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PETITION FOR STAY OF ACTION

On November 14, 2005, Medi-Flex, Inc. ("Medi-Flex") submitted a Citizen Petition asking that FDA refrain from approving ANDA No. 77-271 filed by Cardinal Health, Inc. ("Cardinal") because it seems that Cardinal is seeking to circumvent Medi-Flex's three-year exclusivity and patents. Now, Medi-Flex submits this Petition for a Stay of Action under 21 C.F.R. § 10.35 to request that the Commissioner of Food and Drugs stay approval of Cardinal's ANDA No. 77-271 until FDA rules on Medi-Flex's Citizen Petition (Docket No. 2005P-0458) (the "Citizen Petition"). As approval of ANDA 77-271 appears to be imminent, Medi-Flex respectfully requests that FDA respond to this Petition for Stay of Action by January 20, 2006 so that Medi-Flex may seek judicial relief if necessary.

I. DECISION INVOLVED

The decision involved is FDA's approval of ANDA No. 77-271, which was submitted by Cardinal for a generic version of Medi-Flex's ChlorPrep® with Tint (chlorhexidine gluconate 2% and isopropyl alcohol 70%).

II. ACTION REQUESTED

Medi-Flex requests that FDA stay approval of Cardinal's ANDA 77-271 until FDA rules on Medi-Flex's Citizen Petition (Docket No. 2005P-0458), which is incorporated herein by reference. In particular, Medi-Flex has recently obtained information indicating that Cardinal is

2005P-0458

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seeking to circumvent Medi-Flex's three-year exclusivity and patents associated with ChloroPrep® with Tint by relying on the wrong reference listed drug ("RLD") and by certifying to the wrong patents. Accordingly, Medi-Flex submitted its Citizen Petition requesting that FDA: (1) refrain from approving ANDA 77-271 until the applicable three-year exclusivity for the product expires on May 3, 2008; and (2) require ANDA 77-271 to rely on the appropriate RLD, which is ChloroPrep® with Tint, and to provide certifications for the patents listed with respect to that RLD. Medi-Flex now believes that final approval of Cardinal's ANDA is imminent. It thus asks that FDA stay approval of the ANDA until FDA rules on Medi-Flex's Citizen Petition. Due to the important issues involved in this matter and the imminent approval of ANDA 77-271, Medi-Flex respectfully requests that FDA respond to this Petition for Stay of Action by January 20, 2006.

As detailed in the Citizen Petition, Medi-Flex only recently became aware of Cardinal's ANDA and the underlying issues. Immediately upon learning about the ANDA, Medi-Flex contacted Cardinal to obtain more details about the facts and to obtain a resolution to the issues. Unfortunately, Cardinal has been unwilling to provide Medi-Flex with any additional information. Nor has Cardinal made any effort to resolve these important issues. Consequently, Medi-Flex believes that it had no choice but to submit its Citizen Petition and Petition for Stay of Action.

III. STATEMENT OF GROUNDS

A. Background

Medi-Flex is a small, privately owned company that was founded in 1985.¹ A significant portion of Medi-Flex's revenue is derived from two over-the-counter products containing the combination of active ingredients chlorhexidine gluconate 2% and isopropyl alcohol 70%. Declaration of James R. Majerle ("Majerle Decl.") ¶ 2 (Tab 1). These products, which are delivered by a topical sponge, are broad spectrum antiseptics used for preparing a patient's skin before surgery. Medi-Flex is the only company on the market with products approved by FDA containing this combination of ingredients and strength. *Id.*

Medi-Flex's first product, ChloroPrep® One-Step (chlorhexidine gluconate 2%, isopropyl alcohol 70%), was approved under NDA 20-832 on July 14, 2000. It was designated by FDA as the RLD for generic applications. This product is available in the following applicator volumes: 1.5 ml, 3.0 ml, and 10.5 ml. There are no Hatch-Waxman Act market exclusivity periods associated with this product; however, there are several patents listed for the product in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations 25th Ed.* (2005) (the "Orange Book").

