultants.

Pharmaceutical Consultants is owned by Mr. Raj Matkari, who also does business as Napean Inc. Mr. Antis thought that the firms owned by Mr. Matkari operate as a drug broker and/or distributor. He personally knows Mr. Matkari for they both worked for the same drug manufacturer in Detroit, MI.

According to Mr. Antis, he first received a telephone call from Mr. Runsdorf

informing him that Sage was drop shipping Menogen H.S. to Pegasus. This initial telephone conversation was later followed by a telephone call from Mr. Matkari requesting that Pegasus fill Menogen H.S. orders for him. The job would only involve addressing the cartons and drop shipping product. According to Mr. Antis, the finished drugs were received from Sage bearing two different labels, but all were Menogen H.S. The shipment consisted of 3,072/100 tablet bottles of the drug labeled as being distributed by Breckenridge, and 384 bottles labeled as being distributed by Sage (see Attachment 2).

Mr. Antis stated that he would receive written orders to ship product from Mr. Matkari via FAX (Attachment 5). Mr. Matkari would then FAX copies of pre-printed Packing Slips which identified the business and mailing address. The packing slips were then photocopied by Pegasus and inserted into the shipping boxes. Mr. Antis provided photocopies of the packing slips that he identified as being supplied by Mr. Matkari (Attachment 6). He said that he did not know why these records are identified as Sage "Packing Slips", but lists Napean as issuing the invoices.

An affidavit was prepared attesting to the documents collected during this investigation and information supplied by the owner of Pegasus. Mr. Antis read the affidavit, agreed with the statements and signed this document. No further follow-up at the firm is planned at this time.

Joan S. Norton

Joan S. Norton, CSO
Tampa-RP

Attached: Form FDA 463a

Attachments

1. Background Information
2. Packing Slip & B/L
3. Inventory/Distribution Print-out
4. UPS Shipping Records
5. Photocopies of FAX Communications
6. 33 Sage Packing Slips

AFFIDAVIT

SAMPLE NO.

STATE OF: Florida

COUNTY OF: Escambia

Before me, Joan S. Norton, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Jack B. Antis in the county and State aforesaid, who, being duly sworn, deposes and says:

I am Jack B. Antis, President and owner of Pegasus Laboratories, Inc., 8809 Ely Rd. Pensacola, FL 32514; as such, I am responsible for all operations of my firm. I have direct knowledge of the receipt of drugs into my firm and subsequent shipping of the drugs to outside firms.

On 8/7/97, the above named FDA Investigator visited with me at my firm. She requested information and records on the receipt of Menogen HS tablets into my firm and subsequent distribution. I provided her with the following account:

In June 1997, I was contacted by Mr. Larry Runsdorf, owner of Breckenridge, Inc., 1515 N. Federal Hwy. Ste 300, Boca Raton, FL 33432 via telephone. He asked if I would drop ship Menogen HS Tablets for his firm. I was later contacted by Mr. Raj Matkari by telephone asking if I would also drop ship Menogen Tablets. Mr. Raj Matkari is the owner of Napean Enterprises, which also does business as Pharmaceutical Consultants. These firms are located at 120 Bunyan Ave, Ste D., Berthoud CO. 80513. To the best of my knowledge Mr. Larry Runsdorf is

AFFIANT'S SIGNATURE AND TITLE: Jack B. Antis, President.

FIRM'S NAME AND ADDRESS (Include ZIP Code): PEGASUS LABORATORIES, INC 8809 ELY RD PENSACOLA, FL 32514

Subscribed and sworn to before me at Pensacola, Florida (City and State)

this 7th day of August, 19 97.

0041

Joan S. Norton (Employee's Signature)

Employee of the Department of Health and Human services designated under Act of January 31, 1925. Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

FORM FDA 463a (4/80) PREVIOUS EDITIONS ARE OBSOLETE PAGE 1 OF 4 PAGES

U.S. GPO: 1988-0-201-859/75073

AFFIDAVIT

SAMPLE NO.

STATE OF Florida | COUNTY OF Escambia

Before me, Joan L. Norton, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Jack H. Curtis in the county and State aforesaid, who, being duly sworn, deposes and says:

a sales representative for Napean Enterprises. My firm was only asked to drop ship the drugs. Pegasus Labs did not repack or relabel any of the Menogen HS tablets.

On 7/8/97, my firm received 3,072/100 tab bottles of Menogen HS tablets labeled with Breckenridge labels and 384/100 tab bottles with Sage Pharmaceutical labeling as shown by Sage Pharmaceutical Packing Slip dated 7/3/97. We received the product via Overnite transportation Company as shown by freight bill 704 891036 dated 7/8/97. This bill of lading shows that Sage Pharmaceuticals, 5408 Interstate Ave., Shreveport, LA 71109 was the shipper of the Menogen HS tablets.

Over the course of the next few days, my firm received product shipping orders from Mr Raj Mattani. It was the usual practice to hand write orders which were FAX'ed to my firm. I provided examples of the FAX instructions dated 7/10, 14, 16 & 21/97. The handwritten orders where then followed up by a Packing Slip that

AFFIANT'S SIGNATURE AND TITLE: Jack H. Curtis President.

FIRM'S NAME AND ADDRESS (Include ZIP Code)

Subscribed and sworn to before me at Pensacola, Florida (City and State)

this 7th day of August, 1997.

0042

Joan L. Norton (Employee's Signature)

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

FORM FDA 483a (4/83) PREVIOUS EDITIONS ARE OBSOLETE PAGE 2 OF 4 PAGE

AFFIDAVIT

SAMPLE NO.

STATE OF: Florida

COUNTY OF: Escambia

Before me, Joan S. Norton, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Jack H. Ortis in the county and State aforesaid, who, being duly sworn, deposes and says:

was FAX'ed from Napran, Inc. My firm included a copy the FAX packing slip with each shipment to out side firms. I do not know why the packing slip is identified as a Sage Pharmaceuticals record. I provide photocopies of the following Sage Pharmaceuticals packing slips to the Investigator:

PSBL0002 dated 7/10/97
PSCOC001/2 dated 7/10/97
PSMA2/1 dated 7/10/97
PSALD002 dated 7/11/97
PSDRL002 dated 7/11/97
PSJEL001/2 dated 7/11/97
PSMO8001 dated 7/11/97
PSMOR001 dated 7/11/97
PSGDS002 dated 7/11/97
PSRAL002 dated 7/11/97
PSGEN001/2 dated 7/11/97
PSRA3003 dated 7/15/97
PSAWD001 dated 7/15/97
PSPEW001 dated 7/17/97
PSRA1002 dated 7/22/97
PSKER002 dated 7/22/97
PSWEP002 dated 7/10/97
PSSAJ001 dated 7/10/97
PSTOP002 dated 7/10/97
PSPAR002 dated 7/11/97
PSA20001 dated 7/11/97
PSBIH003 dated 7/11/97
PSRA3002 dated 7/11/97
PSCOC002 dated 7/11/97
PSDKK001 dated 7/11/97
PSCDS001/2 dated 7/11/97
PSTOP003 dated 7/15/97
PSMO9001 dated 7/15/97
PSMA23 dated 7/15/97
PSBIH003 dated 7/17/97
PSRA5002 dated 7/22/97
PSBRL001 dated 7/22/97

AFFIANT'S SIGNATURE AND TITLE: Jack H. Ortis, President.

FIRM'S NAME AND ADDRESS (Include ZIP Code):

Subscribed and sworn to before me at Pensacola, Florida (City and State)

this 7th day of August, 19 97.

0043

Joan S. Norton (Employee's Signature)

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

SEP-03-1999 10:04 FDA/CDER/RPS 301 827 5562 P.14

AFFIDAVIT

SAMPLE NO.

STATE OF Florida | COUNTY OF Escambia

Before me, Joan L. Norton, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Jack H. Oates in the county and State aforesaid, who, being duly sworn, deposes and says:

PO M01002 dated 7/22/97. All Menogen HS tablets bearing Sage and Breckenridge labeling were shipped by my firm via United Parcel Services (UPS) between 7/10/97 and 7/22/97. I provided photopies of UPS Shipping Records that correspond to the packing slips; both of which names the firms to which the drugs were shipped along with their addresses.

I also provided the Investigator with a Pegasus computer print out showing the amount and date on which Menogen HS tablets were shipped to 33 outside firms. To the best of my knowledge, Menogen bearing Sage labeling were shipped to the following firms:

Blossworth, Tifton GA — Wepfer, Memphis TN
Cochran, Monroe GA — SAS, Pine Bluff, AZ
Major, Indianapolis IN — Top, Bartlett TN

The other shipments were Breckenridge labeled Menogen HS. Tablets.

AFFIANT'S SIGNATURE AND TITLE: Jack H. Oates, President

FIRM'S NAME AND ADDRESS (Include ZIP Code)

Subscribed and sworn to before me at Pensacola Florida (City and State)

this 7th day of August, 19 97.

0044

Joan L. Norton (Employee's Signature)

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

PREVIOUS EDITIONS ARE OBSOLETE

SEP-03-1999 10:05 FDA/CDER/RPS 301 827 5562 p.15

Exhibit 7.

SEP-03-1999 10:05 FDA/CDER/RPS 301 827 5562 P.16

SAGE
PHARMACEUTICALS

[redacted] FILE

2/21/97 XC: 2/14 NAT LETTER only: SHU-RP

February 14, 1997

Mr. James E. Gamet, District Director
U.S. Food and Drug Administration
New Orleans Distriot Office
4298 Elysian Fields Avenue
New Orleans, LA 70122

Dear Mr. Gamet:

Per 21CFR §314.94 please find enclosed the field copy of the Abbreviated New Drug Application (ANDA) for [redacted] Enclosed also are a copy of the application [redacted] and a certification by Sage Pharmaceuticals, Inc. that this is a true copy of a portion of the full submission.

Please call me at (318) 635-4000 if I can provide further information or clarify any part of the submission.

Sincerely,

William J. Roche
General Manager

cc: J. R. Chen
CDER-OGD

RECEIVED IN NOL-DO
DD'S OFFICE ON
2/20/97

0046

5408 Interstate Drive • Shreveport, LA 71109 • Tel: 318-635-1594 FAX: 318-635-1595

SAGE
PHARMACEUTICALS

5/7/97 / CHG
DES / JFC / BI
5/12 File

XC: SHN-RP
Sent 5/12/97 SHN

May 2, 1997

Mr. James E. Gamet
District Director
Department of Health and Human Services
Food and Drug Administration
4298 Elysian Fields Avenue
New Orleans, LA 70122

re: Field copy
ANDA [redacted] Amendment #1

Dear Mr. Gamet:

Per 21 CFR §314.94 please find enclosed the field copy of the above noted amendment to ANDA [redacted]

Note that I am certifying by my signature below that this is a true copy of the entire amendment sent this date to CDER-OGD in Rockville, MD under separate cover.

Please call me at (318) 635-4000 if I can provide further information or clarify any part of the submission.

Sincerely,

William J. Roche
General Manager

WJR/mck

cc: J. R. Chen
J. R. McClellan

RECEIVED
MAY 8 1997
NOL - DO IB

RECEIVED IN NOL-DO
DD'S OFFICE ON
5/7/97

0047

5408 Interstate Drive • Shreveport, LA 71109 • Tel: 318-635-1394 FAX: 318-635-1595

Exhibit 8.

7/29/97 CEB

Packing Slip

DATE	INVOICE NO.
7/3/97	NE136

BILL TO
Napean Enterprises PO Box 1530 Berthoud, CO 80513

SHIP TO
Pegasus Laboratories, Inc 8809 Ely Road Pensacola, Florida 32514

P.O. NO.	TERMS	DUE DATE	SHIP DATE	SHIP VIA	FOB	PROJECT
		7/3/97	7/3/97	OVRNT	Shreveport	

ITEM	DESCRIPTION	QTY	UNITS	RATE	AMOUNT
CS-121-HS	MENOGEN HS - Breckenridge Lot #S7059 Exp: 5/99	3,072	Bottles	0.00	0.00
CS-121-HS	MENOGEN HS - Sage Lot #S7058 Exp: 4/99	384	Bottles	0.00	0.00
	(Total Bottles = 3,456)				
	Done By: DC Checked By: JJJ				
	(1 Skid STC 26 Cartons: 23 Cartons of S7059 3 Cartons of S7058)				

"PACKING SLIP"
THANK YOU FOR YOUR BUSINESS!

Total $0.00

0049

5408 Interstate Drive • Shreveport, LA 71109 • Tel.: 318-635-1594 FAX: 318-635-1595

PLEASE PRINT OR TYPE

STRAIGHT BILL OF LADING-ORIGINAL-NOT NEGOTIABLE-DOMESTIC

OVERNITE TRANSPORTATION COMPANY

CONSIGNEE: PEGASUS LABORATORIES
STREET ADDRESS: 8809 ELY ROAD
STREET ADDRESS:
CITY/STATE: PENSACOLA, FL

SHIPPER: SAGE PHARMACEUTICALS
STREET ADDRESS: 5408 INTERSTATE DR
STREET ADDRESS:
CITY/STATE: SHREVEPORT, LA

DATE: 7/3/97

LINEAL FEET OCCUPIED BY CARGO: 3 2 5 1 4
DATE OF SHIPMENT: 7 1 1 0 9

SHIPPER'S NO.: ~~[illegible]~~ NE136
BILL OF LADING NO.:
P.O. NO.:

No. Packages	Type	Kind of Package, Description of Articles, Special Marks, and Exceptions	Weight (Subject to Correction)	Class or Rate	Value
1		SKID STC 26 CARTONS OF	900	85	
		MENOGEN HS			
		LOT # S7059 (EXP: 5/99) - 23 CARTONS			
		LOT # S7058 (EXP: 5/99) - 3 CARTONS			

Driver assisted in loading? ☐ YES ☐ NO

Linear Feet of Trailer:

Freight charges are to be paid by:
☒ SHIPPER (PREPAID)
☐ CONSIGNEE (COLLECT)

On collect on delivery shipments the letters "COD" must appear before consignee's name or as otherwise provided in Item 430, Sec. 1 of NMFC.

Collect on Delivery

$

C.O.D. Amount
☐ Cash or Certified Check
☐ Consignee Check Acceptable

C.O.D. fee to be paid by: Shipper ☐ Consignee ☐

CARRIER LIABILITY: Carrier liability for loss or damage will be the lesser of (1) the actual invoice value of the article(s) lost, damaged or destroyed; or **(2) the amount determined from applicable limited liability provisions of the NMFC; or (3) fifty dollars ($50.00) per pound, per article, unless a higher value is declared in writing in the "Value" column on the bill of lading at the time of shipment and applicable charges are paid.

**Where a "rate" is dependent on value, the agreed or declared value of the property is hereby specifically stated by the shipper to be not exceeding _____ per _____

Prepaid $ _____ to apply in prepayment of the charges on the property described hereon.

(Agent or Cashier)

CHARGES ADVANCED $

Subject to Section 7 of Conditions, if this shipment is to be delivered to the consignee without recourse on the consignor, the consignor shall sign the following statement.
The carrier shall not make delivery of this shipment without payment of freight and all other lawful charges.

