



SOLVAY PHARMACEUTICALS

September 27, 2007

1382 7 SEP 28 18:09

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Prevention of False and Misleading Labeling & Promotion of Safe and Efficacious Use of Dronabinol

Dear Food and Drug Administration:

CITIZEN PETITION

The undersigned submits this petition under the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. §§ 355, 352, and 321, and the Food and Drug Administration's (FDA) implementing regulations, 21 C.F.R. § 10.30, to request the Commissioner of Food and Drugs to (1) prevent false and misleading labeling and (2) ensure safe and efficacious use of dronabinol, in each case, by requiring abbreviated new drug applications (ANDAs) for generic versions of MARINOL to contain the indication and important safety information for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional treatments *and* the indication and important safety information for the treatment of appetite loss associated with weight loss in patients with AIDS.

A. Action Requested

This petition is respectfully submitted by Unimed Pharmaceuticals, Inc. (Unimed), a wholly-owned subsidiary of Solvay Pharmaceuticals, Inc. (Solvay). Solvay is a research driven group of companies that seeks to fulfill carefully selected, unmet medical needs in the

2007P-0363

CP1

therapeutic areas of neuroscience, cardiometabolic, influenza vaccines, gastroenterology, and men's and women's health.

Unimed requests that the Commissioner (1) prevent false and misleading labeling and (2) ensure the safe and efficacious use of dronabinol, in each case, by requiring ANDAs for generic versions of MARINOL to contain the indication and important safety information for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional treatments (CINV Indication) *and* the indication and important safety information for the treatment of appetite loss associated with weight loss in patients with AIDS (AIDS Indication).

Unimed has reason to believe that one or more ANDAs seeking approval for a generic version of MARINOL have been filed containing solely the CINV Indication. If approved, these generic products will be substituted for MARINOL under state pharmacy laws when prescribed for the AIDS Indication. The generic product, however, will have neither the prescribing information nor the patient information leaflet created specifically for the AIDS Indication. Without such labeling, the generic product (1) will be misbranded because the labeling will not provide material information necessary for a "customary or usual" use of the generic drug, namely, as an appetite stimulant in AIDS patients and (2) will be unable to adequately promote the safe and effective use of dronabinol in AIDS patients.

B. Statement of Grounds

Background

MARINOL is approved in the United States for two separate indications: the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to

respond adequately to conventional treatments (the CINV Indication) and the treatment of appetite loss associated with weight loss in patients with AIDS (the AIDS Indication). MARINOL is marketed by Unimed and has annual U.S. sales of approximately \$145 million. The active ingredient in MARINOL is dronabinol, a synthetic version of a naturally occurring compound known as delta-9-tetrahydrocannabinol (delta-9-THC). Delta-9-THC is an endogenous chemical component of the marijuana plant, *Cannabis sativa L.*

MARINOL was a product of the cooperation between Unimed and the National Cancer Institute, which conducted clinical research on dronabinol for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. FDA approved Unimed's new drug application (NDA) for MARINOL for the CINV Indication in 1985. This indication is no longer afforded any patent protection or market exclusivity.

In 1991, dronabinol received orphan drug designation for appetite loss associated with weight loss in patients with AIDS. Unimed received supplemental NDA approval for MARINOL's AIDS Indication in December 1992. The quantity of MARINOL dispensed for the AIDS Indication represents the largest market segment, with AIDS patients being approximately two-thirds of the MARINOL market in terms of prescriptions (based on IMS Health Incorporated data – July 2006 to June 2007).

The AIDS Indication is afforded patent protection under U.S. Patent No. 6,703,418 (the '418 patent), which does not expire until February 26, 2011. The '418 patent has been listed in FDA's *Orange Book* in connection with MARINOL at all relevant times.