¹ The founder of Medi-Flex, Mr. Joseph Brandmeyer, recently won the Ernst & Young Entrepreneur of the Year® Award for the Central Midwest region in the medical products category. Medi-Flex Press Release (July 7, 2005) (Tab 2). This award recognizes "outstanding entrepreneurs who are building and leading dynamic and growing businesses." *Id.*

Although ChloroPrep® One-Step is a very effective product, Medi-Flex developed a second product with several improvements. The second product is ChloroPrep® with Tint (chlorhexidine gluconate 2%, isopropyl alcohol 70%) in a 26 ml applicator volume. Importantly, ChloroPrep® with Tint contains an additional tint ingredient, FD&C Green No. 3. This tint colors the product so that the user may quickly determine previously treated areas. Furthermore, ChloroPrep® with Tint has an applicator volume of 26 ml, more than double the volume of the previous applicator. Medi-Flex submitted the new tint product to FDA for approval under supplemental NDA 20-832/S-008.

FDA required Medi-Flex to conduct numerous clinical trials over several years to prove that ChloroPrep® with Tint is safe and effective. In particular, FDA was concerned that the tint ingredient could affect efficacy. Consequently, FDA required Medi-Flex to conduct a clinical trial examining bacterial reductions achieved with the new tinted product against the old, untinted product. Medi-Flex invested about \$120,000 to perform this clinical trial, which conclusively demonstrated that the addition of a tint ingredient does not affect efficacy. Majerle Decl. ¶ 5. FDA also required Medi-Flex to conduct several clinical trials establishing that the 26 ml volume is safe. Specifically, FDA was concerned that the increased volume contains a sufficient amount of alcohol that could cause harm to a patient if accidentally ignited. Medi-Flex's safety studies, which cost approximately \$75,000, demonstrated that the 26 ml volume is safe. *Id.*

In light of Medi-Flex's successful clinical trials supporting the new tinted product, FDA approved ChloroPrep® with Tint in a 26 ml applicator volume on May 3, 2005.² FDA designated ChloroPrep® with Tint as the RLD for generic products containing tint and a 26 ml volume. Due to the essential clinical trials involving the tint ingredient and increased applicator volume, ChloroPrep® with Tint received three years of Hatch-Waxman market exclusivity, which expires May 3, 2008. In addition to three-year exclusivity, there are four patents listed in the Orange Book for ChloroPrep® with Tint. Three of these listed patents are also listed with respect to ChloroPrep® One-Step. However, one patent is specifically directed to the tint ingredient (the "Tint Patent") and is listed only with respect to ChloroPrep® with Tint.³

Though marketed for only a short period of time, ChloroPrep® with Tint is already one of Medi-Flex's flagship products. In fact, Medi-Flex anticipates that 59% of its anticipated growth in 2006 will be due to ChloroPrep® with Tint. Majerle Decl. ¶ 10. Based on the anticipated growth, Medi-Flex moved into a new 360,000 square foot manufacturing, packaging, and laboratory facility to support the production of ChloroPrep® with Tint. *Id.*

Medi-Flex has recently obtained information indicating that Cardinal is seeking approval of a generic ChloroPrep® with Tint product despite the three-year exclusivity and without certifying to the appropriate patents, including the Tint Patent. Specifically, Medi-Flex believes that Cardinal is deliberately using the untinted ChloroPrep® One-Step as the RLD for its tinted

² In addition to the 26 ml volume, Medi-Flex is currently pursuing approval of a 10.5 ml volume.

³ U.S. Patent No. 6,729,786 is directed to the approved dosage form containing a tint ingredient.

generic product, instead of the appropriate ChloroPrep® with Tint, to avoid the three-year exclusivity and patents associated with ChloroPrep® with Tint.

As noted in a recent press release, Cardinal is the leading provider of products and services supporting the health care industry.⁴ Not only does Cardinal have annual revenue of \$75 billion and employ over 55,000 people worldwide, but it recently ranked 16th on the Fortune 500 list. Importantly, Cardinal is a major distributor of ChloroPrep® with Tint for Medi-Flex. Approximately 34% of Medi-Flex's business is from the sales of ChloroPrep® products by Cardinal. Majerle Decl. ¶ 12. Despite this relationship, Cardinal appears to be seeking approval of its own generic version of ChloroPrep® with Tint.

On November 18, 2004, Cardinal submitted a Suitability Petition to the FDA seeking permission to file an ANDA for a generic product containing chlorhexidine gluconate 2% and isopropyl alcohol 70% with tint, FD&C Red No. 40, in a 26 ml applicator volume. The Suitability Petition, which was filed before ChloroPrep® with Tint had been approved, stated that Cardinal's ANDA for the generic tint product would use the untinted ChloroPrep® One-Step as the RLD. Furthermore, the Suitability Petition stated that the generic tint product would be based on Cardinal's ANDA 77-271. It is unclear whether FDA granted Cardinal's Suitability Petition for a generic tint product.