(Signature of Consignor)

REMIT C.O.D. CHECK/CASH TO:

RECEIVED, Subject to the classifications and transportation service contracts and/or tariffs in effect on the date of the issue of this Bill of Lading, the property described above, in apparent good order, except as noted (contents and condition of contents of packages unknown), marked, consigned, and destined as shown above which said company (the word company being understood throughout this contract as meaning any person or corporation in possession of the property under the contract) agrees to carry to its usual place of delivery at said destination. If on its own railroad, water line, highway route or routes, or within the territory of its highway operations, otherwise to deliver to another carrier on the route to said destination. It is mutually agreed, as to each carrier of all or any of said property over all or any portion of said route to destination, and as to each party at any time interested in all or any of said property, that every service to be performed hereunder shall be subject to all the conditions not prohibited by law, whether printed or written, herein contained, including the conditions on back hereof, which are hereby agreed to by the shipper and accepted for himself and his assigns.

*Mark with an "X" to designate hazardous materials as defined in title 49 of the Code of Federal Regulations.

It is to certify that the above named materials are properly classified, described, packaged, marked, and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation.

SHIPPER: SAGE PHARMACEUTICALS, INC
PER: Jackie Cooper

CARRIER: Overnite
PER: Bridwell

TOTAL NO. OF PIECES:
DATE RECEIVED: 7-9-97

OVERNITE TRANSPORTATION CO.
SHR 704 891 036

TC-109 (REV. 2/93)
PRINTED IN U.S.A.

SHIPPER COPY

Attachment #16
DOC 97-653-214
7/29/97 CEB

Att[illegible]ent
pa[illegible] of 7
8/[illegible]97

Packing Slip

SAGE PHARMACEUTICALS

DATE	INVOICE NO.
7/3/97	NE136

BILL TO

Nagram Enterprises
PO Box 1530
Redmond, CO 80513

SHIP TO

Pegasus Laboratories, Inc
8809 Ely Road
Pensacola, Florida 32514

P.O. NO.	TERMS	DUE DATE	SHIP DATE	SHIP VIA	FOB	PROJECT
		7/3/97	7/3/97	OVRNT	Shreveport	

ITEM	DESCRIPTION	QTY	UNITS	RATE	AMOUNT
CS-121-HS	MENOGEN HS - Breckenridge Lot #S7059 Exp: 5/99	3,072	Bottles	0.00	0.00
CS-121-HS	MENOGEN HS - Sage Lot #S7058 Exp: 4/99	384	Bottles	0.00	0.00
	(Total Bottles = 3,456)	3456			
	Rec'd 7/8/97				
	Breckenridge				
	Shipped STC 26 Cartons (23 Cartons of S7059 3 Cartons of S7058)				
	PACKING SLIP THANK YOU FOR YOUR BUSINESS!			Total	$0.00

Attachment 2
page 2 of 2
8/12/97

704 091 036

CUSTOMER COPY (BLUE)

CONSIGNEE
PERSEUS LABORATORIES
8809 FLY RD
ISLAND GLA FL 32514-7013
01042171 (904)478-2770

INBOUND TRAILER
287441 OVNT

FREIGHT BILL NUMBER
704 091 036

CITY RTE/BYD SCAC: 26
DEST: MDL
ORIG: SHR

SHIPPER
SADE PHARMACEUTICALS
5409 INTERSTATE AVE
SHREVEPORT LA 71109
07414820 (318)635-1594

ADV CAR
BL# TE 136
AD OV BD

POI NONE

OVERNITE PHONE NUMBER (800)933-7400

PICK UP DATE 07/07/97

COLLECT THIS AMOUNT
$.00
$.00

704 091 036

OVERNITE TRANSPORTATION COMPANY

# PCS	HM	PT	DESCRIPTION OF ARTICLES AND SPECIAL MARKINGS	WEIGHT (LBS)	NMFC	RATE	CHARGES
			1 HANDLING UNIT(S)				
--		CR	HENOGEN HS	900	000999-00		
			1 PIECES STORED FOR				
			OT				

TTL PCS

TTL WT ▶ 900

ODOM | ARRIVE | DEPART

TOTAL CHARGES PPD

PRINT NAME

FIRM

SIGNATURE

DATE 7/8/97

DRIVER NAME

PIECES DLVRD

WRAP INTACT? ☐ YES ☐ NO

RECEIVED THE ABOVE PROPERTY IN GOOD CONDITION EXCEPT AS NOTED
RECORD EXCEPTIONS & DESCRIPTIONS OF GOODS IN BODY OF FORM ABOVE

Exhibit 9.

AKZO NOBEL

Diosynth Inc.
Tax I.D. No. 36-2821750

Tel. (773) 235-7500
Fax (773) 235-7506
(800) 621-1509

Invoice

DIOSYNTH

PLEASE REMIT TO:
DIOSYNTH, INC.
P.O. BOX 70372
CHICAGO, IL 60673-0372

Sold To
NAPEAN ENTERPRISES
P.O. BOX 1530

BERTHOUD CO 80513
USA
ATTN: ACCOUNTS PAYABLE

Shipped To
SAGE PHARMACEUTICALS
RECEIVING CENTER
5408 INTERSTATE AVE
SHREVEPORT LA 71109
USA
ATTN: RECEIVING CENTER

Invoice Number	Invoice Date	Customer P.O. Number	Delivery	Terms
14893	31-MAR-97	031497		NET 30 DAYS

Carrier	Customer Reference No.	Our Order No.
FEDERAL EXPRESS	58033	10781

Product	Batch Number	Quantity	Unit	Unit Price	Total
ESTERIFIED ESTROGENS TYPE CC	10176	2,848.000	GMA	$40.0000	$113,920.00

SUBTOTAL $113,920.00
INVOICE TOTAL (US DOLLARS) $113,920.00

CONFIDENTIAL

Attachment #3
97-653-212
7/17/97
CDER

SEP-07-1999 08:57 FDA/CDER/RPS 301 827 5562 P.08

0054

FDA
7179

2745 NORTH ELSTON AVENUE
CHICAGO, IL 60647-2020
==========
U.S.A.

CONFIDENTIAL

AKZO NOBEL

PACKINGLIST

Invoice nr.	051191	Invoice date	24-03-97

Packing number	Packing specification length cm	width cm	height cm	volume dm³	Gross weight kg	Nett weight kg	Product
1- 10	59,0	59,0	61,0	2123,4	250,000	80,000	ESTERIFIED ESTROGENS USP (12861-0217)-0
			TOTAL	2123,4	250,000	80,000	

THE PRODUCTS ARE PACKED IN 10 CARTON(S)

SAGE PHARMACEUTICALS, RECEIVING CENTER

5408 INTERSTATE AVENUE

SHREVEPORT, LA 71109 - U.S.A.

P.O.NO. 031497 'KEEP IN DRY-ICE

5958/1-10 'VIA CHICAGO'

WEIGHT DRY-ICE: APPROX. 90 KG

D I O S Y N T H B V ~~S.E.G.O.~~

Attachment #4
97-653-212
7/17/97
CB CES

DIOSYNTH BV · P O BOX 20 5340 BH OSS THE NETHERLANDS TELEPHONE 0412 661333 CABLES DIOSYNTH OSS TELEX 57650 TELEFAX 0412 662521
BANKERS ABN AMRO NIJMEGEN NO 45 50 57 496 C REG S HERTOGENBOSCH NO 16050222 VAT NO NL003[illegible]

0055

Exhibit 12.

PACKING SLIP

SAGE PHARMACEUTICALS
[illegible] INTERSTATE AVE, SHREVEPORT, LA 71108
PH. (318) 636 1884 FA. (318) [illegible]

PACKING SLIP NO. PSWEP002

DATE 07/10/97

PURCHASE ORDER NO. 4997 & 70897

SHIP VIA UPS

SHIP TO
WEPFER GODWIN, INC.
4935 OUTLAND CENTER DRIVE
SUITE 110
MEMPHIS, TN 38118

BILL TO

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	72	SAGE	S 7059

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSWEP

Attachment 6
page 1 of 33
8/12/97 JEN

3 cases 24/pack (72)

1 @ 19 UPS 7-10-97

1Z 373 677 03 1000 850 2

PACKING SLIP

SAGE PHARMACEUTICALS
5400 INTERSTATE AVE. SHREVEPORT, LA 71109
PH. (318) 635 1884 FAX. (318) 635 1886

PACKING SLIP NO. PSBLO002

DATE 07/10/97

PURCHASE ORDER NO. 060997

SHIP VIA UPS

SHIP TO
BLOODWORTH WHOLESALE
123 LOVE AVENUE
TIFTON, GA 31794

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	72	SAGE	S 7059

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BEARTHOUD, CO 80513

PSBLO

3 cases 24 pack (72)

1 @ 19 UPS 7-10-97

12 373 677 03 1000 851 1

Attachment 6
page 2 of 33
8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
[illegible] INTERSTATE AVE, SHREVEPORT, LA 71108
PH. (318) [illegible] FA. (318) [illegible]

PACKING SLIP NO. PSCOC001/2

DATE 07/10/97

PURCHASE ORDER NO. 041897

SHIP VIA UPS

SHIP TO
COCHRAN WHOLESALE
1304 S. BROAD ST.
MONROE, GA 30655

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	48	SAGE	S7059

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSCOC

2 cases 24/pack (48)

1@13 UPS 7-10-97

12 373 677 03 1000 852 0

Attachment 6
page 3 of 33
8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
5406 INTERSTATE AVE. SHREVEPORT, LA 71106
PH. (318) 636 1894 FA. (318) 636 1896.

PACKING SLIP NO. PSSAJ001

DATE 07/10/97

PURCHASE ORDER NO. 3112

SHIP VIA UPS

SHIP TO
S A J DISTRIBUTORS
3022 NORTH MIDLAND DRIVE
PINE BLUFF, AR 71603

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	24	SAGE	S 7059

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSSAJ

1 case 24 pack (24)

1 @ 6 ups 7-10-97

12 373 677 03 1000 849 5

Attachment 6
page 4 of 33
8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
[illegible] INTERSTATE AVE, SHREVEPORT, LA 71109
PH. (318) 635 1884 FA. (318) 636 1886.

PACKING SLIP NO._____ PSMA2/1

DATE 07/10/97

PURCHASE ORDER NO.___ 0607BRIAN
M202673 & M202730

SHIP VIA__ UPS

SHIP TO___
MAJOR PHARMACEUTICAL
5110 W 74TH STREET
INDIANAPOLIS, IN 46258

BILL TO___ IF OTHER THAN SHIP TO

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	96	SAGE	S 7059

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSMA2

4 cases 24 pack (96)

1 @ 25 ups 7-10-97

1Z 373 677 03 1000 848 6

Attachment 6
page 5 of 33
8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
[illegible] INTERSTATE AVE, SHREVEPORT, LA 71106
PH. (318) 636 1894 FA. (318) 636 1896.

PACKING SLIP NO. PSTOP002

DATE 07/10/97

PURCHASE ORDER NO. 042887A & 8439

SHIP VIA UPS

SHIP TO
TOP Rx
3141 STAGE POST DRIVE
BARTLETT, TN 38133

BILL TO (if other than ship to)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	72	SAGE	S 7058

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSTOP

3 cases 24/pack (72)

1 (2) 19 lbs

1Z 373 677 03 1000 847 7

UPS 7-10-97

Attachment 6
page 6 of 33
8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
6409 INTERSTATE AVE. SHREVEPORT, LA 71106
PH. (318) 635 1684 FA. (318) 635 1686

PACKING SLIP NO. PSAND002 DATE 07/11/97

PURCHASE ORDER NO. 42387DM & 114752 SHIP VIA UPS

SHIP TO
A N D A GENERICS
4811 S W 47TH AVE, BLDG 1101
FT. LAUDERDALE, FL 33314

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H,S, TABLETS 100'S	1176	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSAND

49 cs-24 PK, 1176

Zone 4

Hundred WT.

8@ 34 Total of 278 LBS

1@ 6

Attachment 6
page 7 of 33
8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
3408 INTERSTATE AVE, SHREVEPORT, LA 71109
PH. (318) 636 1884 FA. (318) 636 1886.

PACKING SLIP NO. PSPAR002

DATE 07/11/97

PURCHASE ORDER NO. 24269

SHIP VIA UPS

SHIP TO
PARMED PHARM.
4220 HYDE PARK BLVD.
NIAGARA FALLS, NY 14305

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	144	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSPAR

6 cs x 24PK 144

1 cs @ 34 LBS 7-11-97

1Z 379 677 03 1000 864 6

Attachment 6
page 8 of 33
8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
[illegible] INTERSTATE AVE. SHREVEPORT, LA 71109
PH. (318) 636 1994 FAX. (318) 636 1998

PACKING SLIP NO. PSORG002

DATE 07/11/97

PURCHASE ORDER NO. 261299

SHIP VIA UPS

SHIP TO
DRUG GUILD DIST. INC.
350 MEADOWLAND PKWY.
SECAUCUS, NJ 07096-1527

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	24	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSORG

1 ca X 24 PK (24)
1 @ 6 LBS 7-11-97

1Z 373 677 03 1000 865 5

Attachment 6
page 9 of 33
8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
[illegible] INTERSTATE AVE. SHREVEPORT, LA 71109
PH. (318) [illegible] FAX (318) [illegible]

PACKING SLIP NO. PSA20001

DATE 07/11/97

PURCHASE ORDER NO. 763132

SHIP VIA UPS

SHIP TO
AMERISOURCE
3910 SEAPORT BLVD.
WEST SACREMENTO, CA 95691

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	24	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
BRECKENRIDGE INC. BOCA RATON, FL 33429

PSA20

1 cs x 24 PK 24

1@ 6 7-11-97

1Z 373 677 03 1000 866 4

Attachment 6
page/Item 3
8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
5406 INTERSTATE AVE. SHREVEPORT, LA 71106
PH. (318) 636 1884 FA. (318) 636 1886.

PACKING SLIP NO. PSJEG001/2

DATE 07/11/97

PURCHASE ORDER NO. 14905

SHIP VIA UPS

SHIP TO
JE GOOLD & CO.
RIVERSIDE INDUST. PKWY
PORTLAND, ME 04104

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	24	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
BRECKENRIDGE INC. BOCA RATON, FL 33429

PSJEG

1 cs x 24 P - 24

1 @ 6 LBs 7-11-97

1Z 373 677 03 1000 867 3

Attachment 6
page 11 of 33
8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
5405 INTERSTATE AVE. SHREVEPORT, LA 71109
PH. (318) 635 1994 FAX (318) 635 1995.