Unimed has anticipated potential generic competition for MARINOL for a number of years and has long assumed that it would receive one or more notices of a Paragraph IV certification (pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)) alleging invalidity and/or non-infringement of the `418 patent. Unimed, however, has not received any such notices. Recently, Unimed became aware that potential ANDA sponsors for generic versions of MARINOL may choose not to challenge the `418 patent; rather, ANDA sponsors may choose to include “(viii) statements” (pursuant to 21 U.S.C. § 355(j)(2)(A)(viii)) in their ANDAs with regard to the `418 patent, indicating that they do not seek approval for the AIDS Indication and seek to “carve out” all labeling directed to that use. Unimed believes that the labeling for a generic MARINOL product with the AIDS Indication “carved-out” would be misleading, resulting in a product that will be less safe and effective for patients. This concern, coupled with the fact that Unimed still has not received any Paragraph IV certifications, led to the filing of this petition.

1) Labeling For a Generic Version of MARINOL without the AIDS Indication Will Be Misleading

As a threshold matter, Unimed does not challenge FDA’s *general* authority to approve a generic drug with “carved out” labeling and acknowledges that FDA’s authority to do so has been upheld generally by the courts. *See Sigma-Tau Pharmaceuticals, Inc. v. Schwetz*, 288 F.3d 141 (4th Cir. 2002); *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493 (D.C. Cir. 1996). Unimed also acknowledges that FDA “does not regulate...the possible substitution of a generic drug for the pioneer drug by doctors or pharmacists.” *Bristol-Myers Squibb*, 91 F.3d at 1496 (citations omitted).

Rather, as discussed herein, Unimed's contention is that, with regard to MARINOL, *in particular*, FDA should require a generic version of MARINOL to contain the AIDS Indication and important related safety information. To not require this would cause the product and patient labeling to be misleading and in violation of sections 352(a) and 321(n) of the FD&C Act. This argument is not foreclosed by the decisions in the *Bristol-Myers Squibb* and *Sigma-Tau* cases. In both cases, the issue before the court was whether FDA's approval of a generic product with exclusivity-protected labeling "carved out" was consistent with the ANDA approval provisions of the FD&C Act in 21 U.S.C. § 355(j). In both cases, there was no discussion of false and misleading labeling or FD&C Act sections 352(a) and 321(n).

FDA's authority to approve a generic product with "carved out" labeling must be read in conjunction with the provisions of the FD&C Act, taken as a whole. In particular, it must be read in conjunction with 21 U.S.C. § 352(a), which states that a drug is deemed misbranded if its labeling is "false or misleading in any particular."

Regarding "misleading," the FD&C Act provides:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made by or suggested by statement, word, design, device, or any combination thereof, but also the extent to which *the labeling* or advertising *fails to reveal facts material* in light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof *or under such conditions of use as are customary or usual*.

21 U.S.C. § 321(n) (emphasis added).

The statutory language of section 321(n) is clear. If a product's labeling fails to reveal material facts concerning the consequences that may result from use of the product under customary or usual conditions of use, the product's labeling is misleading and thus the product is misbranded.

Due to the substantially different daily dose, timing of administration, duration of treatment, and likelihood of CNS adverse effects for the AIDS Indication as opposed to the CINV Indication, MARINOL labeling with information concerning the AIDS Indication "carved out" would fail to reveal material facts concerning the consequences that may result from the use of MARINOL (hereinafter discussed).

Furthermore, there is no need to speculate about what the "customary or usual" use of a generic version of MARINOL will be. As a matter of state formulary laws and despite the "carve out," it is certain that the generic drug will be dispensed for use as an appetite stimulant for AIDS patients (as hereinafter discussed). As noted above, this use of MARINOL accounts for two-thirds of the patients for whom MARINOL is prescribed and is properly considered the drug's most "customary or usual" condition of use.

With regard to section 321(n), it is important to note that Congress used the word "or" to indicate that both the conditions of use prescribed in the labeling, as well as "such conditions of use as are customary or usual," must be examined separately. In addition, Regulation 21 C.F.R. § 201.5(a) makes explicit that, in determining the adequacy of a drug's directions for use, consideration must be given to not only the conditions set forth in labeling and advertising but also the "uses for which the drug is commonly used." Since the appetite stimulant use in AIDS patients constitutes approximately two-thirds of all prescriptions for MARINOL and a generic

version of MARINOL with “carved out” labeling will be substituted for MARINOL for this use under state pharmacy laws, there should be no doubt that the appetite stimulant use in AIDS patients will be a “customary or usual” condition of use for purposes of sections 352(a) and 321(n) of the FD&C Act.