On September 13, 2005, well after ChloroPrep® with Tint had been approved and was available as an RLD, Cardinal sent Medi-Flex a letter.⁵ The letter reported that Cardinal had filed ANDA 77-271 for a generic chlorhexidine gluconate and isopropyl alcohol product using ChloroPrep® One-Step as the RLD. The letter also indicated that Cardinal had filed paragraph IV certifications for all of the patents listed in the Orange Book with respect to ChloroPrep® One-Step. Cardinal did not provide a certification for the Tint Patent, which is listed only for ChloroPrep® with Tint.

Medi-Flex replied to Cardinal on September 19, 2005. That letter was followed by several telephone calls, all of which sought to determine whether Cardinal's ANDA covers a generic product with tint and which sought to resolve any outstanding exclusivity and patent issues. Unfortunately, Cardinal has not cooperated and has provided no additional information. Rather, Cardinal simply sent a letter to Medi-Flex stating that Cardinal now withdrew its paragraph IV certifications. The letter provided no other information.

Based on the available facts, Medi-Flex believes that Cardinal's ANDA 77-271 seeks approval of a generic product with tint in a 26 ml applicator, and that Cardinal's ANDA inappropriately relies on the untinted ChloroPrep® One-Step in a 10.5 ml applicator as the RLD to circumvent the three-year exclusivity and patents associated with the appropriate RLD, ChloroPrep® with Tint. Accordingly, Medi-Flex submitted its Citizen Petition requesting that

⁴ Cardinal Press Release, Cardinal Health First-Quarter Results Reflect Strong Demand, Continued Earnings Improvement, PRNewswire (October 26, 2005) ("Cardinal Press Release") at 1, 4 (Tab 3).

⁵ Cardinal previously attempted to send that letter to Medi-Flex on August 29, 2005; however, the letter was sent to the wrong address.

FDA: (1) refrain from approving Cardinal's ANDA until the applicable three-year exclusivity for the product expires; and (2) require Cardinal to rely on the appropriate RLD, ChloroPrep® with Tint, and to provide certifications for the patents listed with respect to that RLD.

Medi-Flex now believes that FDA may approve Cardinal's ANDA in the near future. In particular, Medi-Flex believes that Cardinal may receive approval for its ANDA as early as January 2006. Accordingly, Medi-Flex submits this Petition for Stay of Action requesting that FDA stay approval of Cardinal's ANDA until FDA rules on Medi-Flex's Citizen Petition.

B. Argument

Under 21 C.F.R. § 10.35, FDA is required to grant a petition for a stay of action if: (1) the petitioner will otherwise suffer irreparable injury; (2) the petitioner's case is not frivolous and is being pursued in good faith; (3) the petitioner has demonstrated sound public policy grounds supporting the stay; and (4) the delay resulting from the stay is not outweighed by public health or other public interests. Furthermore, FDA's regulation also authorizes FDA to grant a discretionary stay of action "if it is in the public interest and the interest of justice." *Id.* As detailed below, FDA should grant Medi-Flex's request for a stay of action.

1. Medi-Flex Will Suffer Irreparable Injury Without the Stay

Medi-Flex will suffer irreparable injury if FDA were to deny this request for a stay and allow Cardinal to go to market during Medi-Flex's three-year exclusivity period. Medi-Flex is a small, privately owned company whose main products include its ChloroPrep® line, such as ChloroPrep® One- Step and ChloroPrep® with Tint. ChloroPrep® with Tint represents a significant part of Medi-Flex's revenue and is growing rapidly. Majerle Decl. ¶ 10. In fact, Medi-Flex anticipates that 59% of its growth in 2006 will be from the sale of ChloroPrep® with Tint. *Id.* Based on that anticipated growth, Medi-Flex recently invested in a new 360,000 square foot manufacturing, packaging, and laboratory facility. *Id.*

If Cardinal's generic version of ChloroPrep® with Tint were approved, Medi-Flex's market position would likely collapse within a very short period of time. *Id.* ¶ 11. Cardinal is the leading provider of products and services supporting the health care industry.⁶ It has annual revenue of \$75 billion and employs over 55,000 people worldwide. Recently, Cardinal ranked 16th on the Fortune 500 list. Importantly, Cardinal is a major distributor of Medi-Flex's ChloroPrep® with Tint. Approximately 34% of Medi-Flex's business is from the sales of ChloroPrep® products by Cardinal. Majerle Decl. ¶ 12. Thus, Cardinal already has an established marketing network for this product and directly controls a significant portion of Medi-Flex's sales.