PACKING SLIP NO. PSBIH003

DATE 07/11/97

PURCHASE ORDER NO. 58612-GD

SHIP VIA UPS

SHIP TO
BINDLEY WESTERN DRUG
642 COVINA BLVD
SAN DIMAS, CA 91773

BILL TO (if other than ship to)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	24	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
BRECKENRIDGE INC. BOCA RATON, FL 33429

PSBIH

1 CA X 24.PK 24

1 CA @ 6 7-11-97

17 373 677 03 1000 868 2

Attachment 6
page 12 of 33
8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
5406 INTERSTATE AVE. SHREVEPORT, LA 71109
PH. (318) 636 1664 FA. (318) 636 1664

PACKING SLIP NO. PSMO8001

DATE 07/11/97

PURCHASE ORDER NO. 182127025

SHIP VIA UPS

SHIP TO
MCKESSON DRUG CO.
3775 SEAPORT BLVD
W SACREMENTO, CA 95691

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	24	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
BRECKENRIDGE INC. BOCA RATON, FL 33429

PSMO8

1 Ca X 24 PK 24

1@ 6 LBS 7-11-97

1Z 373 677 03 1000 869 1

Attachment 6
page 13 of 33
8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
[illegible] INTERSTATE AVE. SHREVEPORT, LA 71108
PH. (318) [illegible] FA. (318) [illegible]

PACKING SLIP NO. PSRA3002

DATE 07/11/97

PURCHASE ORDER NO. 1558331

SHIP VIA UPS

SHIP TO
RITE AID CORP.
NEW YORK DISTRIB. CTR.
5865 SUCCESS DRIVE
ROME, NY 13440

BILL TO (if other than ship to)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	24	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
BRECKENRIDGE INC. BOCA RATON, FL 33429

PSRA3

1 cs x 24 PK 24

1 @ 6 7-11-97

1Z 373 677 03 1000 870 8

Attachment 6
page 11 of 33
8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
[illegible] INTERSTATE AVE. SHREVEPORT, LA 71109
PH. (318) 636 1894 FA. (318) 636 1586

PACKING SLIP NO. PSMOR001

DATE 07/11/97

PURCHASE ORDER NO. 34987X410

SHIP VIA UPS

SHIP TO
MORRIS & DICKSON CO.
DOCK 410, 410 KAY LANE
SHREVEPORT, LA 71115

BILL TO: (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	24	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
BRECKENRIDGE INC. BOCA RATON, FL 33429

PSMOR

1 Ca X 24 PK 24

1 @ 6 7-11-97

1Z 373 677 03 1000 871 7

Attachment 6
page 15 of 33
8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
6406 INTERSTATE AVE. SHREVEPORT, LA 71106
PH. (318) 636 1884 FA. (318) 636 1886

PACKING SLIP NO. PSCOC002

DATE 07/11/97

PURCHASE ORDER NO. 061797

SHIP VIA UPS

SHIP TO
COCHRAN WHOLESALE
1304 S. BROAD ST.
MONROE, GA 30655

BILL TO (if other than ship to)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	36	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSCOC

1-24 PK X 1-12 PK (36)

1 @ 9 LBs 7-11-97

1Z 373 677 03 1000 872 6

Attachment 6
page 16 of 33
8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
8408 INTERSTATE AVE. SHREVEPORT, LA 71109
PH. (318) 635 1884 FA. (318) 636 1886.

PACKING SLIP NO. PSGDS002

DATE 07/11/97

PURCHASE ORDER NO. 070997EC09

SHIP VIA UPS

SHIP TO
GENERIC DISTRIBUTORS
1611 OLIVE ST.
MONROE, LA 71201

BILL TO (if other than ship to)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	72	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSGDS

3 cs X 24PK (72)
1 cs @ 17 7-11-97

1Z 373 677 03 1000 873 5

Attachment 6
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PACKING SLIP

SAGE PHARMACEUTICALS
5408 INTERSTATE AVE, SHREVEPORT, LA 71109
PH. (318) 635 1884 FA. (318) 635 1886.

PACKING SLIP NO. PSDKK001 DATE 07/11/97

PURCHASE ORDER NO. 241137 SHIP VIA UPS

SHIP TO
D & K WHOLESALE LEX
516 WEST 4TH STREET
LEXINGTON, KY 40508

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	72	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
BRECKENRIDGE INC. BOCA RATON, FL 33428

PSDKK

3 ca X 24 PK 72
1 @ 17 7-11-97

1Z 373 677 03 1000 874 4

Attachment 6
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8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
8406 INTERSTATE AVE, SHREVEPORT, LA 71108
PH. (318) 635 1884 FAX (318) 635 1886

PACKING SLIP NO. PSRA4002

DATE 07/11/97

PURCHASE ORDER NO. 1558705

SHIP VIA UPS

SHIP TO
RITE AID CORP.
WEST VIRGINIA DC
ROCK BRANCH INDUSTR
POCA, WV 25159

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	288	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
BRECKENRIDGE INC. BOCA RATON, FL 33429

PSRA4

12 CaX 24 PK (288)

2 @ 34 7-11-97

1Z 373 677 03 1000 875 3

1Z 373 677 03 1000 876 2

Attachment 6
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8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
5406 INTERSTATE AVE. SHREVEPORT, LA 71106
PH. (318) 636 1894 FA. (318) 636 1896.

PACKING SLIP NO. PSCDS001/2

DATE 07/11/97

PURCHASE ORDER NO. 182120

SHIP VIA UPS

SHIP TO
C D SMITH DRUG CO
3907 SOUTH 48 TERR
ST.JOSEPH, MO 64502

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	120	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
BRECKENRIDGE INC. BOCA RATON, FL 33428

PSCDS

5ea X 24 PK (120)
1 @ 28 7-11-97

1Z 373 677 03 1000 877 1

Attachment 6
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PACKING SLIP

SAGE PHARMACEUTICALS
8406 INTERSTATE AVE. SHREVEPORT, LA 71108
PH. (318) 635 1894 FA. (318) 635 1895.

PACKING SLIP NO. PSGEN001/2

DATE 07/11/97

PURCHASE ORDER NO. 0116324

SHIP VIA UPS

SHIP TO
GENETCO, INC.
711 UNION PARKWAY
RONKONKOMA, NY 11779

BILL TO (if other than ship to)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	360	BRECKENRIDGE	S7058

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSGEN

15 X 24 PK

360

1 @ 17
2 @ 34

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1Z 373 677 03 1000 878 0
1Z 373 677 03 1000 879 9
1Z 373 677 03 1000 880 6

PACKING SLIP

SAGE PHARMACEUTICALS
5404 INTERSTATE AVE. SHREVEPORT, LA 71106
PH. (318) 636 1894 FAX (318) 636 1896

PACKING SLIP NO. PSTOP003

DATE 07/15/97

PURCHASE ORDER NO. 071497

SHIP VIA UPS

SHIP TO
TOP Rx
3141 STAGE POST DRIVE
BARTLETT, TN 38133

BILL TO (if other than ship to)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	48	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSTOP

2 cs @ 12 lbs.
7-15-97

Attachment 6
page 22 of 33
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1Z 373 677 03 1001 001 7

PACKING SLIP

SAGE PHARMACEUTICALS
6406 INTERSTATE AVE, SHREVEPORT, LA 71108
PH. (318) 636 1884 FA. (318) 635 1886

PACKING SLIP NO. PSRA3003 DATE 07/15/97

PURCHASE ORDER NO. 1562198 SHIP VIA UPS

SHIP TO
RITE AID CORP.
NEW YORK DISTRIB. CTR.
5865 SUCCESS DRIVE
ROME, NY 13440

BILL TO

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	72	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
BRECKENRIDGE INC. BOCA RATON, FL 33429

PSRA3

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3 cs. @ 18 lbs
7-15-97

1Z 373 677 03 1001 002 6

0079

PACKING SLIP

SAGE PHARMACEUTICALS
5406 INTERSTATE AVE. SHREVEPORT, LA 71106
PH. (318) 636 1884 FA. (318) 636 1886.

PACKING SLIP NO. PSM09001

DATE 07/15/97

PURCHASE ORDER NO. 147134035

SHIP VIA UPS

SHIP TO
MCKESSON DRUG CO.
SOCAL
9501 NORWALK BLVD
SANTE FE SPRINGS, CA 90670

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	24	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
BRECKENRIDGE INC. BOCA RATON, FL 33429

PSM09

Attachment 6
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8/12/97 JSN

1Z 373 677 03 1001 003 5

1 cs. @ 6 lbs
7-15-97

PACKING SLIP

SAGE PHARMACEUTICALS
6406 INTERSTATE AVE. SHREVEPORT, LA 71109
PH. (318) 635 1884 FA. (318) 635 1886

PACKING SLIP NO. PSAWD001

DATE 07/15/97

PURCHASE ORDER NO. PHIL0714

SHIP VIA UPS

SHIP TO
ALLIANCE WHOLESALE
22325 GOVERNORS HYWY.
RICHTON PARK, IL 60471

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	24	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSAWD

Attachment 6
page 25 of 33
8/12/97 JSN

1Z 373 677 03 1001 004 4

1 cs. @ 4 lbs
7-15-97

0081

PACKING SLIP

SAGE PHARMACEUTICALS
8406 INTERSTATE ... SHREVEPORT, LA 71106
PH. (318) 636 13... FA. (318) 636 1886.

PACKING SLIP NO. PSMA23

DATE 07/15/97

PURCHASE ORDER NO. H203027

SHIP VIA UPS

SHIP TO
MAJOR PHARMACEUTICAL
5110 W 74TH STREET
INDIANAPOLIS, IN 46268

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	48	BRECKENRIDGE	S 7058

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSMA2

Attachment 6
page 26 of 33
8/12/97 JSN

1Z 373 677 03 1001 005 3

2 cs. @ 12lbs
7-15-97

PACKING SLIP

SAGE PHARMACEUTICALS
5405 INTERSTATE AVE. SHREVEPORT, LA 71106
PH. (318) 636 1504 FA. (318) 635 1586.

PACKING SLIP NO. PSPEW001

DATE 07/17/97

PURCHASE ORDER NO. GREG

SHIP VIA UPS

SHIP TO
PENNER AND WELSCH
802 SHORT STREET
BLDG J
KENNER, LA 70062

BILL TO

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	24	BRECKENRIDGE	~~S 7058~~ S7059

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSPEW

1 Cs 24 Pack
1 @ 6#

UPS 7-17-97

Attachment 6
page 7 of 33
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1Z 373 677 03 1001 021 3

PACKING SLIP

SAGE PHARMACEUTICALS
5408 INTERSTATE AVE. SHREVEPORT, LA 71106
PH. (318) 636 1884 FAX (318) 636 1886

PACKING SLIP NO. PS81H004

DATE 07/17/97

PURCHASE ORDER NO. 59361-GD

SHIP VIA UPS

SHIP TO
BINDLEY WESTERN DRUG
542 COVINA BLVD
SAN DIMAS, CA 91773

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	24	BRECKENRIDGE	57059 ~~S 7068~~

SHIPMENT WILL BE INVOICED BY:
BRECKENRIDGE INC. BOCA RATON, FL 33429

PS81H

1 Cs 24 Pack
1@6#

UPS 7-17-97

Attachment 4
page 28 of 33
8/12/97 JSN

1Z 373 677 03 1001 022 2

PACKING SLIP

SAGE PHARMACEUTICALS
8406 INTERSTATE AVE. SHREVEPORT, LA 71109
PH. (318) 635 1894 FA. (318) 635 1896.

PACKING SLIP NO. PSRA1002

DATE 07/22/97

PURCHASE ORDER NO. 1566935

SHIP VIA UPS

SHIP TO
RITE AID CORP.
WOODLAND DIST.CTR.
1755 E BEAMER
WOODLAND, CA 95695

BILL TO (if other than ship to)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	216	BRECKENRIDGE	S 7059

SHIPMENT WILL BE INVOICED BY:
BRECKENRIDGE INC. BOCA RATON, FL 33429

PSRA1

9 cases - 24 Pack 216

1 @ 34 lbs 1Z 373 677 03 1001 049 1

1 @ 18 lbs 1Z 373 677 03 1001 050 8

Attachment 6
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8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
5408 INTERSTATE AVE. SHREVEPORT, LA 71109
PH. (318) 636 1994 FA. (318) 636 1996.

PACKING SLIP NO. PSRA5002

DATE 07/22/97

PURCHASE ORDER NO. 1565809

SHIP VIA UPS

SHIP TO
RITE AID CORP.
HARRISBURG DIST.CTR.
431 RAILROAD AVE.
SHIREMANSTOWN, PA 17011

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	72	BRECKENRIDGE	S 7069

SHIPMENT WILL BE INVOICED BY:
BRECKENRIDGE INC. BOCA RATON, FL 33429

PSRA5

3 cs 24 pack 72

1 @ 18 lbs

1Z 373 677 03 1001 048 2

7-22-97

Attachment 6
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8/12/97 JSN

PACKING SLIP

SAGE PHARMACEUTICALS
5405 INTERSTATE AVE, SHREVEPORT, LA 71109
PH. (318) 636 1884 FA. (318) 636 1886

PACKING SLIP NO. PSKER002

DATE 07/22/97

PURCHASE ORDER NO. 77678

SHIP VIA UPS

SHIP TO
FRANK W KERR, INC.
43155 W. NINE MILE
NOVI, MI 48376-8028

BILL TO (if other than ship to)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	48	BRECKENRIDGE	S 7059

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSKER

2 cs 24 Pack 48

1 @ 13 1Z 373 677 03 1001 051 7

Attachment 6
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8/12/97 JSN

0087

PACKING SLIP

SAGE PHARMACEUTICALS
6406 INTERSTATE [illegible] SHREVEPORT, LA 71109
PH. (318) 636 1[illegible] FAX (318) 636 1[illegible]

PACKING SLIP NO. PSBRL001 DATE 07/22/97

PURCHASE ORDER NO. 79941 SHIP VIA UPS

SHIP TO
BURLINGTON DRUG CO.
92 CATAMOUNT DRIVE
MILTON, VT [redacted] 05468

BILL TO (IF OTHER THAN SHIP TO)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	12	BRECKENRIDGE	S 7059

SHIPMENT WILL BE INVOICED BY:
NAPEAN INC. BERTHOUD, CO 80513

PSBRL

1 Ca 12 Pack 12

1 @ .4 LBS

1Z 373 677 03 1001 053 5

Attachment 6
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8/12/97 JSN

2-1-86
T.L.

PACKING SLIP

SAGE PHARMACEUTICALS
5406 INTERSTATE AVE. SHREVEPORT, LA 71109
PH. (318) 636 1894 FAX (318) 636 1896

PACKING SLIP NO. PSM01002

DATE 07/22/97

PURCHASE ORDER NO. 161140021

SHIP VIA UPS

SHIP TO
MCKESSON DRUG CO.
1355 ENTERPRISE DRIVE
ROMEOVILLE, IL 60446

BILL TO (if other than ship to)

DESCRIPTION	QUANTITY	LABEL	LOT #
MENOGEN H.S. TABLETS 100'S	24	BRECKENRIDGE	S 7059

SHIPMENT WILL BE INVOICED BY:
BRECKENRIDGE INC. BOCA RATON, FL 33429

PSM01

1 Cs 24 PK 24
1 @ 6LB

1Z 373 677 03 1001 052 6

Attachment 6
page 22 of 33
8/12/97 JSN

0089

NAPEAN ENTERPRISES
POST OFFICE BOX 1530
BERTHOUD, CO 80513
(303) 532-2388
FAX (303) 532-4462

February 15, 1996

Jivn-Ren Chen, Ph.D.
President
SAGE PHARMACEUTICALS
5408 Interstate Avenue
Shreveport, LA 71109

Dear Dr. Chen:

This document is divided in three parts as follows:

Part I: General manufacturing agreement between SAGE PHARMACEUTICALS and NAPEAN ENTERPRISES with regard to manufacturer and purchase of generic ESTROTEST and ESTROTEST H.S.

Part II: Cost projections for analytical and formulation development of pilot and production batches of the above mentioned products as well as stability costs.

Part III: Terms of payment of the costs of the items mentioned in part II.

PART I.

This section is to confirm that SAGE PHARMACEUTICALS, INC. and NAPEAN ENTERPRISES. do hereby enter into a mutual agreement for the manufacturing of generic ESTROTEST and ESTROTEST H.S. Tablets under the following terms and conditions. This agreement will be binding to both parties unless changes are mutually acceptable and are made in writing.

1. SAGE will manufacture generic ESTROTEST and ESTROTEST H. S. exclusively for NAPEAN for distribution in the United States provided SAGE is the sole manufacturer of the products for NAPEAN.