This conclusion regarding “customary or usual” use is supported by FDA’s own interpretation in adopting its former rule to require drug sponsors to conduct pediatric clinical studies of drugs that are likely to have clinically significant use in pediatric patients, even if the drug is not labeled for pediatric use. In the preamble to FDA’s proposed rule, FDA explained that the agency may consider pediatric use to be “customary or usual” or “commonly used” where the drug is indicated for a disease or condition that affects both children and adults, and the drug is not contraindicated in pediatric patients. *See 62 Federal Register 43,900, 43,907-08 (Aug. 15, 1997)*. Subsequently, in the preamble to its final rule, FDA discussed at length its view that the uses for which a drug must be adequately labeled go beyond the uses explicitly included in the manufacturer’s labeling, and cited FD&C Act section 321(n) and 21 C.F.R. § 201.5 in support. *63 Federal Register 66,632, 66,657-58 (Dec. 2, 1998)*. Having articulated this rationale in the past, FDA cannot disavow it without a clear explanation of the policy basis for doing so. *See Motor Vehicle Manufacturers Association of the United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 57 (1983).¹

¹ Unimed acknowledges that FDA’s former pediatric studies rule was held invalid in *Association of American Physicians and Surgeons, Inc. v. U.S. Food and Drug Administration*, 226 F. Supp. 2d 204 (D.D.C. 2002). There, the district court held that FDA’s authority under provisions of the FD&C Act pertaining to drug labeling, including section 321(n), did not give the agency the authority to require drug sponsors to conduct studies. Importantly, however, nothing in the district court’s opinion undercut the agency’s interpretation that a drug’s customary or usual uses, even if not set forth in the product’s labeling, should be taken into account in determining whether the drug is properly labeled.

Unimed acknowledges that a generic manufacturer that files an ANDA that excludes the AIDS Indication and important safety information might do so in reliance upon the fact that a generic version of MARINOL will be a prescription drug and that, by regulation, such a generic manufacturer is therefore not required to provide patients with “adequate directions for use” of its drug, *see* 21 C.F.R. § 201.100. This argument, however, overlooks both important safety and efficacy implications to AIDS patients that will result and the manufacturer’s statutory obligation to provide labeling that is not misleading.

In *Pharmaceutical Manufacturers Association v. Food and Drug Administration*, 484 F. Supp. 1179 (D. Del. 1980), *affirmed per curiam*, 634 F.2d 106 (3d Cir. 1980), a number of medical associations and pharmaceutical industry trade associations challenged the validity of an FDA regulation that required manufacturers of estrogens-containing drug products to provide, and drug dispensers (such as physicians and pharmacists) to disseminate, a patient package insert each time the drug was dispensed or administered. FDA’s stated statutory authority for the challenged regulation included FD&C Act sections 352(a) and 321(n). The court upheld the validity of the FDA regulation. In so doing, the court flatly rejected plaintiffs’ assertion that section 352(a) “was never intended to apply to drugs dispensed on prescription.” 484 F. Supp. at 1184. As a result, despite 21 C.F.R. § 201.100, FD&C Act section 352(a) still applies to and, in fact, requires generic manufacturers to produce labeling that is not misleading.

2) Labeling For a Generic Version of MARINOL Must Contain the AIDS Indication & Important Safety Information to Ensure the Safe and Efficacious Use of Dronabinol

By regulation, FDA interprets the FD&C Act to allow an ANDA applicant to seek approval even though there are differences between the labeling of its proposed drug and the labeling of the reference product being copied “because the drug product and the reference listed drug are produced or distributed by different manufacturers or because aspects of the listed drug’s labeling are protected by patent, or by exclusivity, and such differences do not render the proposed product less safe or effective than the listed drug for all remaining, non-protected conditions of use.” 21 C.F.R. § 314.127(a)(7) (setting forth conditions when FDA can refuse to approve an ANDA). However, as FDA explained in its rulemaking preamble, the intended reach of this regulation is broader than the quoted regulatory text would suggest. In the preamble, FDA stated: “FDA cautions that it will not approve an ANDA with different labeling *if the labeling differences affect product safety or efficacy.*” 57 Fed. Reg. 17,950, 17,968 (Apr. 28, 1992) (emphasis added).