Cardinal's large size and current business relationships with Medi-Flex's customers compound the injury to Medi-Flex and will allow Cardinal to take a significant share of the market extremely quickly. Medi-Flex predicts, once Cardinal goes to market, that Medi-Flex will lose all of Cardinal's business and potentially as much as 80% of its total projected business.

⁶ Cardinal Press Release at 1, 4.

Id. A study of generic competition by the U.S. Congressional Budget Office showed that “generic copies quickly gain a large share of the market” and may take over 65% of the market.⁷ Additionally, Medi-Flex would likely lose its reputation and customer goodwill when its major distributor, Cardinal, starts selling a different product.

These injuries would have a direct and incalculable impact on Medi-Flex’s operational activities. Medi-Flex is relying on the anticipated demand and revenue from Chloraprep® with Tint to support its new manufacturing facility. Obviously, a substantial reduction in market share would threaten that facility. *Majerle Decl.* ¶ 13. Additionally, Medi-Flex would not be able to invest the lost revenue in new research and development activities, which are critical to the future success of Medi-Flex. *Id.* The founder of Medi-Flex, Mr. Joseph Brandmeyer, worked hard over many years to build Medi-Flex into a successful company. In fact, as noted, he was recently named Entrepreneur of the Year® by Ernst & Young for the Central Midwest region in the medical products category. To allow Cardinal to go market during Medi-Flex’s exclusivity period would cause irreparable injury to Medi-Flex and devastate this small success story. *Id.* ¶ 14.

Courts in the District of Columbia Circuit have consistently found irreparable injury when a pharmaceutical company’s statutory exclusivity period or “head start” would be deprived, particularly when the company is small. In *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998), the court upheld a preliminary injunction prohibiting FDA from approving any ANDA until Mova’s six-month statutory period of exclusivity had expired. As the court noted, “the district court found that Mova would be harmed by the loss of its ‘officially sanctioned head start,’ and that Mova’s small size put it at a particular disadvantage. This suffices to show severe economic impact to Mova.” *Id.* at 1067 n. 6.

Additionally, in *CollaGenex Pharms., Inc. v. Thompson*, 2003 U.S. Dist. LEXIS 12523 (D.D.C. 2003) (Tab 5), the court granted CollaGenex’s request for a preliminary injunction prohibiting FDA from approving any ANDA for CollaGenex’s brand product, Periostat®. In concluding that CollaGenex would suffer irreparable injury if a generic entered the market, the court noted that CollaGenex depends on Periostat® for 80% of its revenue and that a generic product can obtain 91% conversion within weeks of entering the market. *Id.* at *31-32. According to the court:

It is not at all difficult to foresee that CollaGenex’s market position would collapse as soon as one or more generic drugs became available. CollaGenex would lose its head start in the market and its continued viability would be at issue Its David-and-Goliath size comparison to Mutual could make competition between the two a very uneven match.

Id. at *33. Similarly, there is a presumption of irreparable injury in patent law to protect the market exclusivity period afforded by a patent. As explained by one court, “The nature of the patent grant thus weighs against holding that monetary damages will always suffice to make the

⁷ The Congress of the United States, Congressional Budget Office, *A CBO Study: How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998) at 28 (relevant portion attached at Tab 4).

patentee whole, for the principal value of a patent is its statutory right to exclude.” *H.H. Robertson, Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 390 (Fed. Cir. 1987).

Allowing Cardinal to enter the market with a generic ChloroPrep® with Tint product would severely undercut the “head start” Medi-Flex derives from the statutory three-year exclusivity period it earned. Majerle Decl. ¶ 14. Medi-Flex’s exclusivity period expires May 3, 2008. Unless FDA were to extend that exclusivity period, every day that Cardinal would be on the market during that period would cause irreparable harm to Medi-Flex. *See Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 29 (D.D.C. 1997) (“there is a significant economic advantage to receiving first approval and being the first company to enter the market, an advantage that can never be fully recouped through money damages or by ‘playing catch-up’” (citations omitted) (emphasis added)).