2. NAPEAN will pay for all development costs related to the manufacture of said products.

3. NAPEAN shall pay all invoices within 15 days of the date on the invoice, taking a 1% discount. Notification of each invoice will be sent by FAX to (970) 532-4462 and the original

0090

EXHIBIT
A

invoice will be mailed along with a C of A to NAPEAN at the address shown on the letterhead above.

4. NAPEAN will furnish to SAGE all active raw materials necessary for the development of the two products.

5. NAPEAN will pay NATOLI invoice for 16 station tooling (upper and lower) for generic ESTROTEST (high strength) imprinted with NE 570.

6. NAPEAN will order a minimum of one million (1,000,000) Tablets within one month of notification from SAGE that all development has been completed and acceptable stability studies have been met, as required by GMP.

7. NAPEAN shall be responsible for all regulatory compliance for the marketing of generic ESTROTEST and ESTROTEST H. S. in the United States.

8. SAGE will be responsible for all GMP practices during the manufacturing process of the tablets.

PART II

A. The cost estimation to develop the generic form of ESTROTEST and ESTROTEST H.S. Tablets is as follows:

1. Analytical method Development Raw material (USP, HPLC) Product (HPLC)	$ 14,000.00
2. Film coated tablets Formulation development and one lot of stability - batch manufacturing (high strength) 100,000 tablets. The potential for marketing this pilot batch is probable.	$ 9,500.00
3. Stability study- one lot, 3 months accelerated and extended to 36 months at room temperature.	$ 8,000.00
4. Active ingredient cost based on 100,000 Tablets.	
a. Esterified Estrogen (125GM + 10% excess - total 137.5GM) Minimum order 25KG (active 937.5GM)	** $[5,420.00] ** $[37,500.00]
b. Methyltestosterone (Minimum order 1KG)	** $[600.00]
** Paid for by NAPEAN ENTERPRISES	
TOTAL DEVELOPMENT COST	$ 31,500.00

B. Tentative estimation of product price: Minimum production batch order 1,000,000 Tablets with the exception that the first production batch of each strength Tablet will be for 500,000.

Bottle of 100 tablets (high strength formulation)	$ 10.20
Bottle of 100 tablets (low strength formulation)	$ 7.60

C. The price of 100 tablets includes the cost of manufacturing, including the costs of the active ingredients, complete packaging and labeling, quality control analysis, stability studies and any other listed requirements under the FDA regulations for GMP.

D. Pricing, subject to annual review, is based on the current active ingredients costs of esterified estrogens at $ 40./gm ($1,500.00/kg raw material containing 3.75% active) and methyltestosterone at $600.00/kg. In the event of raw material price changes, active or inactive, or in the event that GMP regulatory requirements are increased during the course of the year, price adjustments for said changes will be negotiated annually in accordance with invoices, price increase notices from pertinent distributors/manufacturers or federal regulatory agency notices.

E If, as expected, this project reaches a successful conclusion and production batch quantities of the generic ESTROTEST and ESTROTEST H. S. are purchased from SAGE by NAPEAN, then SAGE agrees to repay NAPEAN 25 % of the total development costs which would amount to $ 7,875.00 in four equal installments. NAPEAN will take payment of the above stated amount by deducting $1,968.75 from each of the first four invoices submitted to NAPEAN by SAGE.

PART III

The total development cost listed in PART II under items 1,2, & 3 is $ 31,500.00

1. An initial payment of approximately 1/3 will be made upon the signing of this agreement. $ 10,000.00

2. Upon receipt by NAPEAN of development status including the 1 st month stability result, another payment of approximately 1/6 of the total will be paid. This development status report must be completed within 6 weeks of receipt by SAGE of tooling and active ingredients. $ 5,500.00

3. Upon receipt of 3 month stability data which falls within acceptable limits, NAPEAN will make final payment of approximately 1/2 the total development costs. This data must be provided within 14 weeks of the receipt of tooling and active ingredients by SAGE. $ 16,000.00

4. The pilot stability batch of 100,000 tablets is the property of NAPEAN ENTERPRISES.

If the listed representatives for both SAGE PHARMACEUTICALS, INC. and NAPEAN ENTERPRISES concur with the contents of this document, please signify by signing and dating it in the space so provided below.

We, the undersigned accept all the terms to take effect immediately upon affixing our signatures and the date.

FOR NAPEAN ENTERPRISES

Raj Matakari — Date 3/1/96

FOR SAGE PHARMACEUTICALS,

Jivn-Rén Chen — Date 3/1/96

SAGE01

5'pact

U.S. DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
FILED

MAR 20 1998

ROBERT H. SHEMWELL, CLERK
BY [illegible] DEPUTY

MINUTE ENTRY ORDER
March 20, 1998

ROY S. PAYNE
U.S. MAGISTRATE JUDGE
300 Fannin, Suite 4300
Shreveport, LA 71101-3087

SHREVEPORT DIVISION

SAGE PHARMACEUTICALS, INC.

versus

NAPEAN ENTERPRISES, INC., ET AL.

CIVIL ACTION NO. 97-1983

JUDGE STAGG

MAGISTRATE JUDGE PAYNE

****

In accordance with the February 26, 1998 Scheduling Conference, the Motions to Strike filed by defendant on February 9, 1998 (Docket No. 9) and on February 12, 1998 (Docket No. 12) are **DENIED**, and the Motion for Protective Order filed by defendant Matkari on February 9, 1998 (Docket No. 10) is **GRANTED** as to discovery sought from Matkari, other than discovery that relates to the issue of personal jurisdiction. Defendants were directed to respond to the outstanding written discovery by **March 18, 1998.**

With respect to the Motion to Dismiss filed on February 9, 1998, plaintiff need not file any opposition until a date to be set during a **TELEPHONE STATUS CONFERENCE** on **April 3, 1998 at 11:00 a.m.**, at which time the court will determine whether the motion will be determined on the briefs or after an evidentiary hearing.

RSP

(15)

COPY SENT BY MWC ON 03-20-98
RSP, HARPER, MILLS

V. MOTION TO STRIKE

Defendant, Matkari, has filed a motion to strike requesting that a portion of paragraph 22 be stricken as the allegations are immaterial, impertinent, or scandalous. Paragraph 22 reads in its entirety as follows:

> 22. During the course of the Florida Litigation, Sage also learned, for the first time, that Matkari had been debarred by the Food and Drug Administration **for having been convicted of a felony under federal law relating to the development or approval of a drug product, having offered an illegal gratuity to an FDA chemistry review branch chief who was involved in the regulation of Matkari's drug product approvals. (emphasis added)**

Mover, Matkari, requests this Honorable Court to strike the portion of paragraph 22 which has been bolded hereinabove. The allegations concerning the conviction of a felony and the alleged underlying facts are immaterial, impertinent, and scandalous allegations. A full reading of the complaint shows that these allegations have nothing to do with Plaintiff's alleged cause of action and the fact of a felony conviction is not relevant evidence.

The information provided in paragraph 22 is inappropriate for the pleadings, as such discussions of a felony are even limited in the trial on the merits. In asking about a prior conviction, counsel may ask about "the name of the crime, the time and place of

the conviction, and the punishment, " and is limited to such inquiry at trial on the merits. [25] Additionally, the United States District Court for the Eastern District of Louisiana ruled in Gaudin v. Shell Oil Co., that "defense counsel may not inquire into the detail of the plaintiff's conviction, other than the name of the crime, the time and place of the conviction and the punishment"[26].

The only basis for injecting alleged felony convictions within the proceedings in any way would be for the possible impeachment of a witness. Even then, the underlying facts of the felony conviction are inadmissible evidence. It appears that the statements in paragraph 22 are designed solely to embarrass the Defendant, Matkari, or to inflame the trier of fact and they should be stricken from the record. [27]

Matters which have no bearing on a controversy, which are

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[25] McCormick, Evidence Sec. 43 at 98 (1984); See United States v. Breckenridge, 782 F.2d 1317, 1323 (5th Cir. 1986) cert. denied, 479 U.S. 837, 107 S.Ct. 136, 93 L.Ed.2d 79 (1986); United States v. Barnes, 622 F.2d 107 (5th Cir. 1980); Tucker v. United States, 409 F.2d 1291, 1294, n.1 (5th Cir. 1969), aff'd sub nom.; United States v. Woodall, 438 F.2d 1317 (5th Cir. 1970), cert. denied, 403 U.S. 933, 91 S.Ct. 2262, 29 L.Ed. 2d 712 (1971); Beaudine v. United States, 368 F.2d 417 (5th Cir. 1966).

[26] 132 FRD 178 (E.D. La 1990).

[27] See for example: Goldstein v. North Jersey Trust Co., Inc.,132 FRD 178 (E.D. La 1990), a case directly on point court directly on point, in which the court struck from the pleadings similar allegations; Bureerong v. Uvawas, C.D. Cal. 1996, 922 F. Supp 1450 alleging a "sweat shop."

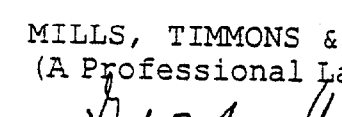
irrelevant or immaterial, are properly subject to a motion to strike from the pleadings. [28] Even relevant portions of a complaint may be stricken where they are scandalous and set out in needless detail. [29]

VI. CONCLUSION

Defendants Motion to Dismiss and Motion to Strike should be granted.

Respectfully submitted,

MILLS, TIMMONS & FLOWERS
(A Professional Law Corporation)

BY: 

George H. Mills, Jr. (#9583)
331 Milam Street
Post Office Box 1784
Shreveport, Louisiana 71166
318/222-0337

Attorneys for Defendant

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[28] Salem Engineering Co. V. APF Electronics, Inc., 75 F. Supp 993 (W.D. Pa. 1948).

[29] Gleason v. Chain Service Restaurant, 300 F. Supp. 1241 (S.D. N.Y. 1969), affirmed 422 F. 2d 342 (2nd Cir. 1990).

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 97-8417-CIV-RYSKAMP

FILED by D.C.
MAR 18 1998
CARLOS JUENKE
CLERK U.S. DIST. CT.
S.D. OF FLA. - W.P.B.

FLORIDA BRECKENRIDGE, INC.,
d/b/a BRECKENRIDGE
PHARMACEUTICAL, INC.,

Plaintiff and Counterclaim Defendant,

vs.

SOLVAY PHARMACEUTICALS, INC.,

Defendant and Counterclaim Plaintiff,

vs.

NAPEAN ENTERPRISES, INC.,

Counterclaim Defendant.

_____/

SUMMARY JUDGMENT ORDER

THIS CAUSE came before the Court upon Solvay Pharmaceuticals, Inc.'s ("Solvay") motion for summary judgment [DE-97] and upon Florida Breckenridge, Inc. d/b/a Florida Breckenridge Pharmaceutical, Inc.'s ("Breckenridge") cross-motion for summary judgment [DE-104]. The motions have been fully briefed and the Court has heard oral argument. For the reasons stated in this Order, the Court will deny Solvay's motion for summary judgment and will grant Breckenridge's cross-motion for summary judgment.

I. BACKGROUND

A. The Estratest Drugs

Solvay is a pharmaceutical drug company that manufactures and sells the drug ESTRATEST®, a hormone replacement therapy for menopausal women. (Solvay's Facts ¶ 11.) Solvay has manufactured ESTRATEST® since 1964, and has manufactured ESTRATEST® H.S., a half-strength version of ESTRATEST®, since 1975. (*Id.*) ESTRATEST® and ESTRATEST® H.S. (collectively, "the Estratest Drugs") contain the hormones estrogen and androgen. They are "second line" hormone replacement drugs because women often use the Estratest Drugs if they are unable to obtain relief through "first line" estrogen-only drugs. (*Id.* ¶ 7, 9, 10.) The Estratest Drugs are sold by prescription only, but are not patented or regulated by the United States Food and Drug Administration ("FDA") (Breckenridge's Facts ¶ 14.)[1] Solvay has been the sole producer of this particular second line hormone replacement drug for over thirty years.

1. Appearance of the Estratest Drugs

Solvay's ESTRATEST® full-strength pill comes as a rounded oval caplet (a tablet shaped like a capsule), about ½ inch long, with a smooth, glossy dark green sugar coating and white lettering on one side. The white lettering reads "Solvay" and "1026." The

[1] The reasons why the Estratest Drugs are not regulated by the FDA are unknown to the Court. The parties have stated that the FDA's lack of regulation is an historical anomaly.

ESTRATEST® H.S. half-strength caplet is of identical shape, but bears a smooth, glossy light green coating. "Solvay" and "1023" are stamped in black on one side of the caplet.

2. Chemical Makeup of the Estratest Drugs

Solvay's product description in the Physicians Desk Reference ("PDR") states that ESTRATEST® contains 1.25 milligrams of esterified estrogens USP and 2.5 milligrams of methyltestosterone USP, and that ESTRATEST® H.S. contains .625 milligrams of esterified estrogens USP and 1.25 milligrams of methyltestosterone USP. (Breckenridge's Resp. to Solvay's Facts ¶ 48-49.)

The designation "USP" in conjunction with the name of an ingredient means that the ingredient "purports to comply with [United States Pharmacopeia] standards." (Solvay's Resp. to Breckenridge's Mot. for Summ. J. ("Solvay's Resp.") at 9.) The United States Pharmacopeia establishes monographs, or standards, for determining the "identity, strength, quality, and purity" of drug ingredients. (*Id.* at 8.) To meet the USP monograph for esterified estrogens, a drug must contain a certain amount of two particular estrogenic substances in certain amounts. (*Id.* at 9.) It is undisputed that the Estratest Drugs comply with the USP monograph.

After the Court denied Solvay's request for a preliminary injunction, Solvay performed additional tests on its Estratest Drugs – tests not required to establish that a drug's ingredients comply with USP. (Breckenridge's Additional Facts ¶61;

Breckenridge's Facts, App. II, Tab 12 ("Chalgeri Aff.").) Solvay's tests revealed that the Estratest Drugs contain two additional estrogenic substances which are not listed in the PDR: 17 ∝ dihydroequilin sodium sulfate and 17 ∝ dihydroequilinen sodium sulfate. (Solvay's Resp. at 10-11; Breckenridge's Additional Facts ¶ 59; Lobo Decl. ¶ 9.) Solvay claims that these additional ingredients are estrogenically active and that they enhance the operation of the Estratest Drugs. (Solvay's Resp. at 11.) Breckenridge disputes Solvay's contention that the additional ingredients are active.

The Estratest Drugs take as long as forty-eight minutes to break down completely in the bloodstream, (Solvay's Facts ¶ 34,) and are not fully absorbed into the bloodstream until 120 minutes after ingestion. (*Id.*)

B. The Menogen Drugs

Breckenridge, a generic pharmaceutical drug company, markets the drugs MENOGEN and MENOGEN H.S. (collectively, "the Menogen Drugs") as a substitute for Solvay's Estratest Drugs. (*Id.* ¶ 16, 18.) Breckenridge sends its orders to Napean Enterprises ("Napean") which provides instructions to the drug manufacturer regarding the shipping of the drugs. Napean also coordinates the overall management of the business enterprise between Breckenridge and the drug manufacturer. (*Id.* ¶ 17.)[2]

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[2] The Menogen Drugs have not been manufactured or sold since approximately July 1997.