Here, the omission of the prescribing information for the AIDS Indication and the patient leaflet related to the AIDS Indication would certainly “affect” product safety or efficacy if the generic product is dispensed for use as an appetite stimulant in AIDS patients under state pharmacy laws. As discussed herein, omission of such information would present a real risk of medication errors due to improper dosage and usage. Thus, approval of a generic product with “carved out” labeling would be contrary to FDA’s intended interpretation of its own regulations.

FDA defines “medication error” as a “preventable event that may cause or lead to inappropriate medication use or patient harm while the medicine is in the control of a health care professional, patient, *or consumer.*” 68 Fed. Reg. 12,406 (May 14, 2003) (emphasis added). According to the National Academy of Sciences’ Institute of Medicine, 44,000 to 98,000

Americans die each year from preventable medical errors. See Tamar Nordenberg, "Make No Mistake: Medical Errors Can Be Deadly Serious," *FDA Consumer Magazine* (Sep.-Oct. 2000).

FDA has enhanced its efforts to reduce medication errors by dedicating more resources to drug safety, including the formation of the Division of Medication Errors and Technical Support (DMETS) in the Center for Drug Evaluation and Research. According to the former Director of DMETS, Jerry Phillips, R.Ph., FDA's goal is to "work to prevent medication errors before a drug reaches the market." See Michelle Meadows, "Strategies To Reduce Medication Errors: How The FDA Is Working To Improve Medication Safety And What You Can Do To Help," *FDA Consumer Magazine* (May-Jun. 2003). Approving generic versions of MARINOL without prescribing and patient information that is necessary for the safe and efficacious use of the drug in two-thirds of the users of the drug would not support the agency's stated goal. In fact, denying AIDS patients the benefit of this information would increase the risk of such preventable medication errors.

As indicated in the FDA-approved product labeling (prescribing information) (Exhibit A), the recommended dosing regimens for the two MARINOL indications are substantially different in terms of daily dose, timing of administration, and duration of treatment. As described in the "Individualization of Doses" and "Dosage and Administration" sections of the prescribing information, the recommended starting dosage for the CINV Indication is 5 mg/m², or 5 mg, given one to three hours prior to chemotherapy, then every two to four hours after chemotherapy, for a total of four to six times a day. *MARINOL prescribing information* The dose is titrated upward to achieve clinical response, with most patients responding to 5 mg three or four times daily. *MARINOL prescribing information* In contrast, the recommended initial

dosing for the AIDS Indication is 2.5 mg twice daily, before lunch and dinner, with upward titration to a maximum of 10 mg twice a day (20mg daily) or downward titration to 2.5 mg once daily, based upon tolerability of adverse effects. Thus, the daily dose for the CINV Indication could be two to sixteen times higher than for the AIDS indication.

The difference in daily dose between these populations reflects the very different needs of the two patient populations. In the case of CINV patients, MARINOL is used to treat side effects of chemotherapy over a short period of time, typically less than a week in clinical trials, in patients who are not usually functioning in their normal capacity (e.g., are on bed rest, limited activity, etc). For these patients MARINOL is administered at relatively high doses, at frequent intervals during the day (as much as six times daily) and titrated to achieve a clinical effect.

For AIDS patients, MARINOL is typically prescribed for a longer period of time (five weeks to one year in clinical trials). For these patients, MARINOL is administered at lower doses, less frequently (once or twice daily before meals) and titrated based on tolerability of adverse effects. The most common adverse effects of MARINOL are related to the central nervous system and include symptoms such as dizziness, euphoria, hallucinations, paranoid reactions, somnolence, and abnormal thinking. *MARINOL prescribing information* These adverse events may be less tolerated by, as well as more dangerous to, the patient over a long term treatment regimen used with AIDS patients. Therefore, explicit dosing instructions for physicians and safety information for patients is necessary for each of the two MARINOL indications in order to prevent inappropriate medication use and patient harm in the form of preventable or controllable adverse events.

