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January 27, 2005

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**BY HAND DELIVERY AND ELECTRONIC MAIL**

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 2004P-0472: Citizen Petition Regarding Approval of ANDA 76-258 for Generic Fentanyl Transdermal System

Dear Sir or Madam:

Please file the attached document in Docket Number 2004P-0472.

Sincerely,

Andrew S. Krulwich
Counsel for Noven Pharmaceuticals, Inc.

cc: Gary J. Buehler, Director, Office of Generic Drugs
Gerald F. Masoudi, Acting Associate General Counsel/Chief Counsel
Elizabeth H. Dickinson, Associate Chief Counsel

DONALD R. JASINSKI, M.D.

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## STATEMENT OF DONALD R JASINSKI, MD

In December, 2004, Noven Pharmaceuticals, Inc. requested that I review the material submitted in the Brookhoff & Voth and Alza Citizen Petitions submitted to the FDA, requesting that it delay the approval of the generic versions of the Duragesic® transdermal fentanyl patch because of an alleged greater abuse potential than the already marketed Duragesic® patch. I reviewed the Citizen Petitions as well as Noven's comments to those Petitions and the available literature on abuse of the Duragesic® patch. A list of sources and references I reviewed is attached. These references were obtained from a presentation entitled "Considerations in abuse potential assessment of novel analgesic formulations" by Kenzie Preston, PhD in a symposium Prescription Drug Abuse: Quantifying the Risk of Diversion at the 2004 annual meeting of the American Society for Clinical Pharmacology and Therapeutics. Dr Preston could find no abuse potential studies of the Duragesic® patch but did find evidence that the patch was subverted for abuse through illegitimate access. I was consulted by Noven because of my experience in assessing abuse potential, as well as my familiarity with the abuse potential of matrix patch technology. A copy of my curriculum vitae is attached. This statement summarizes my opinion.

Fentanyl and fentanyl-containing preparations are in Schedule II of the Controlled Substances Act. As the Petitions make clear, the incidence of abuse of prescription fentanyl has been low compared to other Schedule II opioids. Despite this fact, the DEA reports instances of diversion and abuse of the Duragesic® patch across the country (NDIC *Narcotics Digest Weekly* 2004; 3(20):1). There is also a small number of literature reports of overdose and death associated with abuse of Duragesic® patches both by patients and non-patients. According to these sources, the patches have been abused transdermally, with and without the application of external heat, and by being licked and sucked. The reservoir has also been bitten into and the gel swallowed. The gel has been injected intravenously, smoked and applied to mucous membranes.

The purported higher abuse potential of the generic patch is attributed to the difference in structure from the Duragesic® patch. The Noven transdermal patch consists of a backing, a layer containing silicone and acrylic adhesives admixed with fentanyl, and a protective liner that is removed before use. The package insert for Duragesic® describes it as "1) a backing layer of polyester film; 2) a drug reservoir of fentanyl and alcohol USP gelled with hydroxyethyl cellulose; 3) an ethylene-vinyl acetate copolymer membrane that controls the rate of fentanyl delivery to the skin surface; and 4) a fentanyl-containing

silicone adhesive. Before use, a protective liner covering the adhesive layer is removed and discarded." The relative amounts of fentanyl in the silicone adhesive layer and in the reservoir of the Duragesic® patch are not publicly available. Despite the obvious differences between the two systems it should be pointed out that, from one viewpoint, the Duragesic® patch and the generic patches have great similarity of structure since both, in fact, deliver fentanyl from an adhesive matrix.

The following are considerations in evaluating the differences in the abuse potential of the Duragesic® and the generic matrix patch. Since the two patches are presumed to be bioequivalent in the delivery of fentanyl transdermally, and since the initial fentanyl is delivered from a matrix system in both cases, there should be no difference in abuse potential by the transdermal route with or without heat, or by sucking or licking the patches. Unlike the Duragesic® patch, the generic matrix patch lacks a reservoir from which fentanyl in solution can be mechanically extracted by biting, cutting or piercing so that fentanyl can be swallowed, placed on mucous membranes, injected or smoked. Both patches contain fentanyl in a silicone adhesive matrix, the Noven patch containing acrylic adhesive as well. Both should, naturally, be liable to extraction from the matrix. Interestingly, there are no reports of the fentanyl being extracted from the silicone matrix component of Duragesic® for purposes of abuse. In addition, both the Duragesic® and an adhesive matrix patch have been marketed in Europe where there are no reports of significant abuse of either patch.