1. Appearance of the Menogen Drugs

The Menogen Drug tablets are a high and squared oval shape, with top, bottom and ends rounded, and with the sides squared. They are approximately 5/8 inch long. The full-strength MENOGEN tablet bears a somewhat rough and dull dark green finish, and is stamped by indentation and without color "NE" on one side and "570" on the other. The MENOGEN H.S. half-strength tablet is an identical squared oval tablet bearing a rough light green finish and the stamp "560" in place of the full-strength's "570."

2. Chemical Makeup of the Menogen Drugs

MENOGEN contains 1.25 milligrams of esterified estrogens USP and 2.5 milligrams of methyltestosterone USP. (Breckenridge's Facts ¶ 10.) MENOGEN H.S. contains .625 milligrams of esterified estrogens USP and 1.25 milligrams of methyltestosterone USP. (Breckenridge's Additional Facts ¶ 52.) The esterified estrogen and methyltestosterone in the Menogen Drugs comply with the USP monograph as do the Estratest Drugs. (*Id.* ¶ 12.) However, the Menogen Drugs do not contain the two 17 ∝ compounds which the Estratest Drugs contain. Apparently, the reason the Menogen Drugs do not contain the 17 ∝ compounds is that Breckenridge's manufacturer obtains its esterified estrogen from a different estrogen producer than does Solvay. (Solvay's Facts ¶ 38.) The Menogen Drugs break down completely in the bloodstream within three

minutes, (Solvay's Facts ¶ 34), and are fully absorbed into the bloodstream after 15 minutes have elapsed. (*Id.*)

C. Breckenridge's Advertising

In April of 1996, Breckenridge's President, Laurence Runsdorf, and at least one other Breckenridge employee began to market the Menogen Drugs over the phone to potential customers. (*Id.* ¶ 19.) In those phone conversations, Runsdorf stated that the Menogen Drugs are the "generic equivalent" of the Estratest Drugs (*Id.*)

On May 1, 1997, Breckenridge issued two press releases. (Breckenridge's Additional Facts ¶ 53.) One of these press releases was sent to various pharmaceutical trade publications including "Medical Marketing and Media." (*Id.* ¶ 20.) The other was sent to roughly 400 pharmaceutical buyers. (*Id.*) The latter press release stated the following:

> Breckenridge Pharmaceutical, Inc. is pleased to introduce another new addition to its growing generic pharmaceutical line, MENOGEN H.S. (half-strength) and MENOGEN Tablets.
>
> MENOGEN H.S. and MENOGEN are the first and only estrogen-androgen combination which compare to ESTRATEST® H.S. and ESTRATEST®.
>
> MENOGEN H.S. and MENOGEN are members of one of the fastest growing women's health categories, Hormone Replacement Therapy (HRT).

> MENOGEN H.S. and MENOGEN are available in 100 tablet bottles.

(*Id.*, App. I, Tab 6, Exh. 13.) Both press releases stated that the Menogen Drugs "compare to" the Estratest Drugs and are in addition to Breckenridge's "generic" line. (Breckenridge's Additional Facts ¶ 53.) At least one industry publication has declared the Menogen Drugs to be "generic equivalents" of the Estratest Drugs. (Solvay's Facts ¶ 22.) Solvay estimates that its market share has dropped as much as 12% since the Menogen Drugs have been on the market. (Solvay's Facts ¶ 45.)

Breckenridge's President admits that Breckenridge did not perform tests to substantiate its statements that the Menogen Drugs are the "generic equivalent" or "compare to" the Estratest Drugs. (*Id.* ¶ 29.) Instead, Breckenridge relied upon the oral assurances of Napean to make such a claim. (*Id.*) Napean did not perform any tests to substantiate such a claim. (*Id.* ¶ 30.) The drug manufacturer, who is no longer a party to this lawsuit, did test the Estratest Drugs to determine if the ingredients esterified estrogen USP and methyltestosterone USP were present in the quantities shown on Solvay's label. (Breckenridge's Resp. to Solvay's Facts ¶ 31.) The Menogen and Estratest Drugs contain the same amount of esterified estrogen USP and methyltestosterone USP.

D. Procedural History

Following Breckenridge's announcement, Solvay and Breckenridge entered into negotiations regarding the trade dress of the Menogen Drug tablets and Breckenridge's

claims regarding the comparability of the Menogen and Estratest Drugs. Those negotiations were unsuccessful and, in May of 1997, Breckenridge filed a complaint for declaratory relief against Solvay. Breckenridge alleged that the trade dress for its Menogen Drugs did not infringe on Solvay's Estratest Drugs. Three weeks later, Solvay filed its answer and counterclaim alleging trade dress infringement and unfair competition. Solvay also requested injunctive relief.

On June 27, 1997, the Court denied Solvay's motion for a preliminary injunction on its trade dress claims and denied without prejudice Solvay's motion for a preliminary injunction as to the false advertising claims. Solvay now moves for summary judgment on its false advertising claim, claiming that Breckenridge's advertisements are literally false. Breckenridge cross-moves for summary judgment on Solvay's trade dress and false advertising claims.

II. DISCUSSION

A. Summary Judgment Standard

Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). "*Some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-248, 106

S.Ct. 2505, 2510, 91 L.Ed.2d 202 (1986) (emphasis in the original). "For factual issues to be considered genuine, they must have a real basis in the record." *Hairston v. Gainesville Sun Pub. Co.*, 9 F.3d 913, 919 (11th Cir. 1993). The party opposing summary judgment may not simply rely upon the pleadings or mere denials of the allegations. Rather, the opposing party must adduce some evidence showing that material facts are in issue. *See Anderson*, 477 at 256; 106 S.Ct. at 2514.

In considering a motion for summary judgment the Court views the facts in the light most favorable to the nonmoving party. *See Poller v. Columbia Broadcasting System, Inc.*, 368 U.S. 464, 473, 82 S.Ct. 486, 491, 7 L.Ed.2d 458 (1962). The Court will enter summary judgment if a party fails "to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex v. Catrett*, 477 U.S. 317, 322, 106 S.Ct. 2548, 2552, 91 L.Ed.2d 265 (1986); Fed. R. Civ. P. 56(e).

Because only Breckenridge has moved for summary judgment on the issue of trade dress, Breckenridge bears the burden of showing that no trade dress infringement exists as a matter of law. Each party has moved for summary judgment on the false advertising claim, and each party bears its own burden on that issue.[3] Although each party bears its

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[3] In its opinion denying Solvay's motion for a preliminary injunction, the Court stated that Solvay will bear the burden of proving false advertising at trial. *See Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997) (in cause of action for false advertising, plaintiff bears burden of proving falsity); *Johnson & Johnson-Merk v. Rhone-Poulenc Rorer*

own burden, the Court will strictly scrutinize Breckenridge's claims of equivalence because courts "traditionally undertake[ ] close scrutiny of drug safety claims." *McNeilab, Inc. v. American Home Products Corp.*, 848 F.2d 34, 37 (2d Cir. 1988) (closely scrutinizing drug company's claim of overall equivalence). *See Syntax Labs, Inc. v. Norwich Pharmacal Co.*, 437 F.2d 566, 569 (2d Cir. 1971) (strictly scrutinizing likelihood of confusion of drug company's use of similar trademark).

B. Trade Dress Infringement

Breckenridge moves for summary judgment on the trade dress infringement claim. Although the Court denied Solvay's motion for preliminary injunction on trade dress infringement, that denial alone is insufficient ground for the Court to now grant Breckenridge's motion. The Court must now examine the record to determine if there is any genuine issue of material fact. Although "the findings of fact and conclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits," the Court may rely upon its findings if they are still uncontested. *University of Texas v. Camenisch*, 451 U.S. 390, 395, 101 S.Ct. 1830, 1834, 68 L.Ed.2d 175 (1981).

Pharm., Inc., 19 F.3d 125, 129 (3d Cir. 1994) (same); *BASF Corp. v. Old World Trading Co.*, 41 F.3d 1081, 1089 (7th Cir. 1994) (same). *See also McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir.1991) (plaintiff bears burden of showing false advertising on preliminary injunction). That Solvay bears the burden of proving its claim does not alter the fact that each party must bear its own burden on the issues upon which it moves for summary judgment.

"[W]hether trade dress has been infringed is a question of law." *Epic Metals Corp. v. Souliers*, 99 F.3d 1034, 1037 (11th Cir. 1996). To prevail on a claim for trade dress infringement, a plaintiff must show: "(1) that the trade dress of the two products is confusingly similar; (2) that the features of the trade dress are primarily non-functional; and, (3) that the trade dress is inherently distinctive or has acquired secondary meaning." *Id.* at 1038. Whether two products are confusingly similar is a question of fact. *See Jellibeans, Inc. v. Skating Clubs of Georgia, Inc.*, 716 F.2d 833, 839 (11th Cir. 1983). Thus, a grant of summary judgment on likelihood of confusion is proper only if no reasonable jury could return a verdict for the party against whom summary judgment is sought. *See Camp Creek Hospitality Inns, Inc. v. Sheraton Franchise Corp.*, 130 F.3d 1009, 1013 (11th Cir. 1997).

In determining whether two products are confusingly similar, courts consider: the type of mark, the similarity of design, the similarity of the product, the identity of the retail outlets and purchasers, the similarity of advertising media used, defendant's intent, and actual confusion. *See Laboratorios Roldan C. por A. v. Tex Int'l, Inc.*, 902 F. Supp 1555, 1566 (S.D. Fla. 1995) (citing *John H. Harland Co. v. Clarke Checks, Inc.*, 711 F.2d 966, 972 (11th Cir. 1983). Solvay argues that genuine issues of material fact exist as to the similarity of the trade dress, Breckenridge's intent, and the relevant consumers. (Solvay's Resp. at 15-16.) The Court disagrees.

1. Similarity of the Trade Dress

In the opinion accompanying the Court's Order denying Solvay's motion for preliminary injunction, the Court found that the overall impression of the Menogen and Estratest pills offers only a very low level of similarity. The Court's finding was based upon the fact that the Menogen tablet is a large high oval with straight and squared-off edges. In contrast, the Estratest caplet is a smaller rounded oval that looks like a traditional capsule. The Menogen tablet is a rough, dull dark green (in the case of the half-strength a rough light green), while the Estratest caplet is a smooth, glossy dark green (in the case of the half-strength a smooth, glossy light green). The Estratest caplet is approximately ½ of an inch long, while the Menogen tablet is approximately 5/8 of an inch long. The Menogen tablet is debossed with uncolored identifying letters and numbers, while the Estratest caplet is printed in a contrasting color with the Solvay mark and identifying numbers. Considering the above findings, the Court ruled that the drugs do not look or feel the same, and a patient would notice the difference in swallowing the larger, less-rounded Menogen tablet.

Since the Court's denied Solvay's motion for preliminary injunction, Solvay has not produced any additional evidence in support of its position that the designs are similar. In light of the Court's earlier findings and Solvay's failure to produce additional evidence, the Court finds rules no reasonable jury could find the designs similar.

2. Breckenridge's Intent

The relevant intent is Breckenridge's intent to appropriate Solvay's reputation and goodwill. *See Ambrit, Inc. v. Kraft, Inc.*, 812 F. 2d 1531, 1542 (11th Cir. 1996), *cert. denied*, 481 U.S. 1041, 107 S.Ct. 1983, 95 L.Ed.2d 822 (1987). In the Court's earlier opinion, the Court found that Solvay produced no direct evidence of Breckenridge's bad intent and that the facts of this case did not provide any circumstantial evidence of Breckenridge's bad intent. The Court considered in detail whether the similarity in color provided any evidence of Breckenridge's bad intent, and the Court concluded that it did not. The Court also considered and rejected the argument that Breckenridge's use of the label "H.S." was evidence of Breckenridge's bad intent.[4] Solvay has produced no evidence since the Court's Order to support its position. A reasonable jury could not infer Breckenridge's bad intent from the available circumstantial evidence.

3. The Relevant Consumers

Solvay argues that the relevant consumers are not pharmacists and physicians, but patients. These patients, argues Solvay, will be confused by Breckenridge's trade dress in a way that pharmacists and physicians may not be. Solvay's argument fails for two reasons: first, the Court earlier rejected the argument that consumer patients would be

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[4] The Court doubted in its earlier opinion whether it should even consider Solvay's H.S. argument. The designation H.S. does not appear on the Menogen Drugs themselves, and appears only on the packaging. Solvay has not challenged the drugs' packaging.

confused. Solvay has not presented any new evidence in support of its argument. A reasonable jury could not find for Solvay on this count. Second, Solvay admits that pharmacists and pharmaceutical suppliers are the purchasers of its prescription drugs. Neither Solvay or Breckenridge now market, or ever have marketed, their prescription drugs directly to consumers. For the above stated reasons, the Court will grant Breckenridge's motion for summary judgment on the trade dress infringement claim.

C. False Advertising

1. Elements of False Advertising Violation

Solvay moves, and Florida Breckenridge cross-moves, for summary judgment on the false advertising claim. The Lanham Act creates a civil remedy for injuries caused by a competitor's false advertisements. The statute imposes liability upon:

> (a)(1) Any person who, on or in connection with any goods or services . . . uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which –
>
> > (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his . . . goods . . .

15 U.S.C. § 1125(a)(1)(B). To prevail on a claim for false advertising under the Lanham Act, a plaintiff must adduce evidence of each of the following five elements:

(1) The defendant made false or misleading statements about its product in an advertisement;

(2) Those advertisements actually deceived consumers or have the tendency to deceive a substantial portion of the targeted audience;

(3) The deception is material, meaning it is likely to influence purchasing decisions;

(4) The defendant's advertised products traveled in interstate commerce; and,

(5) The plaintiff has been or is likely to be injured as a result of the false or misleading advertisements by causally related declining sales or loss of goodwill.

See Tire Kingdom, Inc. v. Morgan Tire & Auto, Inc., 915 F. Supp. 360, 364 (S.D. Fla. 1996), *aff'd mem.*, No. 96-4281 (11th Cir. Jan. 23, 1998). *See also ALPO Petfoods, Inc. v. Ralston Purina Co.*, 913 F. 2d. 958, 964 (D.C. Cir. 1990). This case turns upon the first prong of the five part test: whether the alleged statements were made in an advertisement and whether the alleged statements were false and misleading.

2. Oral Statements Are Advertising

To qualify as commercial advertising, a statement must be:

(1) commercial speech; (2) by a defendant who is in commercial competition with plaintiff; (3) for the purpose of influencing consumers to buy defendant's goods or services. While the representations need not be made in a "classical advertising campaign," but may consist instead of more informal types of "promotion," the representations (4) must be disseminated sufficiently to the relevant purchasing public to constitute "advertising" or "promotion" within that industry.

Seven-Up Co. v. Coca-Cola Co., 86 F.3d 1379, 1384 (5th Cir. 1996). *See Medical Graphics Corp. v. SensorMedics Corp.*, 872 F. Supp. 643, 650 (D. Minn. 1994) (same four part test).

Breckenridge contends that its oral representations are not advertising within the meaning of the Lanham Act. The oral representations consist of the following: Mr. Runsdorf, the President of Breckenridge, and one other Breckenridge representative made various phone calls to customers regarding the Menogen Drugs. (Solvay's Facts, App. II, Tab 6 Runsdorf Dep. at 72, lines 20-23.) During the telephone conversations, Runsdorf would "tell the customer of the existence of the product. I would tell him about the brand product, the sales of the brand product, if I know it, and the sale trend, if I know it. I would tell him about the regulatory status of the product, give him pricing information." (*Id.* at 73, lines 2-7.) Runsdorf also stated that Breckenridge marketed the Menogen Drugs, "a generic equivalent of [the] EstraTest [Drugs]." (*Id.* at 39, lines 8-13; *see id.* at 73, lines 8-13.)