In light of the dosing differences between the two indications for use and the increased danger of adverse events to patients prescribed MARINOL for the AIDS Indication, Unimed produces and disseminates patient labeling materials intended to promote the safe and effective use of MARINOL as an appetite stimulant by AIDS patients (Exhibit B). Specifically, a patient information leaflet addressing issues related to AIDS patients was part of the final approval package (final printed labeling) for the AIDS Indication submitted to the agency in 1993. Although there was no requirement for it to do so, Unimed felt that the importance of the leaflet to patients was significant enough for it to also produce a Spanish language version of the patient information leaflet. This allows Unimed to address the needs of minority AIDS patients that otherwise would not benefit from the information contained in the patient leaflet (Exhibit C). This Spanish version of the patient leaflet was submitted to FDA in a supplement to the MARINOL NDA and approved by FDA.

The patient leaflet is of critical importance because it consists of both drug-specific information and non-drug information relevant to AIDS patients that ensures and enhances the safety and efficacy of MARINOL. To eliminate any potential confusion and to maximize comprehension, statements are written in layman's terms. As a result, the patient leaflet provides a concise and understandable synopsis of the drug-specific and non-drug information relevant to AIDS patients that a layman would not be expected to take away from a reading of the FDA-approved prescribing information, which of course was never intended for the lay reader. Thus, the provision of this patient information enhances the safe and informed use of MARINOL by AIDS patients.

The drug-specific information in the patient leaflet is more than just a recitation of contraindications, warnings, and precautions. Rather, it contains short, factual statements regarding the issues that are material and of the greatest significance to AIDS patients. For AIDS patients, the length of treatment with MARINOL makes adverse effects a material issue of great significance. To address this issue, Unimed includes in its patient leaflet information regarding the adverse effects that could be expected, the best way to minimize or prevent such effects and how to prepare for them. It cannot be forgotten that MARINOL is a schedule III hallucinogenic substance (21 C.F.R. § 1308.13(g)). As such, it is included in a class of substances characterized by the ability to cause changes in a person's perception of reality. Persons using hallucinogenic drugs often report seeing images, hearing sounds, and feeling sensations that seem real but do not exist. *See National Institute on Drug Abuse, Research Report: Hallucinogens and Dissociative Drugs*, March 2001. Moreover, hallucinogens can produce physiological effects including elevated heart rate, increased blood pressure, and dilated pupils. *See Drug Enforcement Administration, Drug Descriptions: Hallucinogens*². Due to a much longer duration of treatment, AIDS patients are more likely than patients taking MARINOL for the CINV Indication to experience such effects. As a result, it is important to clearly communicate these potential adverse effects to patients prescribed MARINOL for the AIDS Indication to afford them with an opportunity to better prepare for and identify adverse effects and minimize the chance of inadvertent misuse of MARINOL.

The non-drug information in the patient leaflet is just as important as the drug-specific information to AIDS patients. This information goes beyond the prescribing information and

² *See* DEA Website <http://www.usdoj.gov/dea/concern/h.html>

gives a meaningful description of other health and lifestyle factors that may contribute to appetite loss associated with weight loss in patients with AIDS. For example, the patient leaflet gives specific, practical suggestions with regard to boosting a patient's food intake (e.g. eating cold foods in a pleasant atmosphere) and provides a list of "staple" foods that are high in calories and protein. As such, the patient leaflet provides information that helps AIDS patients supplement the appetite stimulation provided by MARINOL to assist them in overcoming physical conditions that may contribute to their loss of appetite.

The patient leaflet plays a significant role in promoting the safe and effective use of MARINOL and is one reason why the FDA approved these labeling materials. It is also why Unimed has taken measures to assure that the information contained in the patient leaflet has the best possible chance of reaching AIDS patients in need of it. For example, Unimed distributes 2.5 mg MARINOL – a strength intended primarily for AIDS patients – in "unit of use" packaging with the patient leaflet enclosed. The carton specifically notifies the dispensing pharmacist: "Patient Information Enclosed" and "Dispense Patient Insert with Prescription." These measures make it easier, and more likely, for pharmacists to disseminate the leaflet to patients. A generic MARINOL approved solely for the CINV Indication would not include the information contained in the patient leaflet when provided to a patient prescribed MARINOL for the AIDS Indication. In fact, the information that would be provided in the generic "prescribing information" would describe a dosing regimen that is two to sixteen times higher and twice to six times more frequent than would be appropriate for an AIDS patient with appetite loss. This would increase an otherwise preventable risk that may cause inappropriate medication use or patient harm.