Even if Medi-Flex’s damages are considered purely economic, the damages would be irreparable because Medi-Flex would never recoup its losses. *See Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (economic harm may qualify as irreparable if the monetary loss is not recoverable). Medi-Flex could not recoup its losses from FDA because FDA is immune from paying damages. *See CollaGenex*, 2003 U.S. Dist. LEXIS at *33 (“It could never recoup from FDA any losses that would occur.”). Additionally, Cardinal might not be liable to Medi-Flex for any damages because Cardinal would be marketing pursuant to FDA approval. Importantly, at this point Medi-Flex has no other avenue for recovery that could be used to recoup its losses.

2. Medi-Flex’s Case is Not Frivolous and is Being Pursued in Good Faith

Medi-Flex believes that its case against Cardinal is strong and intends to pursue these issues vigorously. Medi-Flex is currently the only company on the market with a product containing chlorhexidine gluconate 2% and isopropyl alcohol 70% with tint in a 26 ml volume. Majerle Decl. ¶ 2. Medi-Flex invested substantial resources to bring ChloroPrep® with Tint to market. *Id.* ¶ 5. To obtain approval, FDA required numerous clinical trials over several years. In particular, Medi-Flex invested about \$120,000 to perform a trial demonstrating that the addition of a tint ingredient does not affect efficacy. Furthermore, Medi-Flex conducted several clinical trials, at a cost of approximately \$75,000, establishing that the 26 ml volume is safe. As a result of Medi-Flex’s successful clinical trials, ChloroPrep® with Tint received three-years of Hatch-Waxman market exclusivity. Despite the market exclusivity, Cardinal appears to be seeking approval of a generic version of ChloroPrep® with Tint. For the reasons detailed in Medi-Flex’s Citizen Petition, Medi-Flex strongly believes that FDA should not approve Cardinal’s ANDA 77-271 for a generic version of ChloroPrep® with Tint until the three-year exclusivity period for such a product has expired on May 3, 2008.

Furthermore, Cardinal appears to be trying to end-run Medi-Flex’s exclusivity and patent protection by referencing the wrong RLD and by certifying to the wrong patents. Cardinal’s ANDA for a generic tinted product in a 26 ml applicator relies on ChloroPrep® One-Step, which is untinted and uses a 10.5 ml applicator, as its RLD. The FDA has designated ChloroPrep® with Tint as the RLD for generic products containing tint and a 26 ml volume. As such, Medi-Flex believes that Cardinal should use ChloroPrep® with Tint as its RLD. By relying on ChloroPrep® One-Step as its RLD, Cardinal is circumventing those patents listed with

ChlorPrep® with Tint, including the Tint Patent. So far, Cardinal appears to be trying to make an end-run around the Tint Patent, which is the patent most likely to cover Cardinal's generic product. Medi-Flex firmly believes that FDA should not allow such a tactic to succeed.

Additionally, Medi-Flex is pursuing its case in good faith. Medi-Flex only recently became aware of Cardinal's ANDA and the related issues. Immediately upon learning about Cardinal's ANDA, Medi-Flex contacted Cardinal to obtain more details about the facts and to obtain a resolution to the issues. Unfortunately, Cardinal has been unwilling to provide Medi-Flex with any additional information. Nor has Cardinal made any effort to resolve these important issues. Consequently, Medi-Flex believes that it had no choice but to submit its Citizen Petition and Petition for Stay of Action.

3. Sound Public Policy Grounds Support the Stay

There are several strong policy reasons that support the stay. Importantly, FDA should not reward Cardinal's apparent gamesmanship. As described in detail above and in the Citizen Petition, Cardinal seems to be trying to end-run Medi-Flex's exclusivity and patent protection by referencing the wrong RLD and by certifying to the wrong patents. In particular, Cardinal appears to be avoiding Medi-Flex's Tint Patent. FDA has clearly stated that an ANDA applicant should not circumvent patent protection through its choice of RLD. *See* Citizen Petition, Tab 8 at 9 n. 13 ("It should not circumvent the patents on the tablet by citing the capsule as the reference listed drug and filing a suitability petition . . . seeking to change to a tablet dosage form.") To discourage such tactics, FDA should grant Medi-Flex's request for a stay.