It is unclear from Runsdorf's deposition how many times he made the above-described statements. It is clear, however, that Runsdorf's statements were not isolated occurrences, but were instead an integral part of Breckenridge's advertising campaign. The affidavit of Jim Hynd, Solvay's Director of Women's Health Marketing, states that "telephone visits" between sales representatives and their customers are integral to the

sales process in the prescription drug industry. Hynd avers, "I know of no business in the industry that promotes its prescription drugs without such face-to-face or personal attention on the part of the sales representative to the customer. In fact, in my experience, a prescription drug product could not be adequately promoted without such in-person and word-of-mouth promotion." (Solvay's Resp., Exh. B, Hynd Aff. at 4.)

Runsdorf's oral statements, as a matter of law, constitute commercial advertising. Breckenridge has not produced evidence contradicting Hynd's affidavit, nor does it argue that the telephone conversations were an unimportant or insubstantial part of its marketing. Runsdorf's statements were commercial speech made by a defendant in commercial competition with Solvay, for the purpose of influencing customers to buy defendant's goods and services. Runsdorf's statements were an integral part of his company's overall marketing scheme and were sufficiently disseminated to constitute advertising within the pharmaceutical drug industry.

3. ~~Written Statements Are Not~~ Puffery

In its press releases, Breckenridge stated that the Menogen Drugs "compare to" the Estratest Drugs and that Breckenridge was adding the Menogen Drugs to its "generic" line. Solvay contends that Breckenridge's written statements are false and misleading. In response, Breckenridge argues that its statements are general usages which are not

actionable under the Lanham Act, and that they are not literally false. The Court will examine each of these arguments in turn.

Breckenridge first argues that its statements are general, subjective statements which are not actionable. Mere puffery, or sales talk, is not actionable but false statements are actionable. The Eleventh Circuit has never defined puffery, but the courts of appeal are in broad agreement over the term's meaning. A recent circuit court opinion defines puffery as:

> "advertising, blustering, and boasting upon which no reasonable buyer would rely and is not actionable under [Lanham Act] § 43(a)." 3 J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition § 27.04[4][d] at 27-52 (3d ed.1994). While product superiority claims that are vague or highly subjective often amount to nonactionable puffery, *Cook, Perkiss and Liehe v. Northern California Collection Service, Inc.*, 911 F.2d 242, 246 (9th Cir. 1990), "misdescriptions of specific or absolute characteristics of a product are actionable." *Id.* (citation omitted). A specific and measurable advertisement claim of product superiority based on product testing is not puffery. *See . . . W.L. Gore & Assocs., Inc. v. Totes Inc.*, 788 F. Supp. 800, 809 (D. Del.1992) (numerical comparison that product is seven times more breathable "gives the impression that the claim is based upon independent testing" and "is not a claim of general superiority or mere puffing").

Southland Sod Farms, 108 F.3d at 1145 (statement that "Less is More" is nonactionable puffery). In short, "[t]he 'puffing' rule amounts to a seller's privilege to lie his head off, so long as he says nothing specific." *Castrol, Inc. v. Penzoil Co.*, 987 F.2d 939, 945 (3d Cir. 1993) (quoting W. Page Keeton, et al., Prosser and Keeton on the Law of Torts § 109, at 756- 57 (5th ed. 1984)). Whether an alleged misrepresentation is an actionable

statement of fact or mere puffery is a matter of law. *See Cook, Perkiss & Liehe*, 911 F.2d at 245.

In response to Breckenridge's argument that the statements in its press releases are mere puffery, Solvay argues: (1) that Breckenridge has no support for its argument that "compare to" and "generic" can be puffing in a pharmaceutical advertisement; and, (2) Breckenridge's president admitted in his deposition that "compare to" means "generic" equivalence. The Court will not reach Solvay's second argument because it finds the first argument persuasive.

Breckenridge stated in its press release that it was adding its Menogen Drugs to its "growing generic pharmaceutical line" and that the Menogen Drugs "compare to" the Estratest Drugs. These statements are not mere general claims that a product is "better" than another product. *See Nikkal Indus., Ltd. v. Salton, Inc.*, 735 F. Supp. 1227, 1234 n. 3 (S.D.N.Y. 1990) (claim that one product "better than" another is mere puffing). A drug company's claim of generic equivalency is more than mere "blustering and boasting." *Southland Sod Farms*, 108 F.3d at 1145. Rather, it is a claim regarding the absolute characteristics of the drug. The claim implies that the drug in question has satisfied certain tests and may properly be labeled as a generic equivalent. *Cf. American Home Products v. Johnson & Johnson*, 654 F. Supp. 568 (S.D.N.Y. 1987) (drug company's

claim that its drug's safety profile was superior considered puffing where some evidence of superiority existed.)

Having determined that Breckenridge's statements are actionable advertising, the Court must determine whether Breckenridge's ads are literally false or literally true as a matter of law. They are literally true, and the Court will grant Breckenridge's, and deny Solvay's, motion for summary judgment.

4. Solvay Makes a Claim for Literal Falsity Only

An advertisement may be false within the meaning of the Lanham Act in one of two ways: "either . . . the challenged advertisement is literally false, or, although literally true . . . it is still likely to mislead or confuse consumers." *L & F Products v. Proctor & Gamble Co.*, 45 F.3d 709, 711 (2d Cir. 1995). *See C.B. Fleet Co. v. Smithkline Beacham Consumer Healthcare, Ltd.*, 131 F.3d 430, 434 (4th Cir. 1997). Solvay's claim for false advertising is a claim of literal falsity only. Solvay first discussed Breckenridge's alleged false advertising in its motion for preliminary injunction. The preliminary injunction claims that Solvay will be harmed by Breckenridge's trade dress infringement because Breckenridge's advertisements are literally false. On page four of its motion, Solvay asserts that the drug "purportedly compares" to the Estratest Drugs, but has not been demonstrated to compare.[5] Solvay also asserts that "comparable" means "exactly

[5] Solvay did not paginate its motion for preliminary injunction.

substitutable for," and that the Menogen Drugs may not fulfill the test requirements for generic equivalency. (*See* Solvay's Mot. for Prelim. Inj. at 21 (I.C.3), 24 (I.D).)

Whether an advertisement is false is usually a question of fact. *See C.B. Fleet Co.*, 131 F.3d at 434; *L & F Products*, 45 F.3d at 712. However, a court may grant summary judgment to the plaintiff if it finds the defendant's claims to be literally false. *See Lipton v. The Nature Company*, 71 F.3d 464 (2d Cir. 1995) (reversing district court's grant of summary judgment where advertisement not literally false); *Janda v. Riley-Meggs Industries, Inc.*, 764 F. Supp. 1223 (E.D. Mich. 1991) (granting summary judgment where claims literally false). Summary judgment is especially appropriate here, where both parties have moved for summary judgment on literal falsity.

5. Two Burdens for Literal Falsity

Courts may demand a plaintiff who alleges literal falsity to meet one of two burdens of proof, depending upon the type of advertisement at issue. As the Fourth Circuit recently noted:

> When an advertising claim . . . expressly . . . asserts that [it] is testor study-validated . . . [s]uch a claim may . . . be proven literally false by showing only that the test asserted to validate it did not in fact do so . . . [W]here the claim is made . . . with no assertion of test or study validation, its literal falsity may only be proven by proof that the favorable fact baldly asserted is false.

C.B. Fleet Co., 131 F.3d at 435. *See Rhone-Poulenc Rarer Pharms., Inc. v. Marion Merrell Dow, Inc.*, 93 F.3d 511, 514-15 (8th Cir. 1996) (different standards of proof apply

to the two types of advertising claims); *BASF Corp.*, 41 F.3d at 1091 (proof required to prove literal falsity will vary depending upon the statement made); *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 62-63 (2d Cir. 1992) (falsity of "tests show" claim may be proven by showing that the tests were not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition, but falsity of bald claim may be proven only by evidence affirmatively showing claim's falsity).

Neither of these standards are particularly helpful to the Court, as the question of whether Breckenridge's use of "compare to" and "generic equivalent" for a non-FDA regulated drug means, as a matter of law, that Breckenridge satisfied certain tests, is at the heart of the issue which the Court must decide.

6. Advertising Is Literally True

Solvay argues that Breckenridge's statements that the Menogen Drugs are the generic equivalent of, compare to, and are an addition to Breckenridge's generic line of pharmaceutical drugs, are literally false. The Court disagrees. The question of what "generic equivalence" means in the context of a non-FDA regulated pharmaceutical drug appears to be an issue of first impression.[6] The parties have not located, nor has the

[6] It also presents an issue quite unlike most Lanham Act cases. In the majority of Lanham Act cases, the plaintiff attempts to prove false advertising by showing that the defendant copied the plaintiff's product. In this case, the plaintiff is attempting to prove false advertising by showing that the defendant did not copy the plaintiff's product closely enough.

Court's research revealed, any cases directly on point.[7] Solvay urges the Court to apply the FDA's standard for generic equivalency, a standard which requires the drugs to be bioequivalent. Alternatively, Solvay would have the Court apply a chemical equivalence standard, a standard which is less stringent than bioequivalence. Breckenridge argues that the Court should apply the chemical equivalence standard.

a. The Standards

The FDA requires all generic drugs to be bioequivalent to the pioneer drug. All prospective manufacturers of a FDA regulated generic equivalent must perform tests demonstrating that the drug is bioequivalent to the pioneer drug. (Solvay's Facts, App. I, Tab 10 at ix). Once the FDA determines that a generic drug is bioequivalent, it lists the generic drug in its Orange Book. Breckenridge does not now contend that the Menogen Drugs are bioequivalent to the Estratest Drugs, nor did Breckenridge ever advertise that the Menogen Drugs complied with the FDA's Orange Book standards. Solvay contends that, by stating its Menogen Drugs are "generic equivalents," Breckenridge made a literal claim of bioequivalency.

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[7] In *Inwood Laboratories v. Ives Laboratories*, 456 U.S. 844, 102 S.Ct. 2182, 72 L.Ed.2d 606 (1982), the Supreme Court considered whether the manufacturer of a generic drug which was designed to duplicate the appearance of a similar drug marketed by a competitor could be vicariously liable under the Lanham Act. The Supreme Court noted that the non-FDA approved generic drug was bioequivalent and had the same bioavailability. 456 U.S. at 848 n.5, 102 S.Ct. 2185 n.5. However, the Supreme Court did not state that bioequivalency or bioavailability was required.

Chemical equivalence is a lower standard than the FDA's bioequivalence standard. Dr. Raj Matkari, the President, Director and Owner of Napean, stated in his deposition that a drug is the generic equivalent of a pioneer drug if it is chemically equivalent, bioequivalent, or therapeutically equivalent. (Solvay's Facts ¶ 24.) In other words, according to Dr. Matkari, a drug can be a generic equivalent if it meets any one of the three standards. A drug is the chemical equivalent of another if it contains the same active ingredients in the same amount. (*Id.* ¶ 25.)

b. Chemical Equivalence is the Proper Standard

Whether Breckenridge's claims of generic equivalence are literally false hinges upon an issue of first impression: what the term "generic equivalent" means in the context of a non-FDA regulated drug.[8] It means chemical equivalence. In marketing its drugs for the last thirty years, Solvay has made limited representations regarding the contents of its Estratest drugs: it lists the drugs' active ingredients in the PDR and represents that those active ingredients comply with the USP monograph. Solvay is not required to further disclose or test the ingredients of its Estratest Drugs, nor is Breckenridge required to perform the extensive tests mandated for FDA regulated drugs.

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[8] This issue is proper for summary judgment because it is a matter of law which the Court must decide in any event. If this case went to trial, the Court would have to instruct the jury on whether the FDA's standard for generic equivalency or the chemical equivalency standard applies.

Instead, Breckenridge followed a commercially reasonable path and complied with all commercial descriptions which Solvay provided regarding its drugs.

The audience to whom Breckenridge advertised was aware of Solvay's regulatory status. The consumers to whom Breckenridge advertises are sophisticated: Breckenridge does not advertise to consumers uneducated about pharmaceutical drugs, but rather targets knowledgeable pharmaceutical buyers and physicians. Breckenridge's buyers are aware that the Estratest Drugs are not regulated by the FDA and that manufacturers of the Menogen Drugs are not required to perform FDA bioequivalency tests before marketing their drug. Furthermore, Breckenridge President Runsdorf testified that when he calls prospective buyers and represents to them that the Menogen Drugs are the "generic equivalent" of the Estratest Drugs, he informs prospective buyers of the drug's regulatory status. (Solvay's Facts, App. II, Tab 6 Runsdorf Dep. at 73, lines 2-7.) Given these facts, "generic equivalence" cannot mean FDA equivalence but must mean chemical equivalence.

c. The Chemical Equivalence Dispute

Having determined that chemical equivalence is the proper standard, the Court must determine whether Breckenridge's advertisement that the drugs are generically equivalent, *i.e.*, that they are chemically equivalent, is true or false. Solvay argues that the statement is literally false because the Estratest Drugs contain two 17 ∝ compounds

absent from the Menogen Drugs, and because the two drugs dissolve at a different rate. Breckenridge argues that the statement is literally true because Solvay has not shown that the 17 ∝ compounds are active ingredients or that the different dissolution rates are significant. Furthermore, the two drugs have the same PDR description and their ingredients satisfy the USP monograph.

Although Solvay has shown that the 17 ∝ compounds exist and that the drugs dissolve at different rates, Solvay has not shown that these differences have any effect. Solvay's expert, Dr. Rogerio Lobo, states that Solvay's tests confirm "the esterified estrogens USP used in the MENOGEN products does *not* contain the same active ingredients as the esterified estrogens USP used in the ESTRATEST® product, thus confirming that the two manufacturers' products are not 'chemical equivalents,'" (Lobo Decl. ¶ 8) (emphasis in original). Yet, Solvay points to no evidence which suggests that the supposedly "active ingredients" have any effect. Solvay's other expert, Dr. Scott Washburn, admits that "the full effect of these hormones in the human body is unknown" and that "it cannot be said for sure what all the effects of these estrogenic substances may be in the uterus." (Solvay's Reply, Exh. A ¶ 5.)

Solvay likewise has not shown that the different disintegration and dissolution rates play any role in the effectiveness of the Estratest or Menogen Drugs. According to Dr. Lobo, "[s]uch differences could affect the bioavalability of the two drugs." (*Id.* ¶

10.b.) Dr. Washburn avers that, "[w]ithout specific clinical testing, none of these adverse effects can be ruled out." (Solvay's Reply, Exh. A ¶ 5.)[9] At the summary judgment stage, the Court assumes that all the evidence has been submitted. Solvay's evidence is insufficient to carry its summary judgment burden of showing that the drugs contain different active ingredients.