Information in this section is supported by the opinion of Daniel H. Bowers, M.D. (Exhibit D). Dr. Bowers is a Senior Partner at Pacific Oaks Medical Group in Beverly Hills, California, where he specializes in the treatment and care of patients with AIDS.

3) Generic Versions of MARINOL Without Labeling On Use As An Appetite Stimulant In AIDS Patients Will Nevertheless Be Dispensed For That Use

The foregoing sections describe how the approval of a generic MARINOL product containing solely the CINV Indication would (1) create misleading labeling and (2) put at risk the safe and efficacious use of dronabinol. These arguments are predicated upon the substitution by pharmacists of generic MARINOL for the branded product when prescribed for the AIDS Indication.

As the agency is aware, the pharmacy laws and regulations of all states allow a pharmacist to dispense a generic in place of a brand name product when a prescription is written for the brand name product. In a number of states, a pharmacist *must* substitute a generic product for the brand drug product absent express direction from the physician or the patient not to substitute; in other states, substitution is more permissive. Moreover, many state Medicaid programs and most private insurance programs have generic substitution provisions that, at a minimum, strongly encourage generic substitution by virtue of their coverage, reimbursement, and co-payment policies.

State and private insurer generic substitution policies are often based, directly or indirectly, on FDA's *Orange Book*, and apply to generic products that are listed in the *Orange Book* as "therapeutically equivalent" to brand name products. Upon approval, a generic version

of MARINOL with information regarding the AIDS Indication “carved out” will nevertheless be rated as “therapeutically equivalent” (*i.e.*, “AB”) to MARINOL. In fact, there will be no way for a pharmacist to determine, based on the therapeutic equivalence rating in the *Orange Book*, that the generic product with “carved out” labeling has not been approved for the AIDS Indication. Thus, a pharmacist that relies, in whole or in part, on FDA’s *Orange Book* to determine the substitutability of a generic drug product for its brand name counterpart will have no way of ascertaining that a generic dronabinol product is not labeled for the AIDS Indication.

Thus, despite the labeling “carve out,” a generic version of MARINOL will frequently be dispensed for use as an appetite stimulant in AIDS patients. The operation of state pharmacy laws that will require or permit prescriptions for MARINOL used as an appetite stimulant to be filled with a generic version of the product not approved for this use makes this statement a certainty. *See Bristol-Meyers Squibb Co. v. Shalala*, 91 F.3d 1493, 1496 (D.D.C. 1996). This generic version of MARINOL will not contain the necessary patient information for the AIDS Indication. This will render the product misbranded and less safe and effective than it would be if such information was required to be included.

Conclusion

For the foregoing reasons, Unimed respectfully requests that the Commissioner prevent false and misleading labeling and ensure the safe and efficacious use of dronabinol by requiring ANDAs for a generic version of MARINOL to contain the CINV Indication and important safety information *and* the AIDS Indication and important safety information.

C. Environmental Impact

Pursuant to 21 C.F.R. § 25.31, an environmental impact statement is not required for this action.

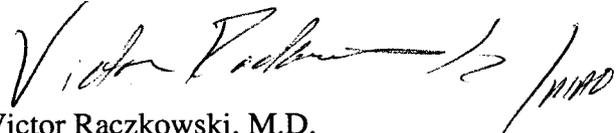
D. Economic Impact

Information on economic impact will be provided upon request.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

Respectfully submitted,



Victor Raczkowski, M.D.
Vice President, U.S. Regulatory Affairs

Enclosures

- A – MARINOL Prescribing Information
- B – MARINOL Patient Information Leaflet For AIDS Patients
- C – MARINOL Patient Information Leaflet For AIDS Patients
(Spanish language version)
- D – Letter From Dan Bowers, M.D.