In addition, Congress specifically provided a drug approval scheme that includes exclusivity periods for new drug innovations. These exclusivity periods induce companies to invest the substantial resources necessary to develop new drugs and other innovations. As the *CollaGenex* court stated, "the barriers to competition that Congress has erected are in the public interest because they encourage the development of innovative drugs by ensuring a period of market exclusivity." *CollaGenex*, 2003 U.S. Dist. LEXIS at *35. FDA should not undermine the public interest in these exclusivity periods by violating Medi-Flex's three-year exclusivity period. Companies must be able to rely on FDA to uphold the integrity of the market exclusivity periods, or those periods will cease to provide the encouragement that Congress intended.

Furthermore, if the stay is not granted, FDA will probably have to withdraw Cardinal's product from the market when the Citizen Petition is ultimately decided. If FDA denies the stay, Cardinal will likely go to market as soon as possible. However, as detailed in Medi-Flex's Citizen Petition, Cardinal should not receive approval until May 3, 2008. Thus, when the Citizen Petition is ruled upon, it is likely that Cardinal's approval will need to be withdrawn. As withdrawal of a drug product from the market creates confusion and potential safety risks, as well as significant regulatory issues, it is in the public interest to stay approval of Cardinal's ANDA until the Citizen Petition is decided.

4. Delay From the Stay is Not Outweighed by Public Health or Other Public Interests

The public health or other public interests do not outweigh the delay resulting from the requested stay. Importantly, there is an ample supply of preoperative antiseptic products

currently on the market to serve the public health need.⁸ While there may be a public interest in having access to generic products, that interest does not outweigh the public interest in the faithful application of the laws. *See Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 131 (D.D.C. 1997) (“the public interest in faithful application of the statutes outweighs the public interest in . . . the availability of low cost generic drug products”), *aff’d*, 140 F.3d 1060 (D.C. Cir. 1998). Additionally, there is a public interest in allowing Medi-Flex to continue its research and drug development activities, which would otherwise be curtailed if the stay were not granted.

5. Discretionary Stay

In addition to a mandatory stay, FDA’s regulations authorize FDA to issue a discretionary stay if “it is in the public interest and the interest of justice.” 21 C.F.R. § 10.35(e). For the reasons detailed above, Medi-Flex believes that staying approval of Cardinal’s ANDA 77-271 until the issues presented in Medi-Flex’s Citizen Petition are decided would serve both the public interest and the interest of justice. Accordingly, even if FDA determines that the requirements for a mandatory stay are not met, FDA should issue a discretionary stay.

C. Conclusion

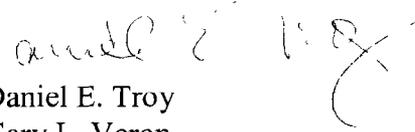
In summary, Medi-Flex believes that Cardinal is seeking approval of a generic version of Medi-Flex’s ChloraPrep® with Tint (chlorhexidine gluconate 2%, isopropyl alcohol 70%) despite the three-year exclusivity for such product. Medi-Flex also believes that Cardinal is attempting to circumvent patent protection for that product, such as the Tint Patent, by relying on the wrong RLD. Accordingly, Medi-Flex filed a Citizen Petition with the FDA shortly after learning about Cardinal’s ANDA requesting that FDA: (1) refrain from approving Cardinal’s ANDA until Medi-Flex’s three-year exclusivity expires on May 3, 2008; and (2) require Cardinal to use the correct RLD and to certify the relevant patents. Medi-Flex now believes that approval of Cardinal’s ANDA is imminent and requests that FDA stay approval of Cardinal’s ANDA until FDA rules on Medi-Flex’s Citizen Petition.

Medi-Flex will suffer irreparable injury if FDA does not stay approval of Cardinal’s ANDA. Medi-Flex, which is a small company, would have no remedy if Cardinal is allowed to enter the market during Medi-Flex’s market exclusivity period. Additionally, Medi-Flex’s case is not frivolous. To the contrary, Medi-Flex has a very strong case and is not pursuing this matter in bad faith. Furthermore, sound public policy grounds support the stay, including discouraging gamesmanship of the drug approval process and protecting the integrity of the statutory exclusivity periods that encourage drug development. Finally, the delay from the stay

⁸ In fact, Cardinal already markets several preoperative antiseptic products under the trade name Prevail® (povidone iodine and alcohol).

would not be outweighed by public health or other public interests. As such, FDA should grant Medi-Flex's request for a stay of approval of Cardinal's ANDA 77-271.

Respectfully submitted,



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