Breckenridge has demonstrated that the drugs are chemically equivalent, *i.e.*, that they contain the same active ingredients. It is true that meeting the USP does not in itself show that the drugs are equivalent. *See AHP v. Chelsea Laboratories*, 572 F. Supp. 278, 279 (D.N.J. 1982) (considering Premarin and observing that not all drugs with same U.S.P. grade are entitled to be substituted), *aff'd*, 722 F.2d 730 (3d Cir. 1983). *See also United States v. An Article of Drug Ova II*, 414 F. Supp. 660, 661 (D.N.J. 1975) (for many of the articles in USP the question whether they are 'safe' and 'effective' cannot be answered directly but will depend on having first considerably more information), *aff'd*, 535 F.2d 1248 (3d Cir. 1976). These cases are distinguishable because they consider USP in the context of FDA regulated drugs only. In this case, there are no FDA requirements. Breckenridge has complied with every commercial description which

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[9] Solvay's main bone of contention with Breckenridge seems to be that "a claim that the ESTRATEST® and the MENOGEN Products are generically equivalent should not be made until such time as well controlled testing has been completed." (Solvay's Reply, Exh. A ¶ 6). In a non-FDA regulated world where "generic equivalence" does not mean FDA "generic equivalence," Solvay cannot prevail on this ground.

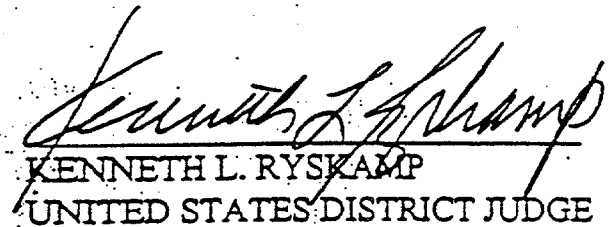
Solvay gave regarding the Estratest Drugs, and Solvay has not shown that the differences between the Estratest and the Menogen Drugs are significant. Based upon the evidence, the Court will grant Breckenridge's motion for summary judgment on the false advertising claim and deny Solvay's motion.

III. CONCLUSION

Having considered the motions and the pertinent portions of the record, it is

ORDERED AND ADJUDGED that Solvay's motion for summary judgment [DE-97] is DENIED and that Breckenridge's cross-motion for summary judgment [DE-104] is GRANTED.

DONE AND ORDERED in Chambers at West Palm Beach, Florida, this 18 day of March, 1998.



KENNETH L. RYSKAMP
UNITED STATES DISTRICT JUDGE

copies provided:

Richard Allen
Lisa K. Bennett
Rod S. Berman
L. Norwood Jameson
Ronald B. Ravikoff

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 97-8417-CIV-RYSKAMP

FLORIDA BRECKENRIDGE, INC.,
d/b/a BRECKENRIDGE
PHARMACEUTICAL, INC.,

CLOSED CASE

Plaintiff and Counterclaim Defendant,

vs.

FINAL JUDGMENT

SOLVAY PHARMACEUTICALS, INC.,

Defendant and Counterclaim Plaintiff,

vs.

NAPEAN ENTERPRISES, INC.,

Counterclaim Defendant.

FILED by D.C.
MAR 18 1998
CARLOS JULIANI
CLERK, U.S. DIST. CT.
S.D. OF FLA. - W.P.B.

THIS CAUSE comes before the Court *sua sponte*. Considering the Court's Order granting Florida Breckenridge's motion for summary judgment and denying Solvay's motion for summary judgment, an entry of final judgment is appropriate. The Clerk of the Court shall CLOSE the case and DENY all pending motions as MOOT.

THE Court has considered the pertinent portions of the record, and being otherwise fully advised, it is hereby

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

ORDERED AND ADJUDGED that final judgement is hereby entered on behalf of the Plaintiff/Counterclaim Defendant in accordance with Fed. R. Civ. P. 58 and 79(a). The Court reserves jurisdiction to consider a motion to tax costs and attorney's fees.

DONE AND ORDERED in Chambers at West Palm Beach, Florida, this 18 day of March, 1998.

KENNETH L. RYSKAMP
UNITED STATES DISTRICT JUDGE

copies provided:

Richard Allen
Lisa K. Bennett
Rod S. Berman
L. Norwood Jameson
Ronald B. Ravikoff

FLORIDA BRECKENRIDGE, INC. d.b.a. Breckenridge Pharmaceutical, Inc., Plaintiff-Counterclaim-Defendant-Appellee,
v.
SOLVAY PHARMACEUTICALS, INC., a Georgia corporation, Defendant-Counterclaim-Plaintiff-Appellant,

No. 98-4606.

United States Court of Appeals,
Eleventh Circuit.

May 11, 1999.

Editor's Note: The opinion of the United States Court of Appeals, Eleventh Circuit, in Florida Breckenridge v. Solvay Pharmaceuticals, published in the advance sheet at this citation, 174 F.3d 1227, was withdrawn from the bound volume at the request of the court.

L. Norwood Jameson, Savita N. Krishna, Christian S. Genetski, King & Spalding, Atlanta, GA, Thomas Meeks, Zuckerman, Spaeder, Goldstein, Taylor & Kolker LLP, Miami, FL, H. Thomas Byron III, Civil Division, Department of Justice, Washington, DC, for Defendant-Counterclaim-Plaintiff-Appellant.

Lisa K. Bennett, Stearns, Weaver, Miller, Weissler, Alhadeff & Sitterson Pa, Ft. Lauderdale, FL, Susan Allison, Jeffer, Mangels, Butler & Marmaro LLP, Los Angeles, CA, for Plaintiff-Counterclaim-Defendant-Appellee.

Appeal from the United States District Court for the Southern District of Florida.

Before COX and BARKETT, Circuit Judges, and FAY, Senior Circuit Judge.

BY THE COURT:

*1 Solvay Pharmaceuticals, Inc. ("Solvay") has marketed Estratest, a hormone replacement drug, for well over thirty years. In the spring of 1997, Florida Breckenridge, Inc. and Napean Enterprises, Inc. (collectively, "Breckenridge") introduced a drug, Menogen, that purported to be a generic equivalent to Estratest. After receiving notice that Solvay believed that Breckenridge was infringing on its trade rights, Breckenridge filed this action for a declaratory judgment that the manufacture, sale and marketing of Menogen did not constitute trade dress infringement or false advertising under the Lanham Act. Solvay then counterclaimed for trade dress infringement and false advertising under the Lanham Act, as well as under Florida statutory and common law of unfair trade practices. Following discovery, both parties moved for summary judgment. The district court denied Solvay's motion and granted summary judgment for Breckenridge. After Solvay filed notice of appeal, both parties submitted briefs and the United States filed an amicus curiae brief to address errors in the district court's order that the government felt needed to be corrected. Both parties and the government presented oral argument before this Court, and were requested to file supplemental briefs. Shortly before the deadline for Solvay to file its brief, it instead filed a motion to dismiss its case with prejudice. Breckenridge responded by requesting attorneys' fees and costs pursuant to Fed.R.App.P. 38, arguing that Solvay's appeal was frivolous. We grant Solvay's motion to dismiss with prejudice, but because of the conduct of the attorneys for both parties before the district court and this Court, we raise, sua sponte, whether this conduct merits referral to our court disciplinary committee for review.

I. BACKGROUND

A. The Regulatory Framework

Since 1938, the Food, Drug, and Cosmetic Act ("FDCA") has required drug companies to get pre-approval by the FDA before they could lawfully market their new drugs. In order to get approval, a company merely had to file a New Drug Application ("NDA") or an Abbreviated New Drug Application ("ANDA") and prove that their product was safe. In 1962, the FDCA was amended to require proof that the product was effective as well as safe. Congress made this new efficacy requirement retroactive to apply to all drugs that already had approved NDAs based on safety. The companies producing these drugs were given a two year window to submit revisions of their NDAs to prove

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their efficacy. In order to facilitate the efficacy evaluations of these drugs, the FDA set up the Drug Efficacy Study Implementation ("DESI") program. Under this program, groups of drugs with approved NDAs were evaluated by an independent panel. If the panel found that the drugs met a certain standard for efficacy, the evidence was submitted to the FDA. If the FDA concurred with the DESI determination, a notice was published in the federal register and a supplemental NDA would be approved for these drugs. Under the FDCA, all drugs are new drugs and therefore require an approved NDA or ANDA before marketing unless they are generally recognized among experts as safe and effective for their labeled use (the "GRASE" exception) or are grandfathered. 21 U.S.C. § 321(p)(1); Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 613, 93 S.Ct. 2469, 2475, 37 L.Ed.2d 207 (1973).

*2 By its terms, the DESI program applied only to drugs that already had approved NDAs as of 1962. In conjunction with the DESI program, the FDA developed a policy whereby drugs that were identical, similar or related ("ISR drugs") to an approved drug in the DESI review program could "piggy-back" off of the DESI review by submitting an ANDA after the DESI review established the efficacy of the pioneer drug. For a time, FDA policy allowed a drug manufacturer to market an ISR drug after filing, but before approval of an ISR drug's ANDA. This policy was challenged in court and overturned in 1975. Hoffmann-Laroche, Inc. v. Weinberger, 425 F.Supp. 890, 894 (D.D.C.1975)("[T]he Court holds that the FDA's policy of permitting new drugs to be marketed without an approved new drug application contravenes the clear statutory requirement of preclearance mandated by 21 U.S.C. § 355."). In response to this case, the FDA published a revision to its policy guidelines that "clarified" the agency's position. CPG 7132c.02, which Breckenridge submitted as an appendix to its brief, reads in part:

> The agency has decided to reaffirm that all products marketed as drugs under the DESI program are new drugs, and therefore, require an approved NDA or ANDA for marketing. In view of the reaffirmation of this policy, the agency must proceed to remove from the market all current DESI-effective prescription products that are not subjects of approved NDA's or ANDA's, and to prevent in the future the marketing of such unapproved products.

FDA Compliance Policy Guidelines § 440.100 (emphasis added). This policy guideline document goes on to create priorities for the removal of unapproved drugs from the market. According to the FDA, there were so many unapproved drugs on the market that they needed to establish a triage system: "Considering the magnitude of the problem, the limitation on FDA's resources, and the resulting long time period before compliance can be fully attained, the agency has developed a strategy to handle unapproved products on a priority basis." Id. In stunning testament to the efficiency of the FDA's strategy, this policy is still in effect today because twenty-four years later, and thirty-six years after the 1962 amendments to the FDCA, there are still thousands of these unapproved drugs on the market. One of these drugs is Estratest, produced by Solvay.

B. Solvay Markets the Estratest Drug

Although the record contains conflicting dates, Solvay began marketing its Estratest drug in 1964 at the earliest. Estratest is a hormone supplement, consisting of esterified estrogens and methyltestosterone, that is widely prescribed to women who are suffering from the physical symptoms associated with menopause and who do not obtain relief from estrogen therapy alone. At the time of Estratest's entry into the marketplace, Solvay did not have, nor has it ever had over the past thirty-five years, an NDA or ANDA approved by the FDA. Obviously, Estratest could not have been directly subject to DESI review because it was not marketed, nor was it the subject of an approved NDA based on its safety, before the 1962 amendments to the FDCA became effective.

*3 As part of the DESI process, a study evaluated the efficacy of a class of drugs that combined estrogens and androgens. The drugs under review all had approved NDAs from before 1962. None of these drugs contained Estratest's combination of esterified estrogens and methyltestosterone. The drugs were evaluated in a published notice, DESI 7661. On November 22, 1972, as noted in the correspondence log submitted by Solvay in their reply brief, Solvay's predecessor corporation contacted the FDA to determine whether Estratest could be considered ISR under the DESI 7661 notice. After an undescribed response from the FDA, there is a gap in the log until a letter from the

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FDA in July of 1979, which indicates that the FDA notified Solvay that Estratest was under legal review and that temporarily no action relating to the NDA requirement would be taken but that any continued marketing of Estratest was at Solvay's risk. Since that time and to this date, Solvay, while continuing to market Estratest, has been trying to get approval of NDAs for Estratest, but has gotten a series of not-approvable letters.

C. Breckenridge Enters the Market

In the spring of 1997, Breckenridge introduced a drug, Menogen, into the marketplace. This drug contained esterified estrogens and methyltestosterone in the same dosages as Estratest and was marketed as the generic equivalent of Estratest. Breckenridge did not obtain approval of an NDA or ANDA before marketing Menogen, and has not obtained approval to this date. Breckenridge relies on Solvay's contention that Estratest is legally on the market without approval to extend also to Menogen. Shortly after Breckenridge began marketing Menogen, they received notification from Solvay that they believed Menogen infringed on Estratest's trade dress and that the generic equivalency claims constituted false advertising. In response, Breckenridge filed this suit for a declaratory judgment that their marketing of Menogen did not infringe the Estratest trade dress or constitute false advertising under the Lanham Act. Solvay counterclaimed, asserting claims for trade dress infringement and false advertising under the Lanham Act, the Florida Deceptive and Unfair Trade Practices Act and common law unfair competition law.

After discovery, both parties moved for summary judgment. The district court granted summary judgment for Breckenridge. On the trade dress infringement claim, the court held that no reasonable fact-finder could find a likelihood of confusion as to source between Estratest and Menogen. On the false advertising claim, the court held that because both parties were allowed on the market without FDA approval, the false advertising analysis was not governed by the FDA regulations regarding generic drugs and that in this world of non-regulated pharmaceuticals, a lower standard of equivalence was sufficient to render Breckenridge's claims literally true.

Solvay appealed the summary judgment to this Court, arguing that the district court erred in its likelihood of confusion analysis and that drugs allowed on the market without FDA approval should still be subject to the FDA equivalency standards for advertised claims of generic equivalency. After Solvay filed its initial brief, the Department of Justice and the FDA filed an amicus curiae brief to address what they perceived as errors in the district court's opinion regarding the regulatory status of Estratest and Menogen and the resulting use of a different equivalency standard for generic drugs than is specified in the FDCA and FDA regulations. The government pointed out that the FDA's position is that neither drug is lawfully on the market because both require an approved NDA or ANDA before they may be legally sold, raising the point that unclean hands might bar either party from benefitting from trade law protection. The government did not explain why the FDA failed, for well over thirty years, to enforce the law and remove Estratest from the market. In response to the government's brief, both Solvay and Breckenridge harshly criticized the government for not reading the record, claiming that neither party ever told the court that they weren't subject to FDA regulation. Both parties continued to maintain, however, that although regulated they were not subject to FDA approval.

*4 At oral argument, both parties continued to assert that they were lawfully on the market, although they could not articulate consistent or specific reasons why. [FN1] They claimed to be surprised by the issue, claiming that it was never raised before the district court. At the end of oral argument, both parties agreed to submit supplemental briefs on the issue of whether protection was available under the Lanham Act for drugs sold in violation of the FDCA. Instead, two days before their supplemental brief was due, Solvay filed this motion to dismiss their appeal with prejudice. Breckenridge responded by requesting sanctions for a frivolous appeal pursuant to Fed.R.App.P. 38, and in the process executed a head-snapping reversal of position regarding Solvay's representations to the district court about Estratest's regulatory status. They did not, however, oppose Solvay's motion to dismiss.

FN1. The parties may have been attempting to argue that, because it declined to order Solvay to remove Estratest from the market and instead

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warned Solvay that continuing to market Estratest was "at its own risk," the FDA's behavior amounted to a waiver of sorts. We need not reach the merits of this argument, because, among other reasons, it was never clearly raised before the district court or before us. Instead, the parties misrepresented the facts to both courts, arguing that neither Estratest nor Menogen needed FDA approval.