Data are presented in the Alza Petition that compared chemical extraction of fentanyl from the Duragesic® patch and their matrix patch at room temperature over 200 minutes. They report more rapid and a greater percentage yield of fentanyl from the matrix patch than from the Duragesic® patch. This is, though, only to be expected, since the extraction would be primarily from the adhesive matrix in both patches. In this regard, it is important to note that only the raw yields are reported; the percentage of the fentanyl extracted as a fraction of the amount of fentanyl in each system's adhesive matrix is not given. Also, the study is stopped at 200 minutes, possibly less time than required for the transfer of fentanyl from the Duragesic® reservoir to begin. Finally, the Petition omits the point that the comparison of the relative speed of chemical extraction from the two formulations may not, strictly speaking, be considered relevant since fentanyl can be easily extracted mechanically from the Duragesic® patch.

It has been opined that the generic matrix patch has a significantly greater possibility of abuse than the Duragesic® patch because of the potential to divide the generic matrix patch into segments of various sizes that would allow better control of the dose for direct abuse or extraction and easier concealment. In this regard, the DEA has anecdotal reports of freezing the Duragesic® patches so that they can be divided prior to abuse, so it appears that this hypothetical technique for abuse could occur with either patch design.

It can be opined, in fact, that the generic matrix patch actually has some advantages over the Duragesic® patch in terms of abuse potential. Unlike the Duragesic® patch, fentanyl in an aqueous solution cannot be mechanically extracted from the matrix patch. Since most abuse reports with overdose and death occurred from the fentanyl in the reservoir,

the generic matrix patch could be argued to be safer and less liable to abuse. The fentanyl in the reservoir of the Duragesic® patch is available for immediate abuse by simple mechanical extraction, whereas the fentanyl in a matrix patch requires chemical extraction, a process at least potentially quite complicated if, indeed, the silicone and acrylic adhesives are extracted as well.

The Alza petition presents data from a study to measure attractiveness of particular opioid prescription products. It was concluded that the difference between the Duragesic® patch and the fentanyl matrix patch was "clinically significant". This implies that statistical significant differences could not be demonstrated. Likely, this reflects the small number of subjects tested. Also it is not clear that the subjects had actual or equal experience with each the various products that they were asked to rate. The utility of data of this type in predicting potential public health and social problems and abuse incidence is not demonstrated. Vicodin® (a combination of hydrocodone and acetaminophen) is rated equally to Avinza® in this data and at a level near the mean of all drugs. Hydrocodone acetaminophen combinations are the most widely diverted and abused prescription opioids.

In summary, both the Duragesic® patch and the generic matrix patch have theoretical abuse potential since both contain large amounts of fentanyl. It is important to note, however, that while being marketed simultaneously in Europe, these two patch types have not shown differential degrees of abuse. As potentially abusable systems, the Duragesic® patch is associated with ease of mechanical extraction of large and potentially lethal doses of fentanyl. With the matrix system there would be, potentially, easier dose control but more difficult chemical extraction. Thus, if this view is accepted, the matrix patch should be associated with fewer overdose deaths. When viewed from a multidimensional public health aspect rather than a one-dimensional aspect, it is my opinion that there is little evidence to indicate that the public health and social problems resulting from abuse of the generic matrix patch will be significantly greater than those already occurring with the Duragesic® patch.

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DeSio, J.M. et al., Intravenous abuse of transdermal fentanyl therapy in a chronic pain patient, *Anesthesiology*, 79, 1139, 1993.

**Donald R Jasinski, MD**

**January 26, 2004**

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BOOK SECTIONS AND REVIEWS:

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