II. ANALYSIS

It seems obvious to this Court that this last-moment motion to dismiss, after the completion of oral arguments and without a settlement agreement, resulted from Solvay's realization that it was caught misrepresenting Estratest's regulatory status and wishes to avoid a published opinion that would alert the world to its misdeeds. This case comes right up to the line where the interests of justice would require us to deny Solvay's motion. See Shellman v. United States Lines, Inc., 528 F.2d 675, 678 (9th Cir.1975). Especially in light of the fact that the motion is unopposed, we will grant it. In our supervisory capacity, however, we feel that we must review the attorneys' conduct before this Court and the district court and determine whether a disciplinary referral is appropriate. [FN2] Careful review of the record has uncovered a pattern of conduct by both parties' attorneys designed to mislead and confuse the court regarding the regulatory status of Estratest and Menogen. Unfortunately, we must remind these attorneys that they are officers of the court. As such, they "owe duties of complete candor and primary loyalty to the court before which they practice." Malautea v. Suzuki Motor Co., 987 F.2d 1536, 1546 (11th Cir.1993). These duties are never subservient to a lawyer's duty to advocate zealously for his or her client. In this case, the attorneys for both parties have frustrated the system of justice, which depends on their candor and loyalty to the court, because they wanted to avoid an unpleasant truth about their clients' conduct. "In short, they have sold out to the client." Id., at 1547.

FN2. Although this order focuses on the conduct of the attorneys for Solvay and Breckenridge, we note that the FDA is also due a share of criticism. It is incomprehensible that Estratest has been allowed on the market without approval for thirty-five years. It seems reasonable that most patients undergoing treatment for menopause fairly assume that any medication freely available and prescribed by their doctor has been proven safe and effective to the satisfaction of the FDA. They have a right to expect that the laws, as passed by Congress to protect them, are being enforced. To this date, Estratest has failed to satisfy the FDA that it is safe or effective as required by the FDCA, and yet the FDA has taken no action to remove the drug from the market. We are accustomed to hearing arguments in situations like this bemoaning scarce governmental resources and the like, but there can be no good excuse for allowing a company to violate the law for thirty-five years. If the drug is not safe or effective enough to be approved, thirty-five years seems like sufficient time to get around to taking some action. Certainly, Solvay was on notice that they were violating the law, and the FDA's inaction in no way excuses Solvay's conduct, but neither does Solvay's notice excuse the FDA's inaction.

Normally, this sort of conduct is caught before it can do much harm by the adversarial nature of our system of justice. In this case, however, the adversarial parties both had an interest in hiding the fact that they needed FDA approval from the court. In Solvay's case, admitting that Estratest was not legally on the market would be fatal to their claims because the Lanham Act only protects parties engaged in lawful commerce. Erva Pharmaceuticals, Inc. v. American Cyanamid Co., 755 F.Supp. 36, 39-40 (D.P.R.1991)(applying federal trademark law to equivalent state unfair competition statute and holding that party who shipped pharmaceutical in violation of the FDCA did not have standing to sue for trademark infringement); Clorox Co. v. Armour- Dial, Inc., 214 U.S.P.Q. 850, 851, 1982 WL 50434 (T.T.A.B.1982)("It has been the consistent position of this Board and the policy of the Patent and Trademark Office that a 'use in commerce' means a 'lawful use in commerce', and the shipment of goods in violation of federal statute, including the Food, Drug and Cosmetic Act, may not be recognized as the basis for establishing trademark rights."). This fundamental rule predates the Lanham Act, and would apply to Solvay's common law claims, as well. Knights of the Ku Klux Klan v. Strayer, 34 F.2d 432, 434 (3rd Cir.1929)(affirming dismissal of case brought by K.K.K. against former members who were using the Klan's trademark, because Klan was using the mark while conducting unlawful activities). [FN3]

FN3. This issue was to have been addressed by the

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parties' supplemental briefs. Instead, Solvay filed its motion to dismiss, thereby seeking to avoid what could very well have been an adverse ruling.

*5 Likewise, Breckenridge had an interest in hiding the FDCA violations from the court. Since this litigation began, the FDA has taken action against Breckenridge for, among other things, marketing Menogen without FDA approval. [FN4] Naturally, they would like to avoid making any admissions in this case. Furthermore, Breckenridge based its entire defense to the false advertising claim on the theory that there is a segment of the pharmaceutical market that is not subject to FDA approval, and that these drugs should be subject to a less stringent equivalency standard for the purposes of advertising generic equivalency. This theory is entirely dependent on misleading the court into believing that neither Estratest nor Menogen require FDA approval.

FN4. Once again, we are baffled as to why the FDA decided to go after the generic manufacturer, which had been marketing the drug for approximately one year, while ignoring Solvay's violations, which had been ongoing for thirty-five years. If we understand the government's argument, Breckenridge had violated other provisions of the FDCA, which made the enforcement action more urgent. Nonetheless, this seems insufficient to explain an enforcement differential of thirty-four years.

As discussed above, we believe that there is no magical exception that allows Solvay or Breckenridge to opt out of the FDA approval process. As the government's brief points out, both Estratest and Menogen are "new drugs" under the FDCA and require approved NDAs or ANDAs before they may be lawfully marketed. Because both parties had incentive to avoid addressing this threshold issue, the attorneys on both sides actively attempted to mislead and confuse the district court and this Court regarding the regulatory status of both drugs.

A. District Court Proceedings

Despite both parties' assertions that the effect of Estratest's regulatory status on Solvay's claims was not before the district court, review of the record reveals that the court was intensely interested in why the drugs were sold without FDA approval. The fact that the court did not specifically address the legal effect of the unapproved sale of Estratest is unsurprising, given that the attorneys misled the court into thinking that their clients did not need approval. It is only because of the attorneys' misconduct that the issue was not directly addressed.

Prior to the summary judgment motions, there were two hearings before Judge Ryskamp at which the attorneys successfully confused and misled the court. On several separate occasions, Judge Ryskamp inquired about why neither drug needed FDA approval. When confronted with these questions, the attorneys either changed the subject without answering or gave a vague explanation claiming that for historical reasons the drugs were either not subject to FDA regulation or did not require FDA approval.

At a hearing on January 15, 1997, L. Norwood Jameson, attorney for Solvay, made the following excerpted statements in response to questions from the judge regarding Estratest's regulatory status:

"Besides, these are not approved or these are not subject to FDA regulation ..."

"It is that this drug [referring to Menogen] is not technically subject to FDA regulation. We can't help that this drug is not subject to FDA regulation, because quite frankly, if it was, there is no chance that their drug would be on the marketplace today."

At the same hearing, Susan Allison, attorney for Florida Breckenridge, made the following statements:

*6 "It's a historical anomaly, but these are not approved drugs and they are not required to be approved drugs."

"It's a historical. That takes the too much time to explain, your honor, but basically for historical reasons, they are allowed on the market at this time without FDA approval."

"That's true, but basically it is a regulatory, historical regulatory issue as to why Estratest is not approved, but as a result, Menogen doesn't have to be literally approved either. That's the situation we are in. We are in an exception, an exceptional case, your Honor."

There can be no question as to whether the attorneys knew that they were confusing the court. Besides the repeated questions about FDA approval, the judge stated, "It just seems strange to me--it does require a doctor's prescription, but apparently it may be so simple it doesn't require FDA

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examination. I don't know why the FDA is involved in it."

At a later hearing, on June 25, 1997, Mr. Jameson made the following statements:

"There are certain exceptions to that rule [referring to FDA approval] and this case falls within that exception."

"Quite frankly, I found it mind boggling when I got involved in this litigation that in fact a company could come on to the marketplace and sell a drug that has not been approved by the FDA, but in fact that can happen. There are certain situations when that can happen and that's what's going on right here."

" ... is that the drugs at issue, okay, the Menogen drug at issue, they don't have to have FDA approval to have it in the marketplace."

Jameson also introduced a colleague he described as an FDA law specialist to bolster his assertions. This specialist, Mr. Howard, said, "Estratest, your Honor, was introduced back in 1966. At that time, it was shortly after the Food and Drug Act [sic] had been substantially revised by Congress and in that context, Estratest was introduced without going through the NDA approval process. Estratest today remains a product that is permitted on the market without prior NDA approval." Once again, there is ample evidence that the attorneys' misrepresentations effectively confused the court. Judge Ryskamp stated, "[I]f I am hearing you correctly, neither one is FDA approved and neither one has been tested by the FDA, and yet it sounds, if I understand Solvay's argument correctly, they say well, we may be grandfathered in because we made this long before certain regulation were in effect, but now there are new regulations that affect the competitor but not us."

The attorneys effectively misled Judge Ryskamp into believing that Estratest's legal status had been established under a grandfather provision that caused them not to be regulated by the FDA. As previously discussed, there is no possibly valid legal argument that would make this characterization true. Both parties admit that they are not subject to the grandfather provisions of the FDCA, and both drugs were introduced after the 1962 amendments. The judge clearly relied on the attorney's representations, and, in fact, based his decision on the false advertising claims on these misrepresentations.

B. Circuit Court Proceedings

*7 In their briefs, the parties continued to make the general assertion that they were allowed on the market without approval. After the government filed its amicus brief, pointing out that both products were marketed unlawfully and that the attorneys had misrepresented the drugs' regulatory status, both parties responded by misrepresenting their own conduct at the trial level. Breckenridge accused the government of not reading any portion of the record below and of fabricating its charge, claiming that neither party ever represented to the court that the drugs were not subject to FDA regulation: "[N]either Solvay nor Breckenridge ever referred to Menogen or Estratest as 'unregulated.' " Solvay then jumped on the government-bashing bandwagon, claiming that "neither party made any such representation," and claiming to be "perplexed by the district court's statement that the drugs were not 'regulated' by the FDA." These assertions are outrageous. As quoted above, Mr. Jameson specifically told the court on two occasions that the drugs were "not subject to FDA regulation." Such mischaracterizations of the record are particularly egregious, considering that both attorneys made them while accusing the government of lying about the record.

At oral argument, the misconduct continued. Jameson first argued that Estratest was lawfully on the market as a direct result of the DESI review process. Jameson's statements give the impression that Estratest, itself, was subject to DESI review. It was not. As discussed above, Estratest was not even on the market in 1962, nor did it ever have an approved NDA. Further, his description of the purpose of DESI as being to examine drugs on the marketplace to see if they should remain on the marketplace is very misleading. The purpose was to examine drugs already approved as safe by the FDA, and to help drug companies provide the FDA with an evaluation of their efficacy. Estratest has never, to this date, been approved by the FDA as safe or effective. Jameson further misled the Court by characterizing the DESI process as an "alternative to the 'formal' approval process." In fact, there are no alternatives to the "formal" approval process for DESI or ISR drugs. All DESI and ISR drugs are "new drugs" under the FDCA and require approval of an NDA or ANDA before

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lawful marketing. FDA Compliance Policy Guidelines § 440.100; United States v. Hiland, 909 F.2d 1114, 1126 (8th Cir.1990). DESI never operates as an alternative to such approval. The falsity of this characterization is further proved by the fact that, subsequent to the publication of the DESI 7661 notice, Solvay filed an ANDA in an attempt to get approval and was warned by the FDA that marketing of the drug was at Solvay's risk. Jameson knew this--the information is all in papers that he appended to his reply brief as evidence that FDA knew that Estratest was on the market.

After realizing that this Court would not be so easily bamboozled, Jameson attempted to refine his argument, arguing that the DESI review somehow operated as conclusive proof that Estratest falls under an exception under the FDCA known as the GRASE exception. Because we dismiss this appeal, we are precluded from ruling definitively on this claim. However, our review of the law, at this stage, points to the conclusion that it is wholly without merit.

*8 If a drug is generally recognized among qualified experts as safe and effective, it is not a new drug under the FDCA and therefore does not need an NDA. 21 U.S.C. § 321(p)(1); Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 613, 93 S.Ct. 2469, 2475, 37 L.Ed.2d 207 (1973). However, GRASE is a term of art, and the Supreme Court has explained that it really is not much of an exception because it requires at least the same exacting proof that NDA approval requires. Hynson, 412 U.S. at 629, 93 S.Ct. 2469 ("We agree with FDA, however, that the statutory scheme and overriding purpose of the 1962 amendments compel the conclusion that the hurdle of 'general recognition' of effectiveness requires at least 'substantial evidence' of effectiveness for approval of an NDA."). Furthermore, GRASE cannot be construed to provide a way to evade the regulatory process by allowing a firm that has repeatedly failed to gain approval of an existing NDA to opt out of the approval process. Id., at 631, 93 S.Ct. 2469 ("But, we cannot construe [the GRASE exception] to deprive the FDA of jurisdiction over a drug which, if subject to FDA regulation, could not be marketed because it had not passed the 'substantial evidence' test. To do so 'would be to impute to Congress a purpose to paralyze with one hand what it sought to promote with the other.' "). Consequently, it would appear that Estratest cannot satisfy the GRASE exception.

Finally, Jameson argued that the FDA's failure to take action to remove them from the market proves that they are GRASE. Obviously, this is nonsense. Courts have already held that the FDA policy of deferring the removal of ISR drugs from the marketplace is not a defense, even to criminal prosecution for marketing a new drug without an approved NDA. Hiland, 909 F.2d at 1125-27. In order to fall under the GRASE exception, a drug must meet requirements at least as stringent as those for NDA approval. Solvay has continually failed to obtain approval based on the evidence it has provided the FDA. They may not, then, circumvent the approval process merely by marketing their drug in defiance of the FDA for thirty-five years. Solvay has been attempting to get approval of its ANDA/NDA for 27 years, and has gotten a continual stream of not-approvable letters. The very fact that they are seeking approval indicates that they do not honestly believe that they fall under the GRASE exception. Furthermore, the exception cannot be used to succeed where the FDA screening process has specifically denied approval. This would pervert the statute, as the Supreme Court noted. Finally, even if Estratest could be said to now, in 1999, to have gained GRASE status, that status would not retroactively render the past thirty-five years of illegal marketing lawful.

After oral argument, Solvay filed this motion to dismiss its appeal with prejudice, pursuant to Fed.R.App.P. 42(b). The motion gave no reason for the dismissal. In response, Breckenridge filed a request for sanctions pursuant to Fed.R.App.P. 38, arguing that the sudden, last-minute request for dismissal confirmed that the appeal was frivolous. In contrast to the fervent and accusatory denial in their brief, suddenly Breckenridge complains that they were prejudiced because of various affirmative misrepresentations that Solvay made to the court regarding Estratest's regulatory status. They even, most helpfully, quote one of Mr. Jameson's claims to the district court that the drugs are not subject to FDA regulation. As a reminder, this is one of those claims that Breckenridge previously insisted was never made. According to Breckenridge, Solvay's continuous misrepresentations kept a frivolous appeal going and forced Breckenridge to defend it. Breckenridge's sudden dismay over the

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misrepresentations brings to mind Captain Renault from Casablanca (Metro-Goldwyn-Mayer 1942) who, in the midst of collecting his nightly winnings, closed Rick's Cafe down because he was "shocked; shocked to find that gambling is going on here!" It is quite bad enough that Breckenridge cooperated with Solvay in misleading the Court; it is offensive that they now complain they were prejudiced by the very misrepresentations that they aided and abetted.

III. CONCLUSION

*9 During the course of this litigation, Mr. Jameson and Ms. Allison (and by extension their respective law firms, King & Spalding and Jeffer, Mangels, Butler & Marmaro) engaged in a pattern of practice designed to mislead and confuse the court regarding the regulatory status of their clients's drugs. Although we grant the unopposed motion, we are referring this matter to the disciplinary committee of this Court for further consideration.

Appellant's motion to dismiss this appeal with prejudice is GRANTED.

Appellee's motion for damages pursuant to Fed.R.App.P. 38 is DENIED.

REFERRED to the disciplinary committee.

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