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September 30, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 78N-0301 – External Analgesic Drug Products for Over-The-Counter Human Use; Reopening of the Administrative Record and Amendment of Tentative Final Monograph

Dear Sir/Madam:

U.S. Dermatologics, Inc. (U.S. Derm) submits the following comments on the Food and Drug Administration's (FDA's) amendment to the tentative final monograph (TFM) for over-the-counter (OTC) external analgesic drug products. The amendment would classify "all OTC external analgesic ingredients in a patch, plaster or poultice dosage form in Category III." 68 Fed. Reg. 12324, 12325-26 (July 17, 2003). U.S. Derm distributes an OTC external analgesic drug product that uses a polyurethane film foam laminate as the active ingredient's delivery platform. U.S. Derm's delivery platform does not incorporate active ingredients into adhesive allowing the delivery platform to remain non-occlusive. Accordingly, U.S. Derm requests the FDA acknowledge that U.S. Derm's patch would not be subject to the proposed ban on patch, plaster, and poultice dosage forms.

U.S. Derm provides a delivery platform for an ointment consisting of capsaicin and menthol. The delivery platform is not a transdermal delivery device. The delivery platform consists of a polyurethane film foam laminate that is breathable and non-occlusive (Appendix 1). The delivery platform allows water vapor and oxygen to pass to and from the skin's surface while at the same time prevents skin irritation. The ointment is situated on parallel stripes in the center of the delivery platform, and an adhesive covers the perimeter of the delivery platform. The adhesive (Appendix 2) does not overlap or otherwise come into contact with the ointment, and it does not cause adhesion in any area other than the periphery of the delivery platform. The central part of the delivery platform provides a breathable loose covering for the ointment.

The platform delivery system provides many advantages over conventional external analgesic ointments, including:

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- Uniform unit dosing of the drug in a pharmaceutical ointment.
- Long-acting, continuous application to the site of pain until the delivery platform is removed.
- No smearing of the drug or eye contamination, which can occur with creams and ointments applied directly to the skin.
- Reduction in skin irritation due to the use of non-occlusive/breathable technology.

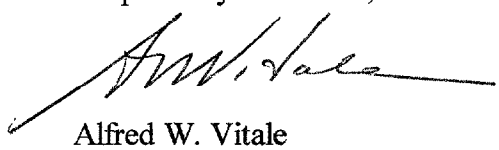
FDA is proposing to amend the TFM for OTC external analgesic drugs to prohibit counterirritant active drug ingredients "for use in a patch, plaster, or poultice dosage from." Id. at 42327 (proposed 21 C.F.R. § 348.2.12). FDA reasoned that "these dosage forms have not been determined to be generally recognized as safe and effective for any OTC external analgesic drug products at this time." Id. at 42326.

U.S. Derm's delivery platform product is unlike the patch, plaster, and poultice dosage forms that are the subject of the proposed amendment to the external analgesic TFM. U.S. Derm's delivery platform serves to deliver a measured amount of drug and does not have an occlusive effect, unlike the patch, plaster, and poultice dosage forms that are the subject of the proposed amendment. Thus, although U.S. Derm's delivery platform is a "patch" in the terms of shape and configuration, it is not a traditional "patch" in that it does not incorporate active ingredients into adhesive and does not have an occlusive effect.

Accordingly, U.S. Derm requests that FDA acknowledge that patches, like U.S. Derm's delivery platform that do not incorporate active ingredients into adhesive and do not have and occlusive effect are not subject to the proposed ban on patch, plaster, and poultice dosage forms for OTC external analgesic drug products.

If you have any questions or need more information, please contact me at

Respectfully submitted,



Alfred W. Vitale
President & CEO

Attachments
AWV/cem

Re: Docket No. 78N-0301
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PRODUCT RATIONALE

The USD analgesic delivery platform is a uniquely designed and patented topical dosage form for the treatment of arthritis and sore muscle pain. It is important to note that the USD delivery platform is not a transdermal delivery device. It is a sophisticated topical dosage form that accurately delivers drug formulations directly to the pain site where it is needed. The dosage form is a two phase system consisting of a (1) delivery platform made up of a patented polyurethane film foam laminate that is breathable and non-occlusive allowing passage of water vapor and oxygen to and from the skin surface that prevents skin irritation; and (2) an ointment containing the active ingredients (capsaicin and menthol), which is applied to the platform in parallel stripes. The platform is held to the skin by an adhesive which attaches to the film foam laminate only around the perimeter of the platform, allowing for a central loose covering over the area containing the ointment. At no time do the ointment and/or active ingredients come in contact with the adhesive. The USD product has numerous advantages over conventional pain ointments and other occlusive formulations. These include but are not limited to...

- Uniform unit dosing of drug formulation. No need to try and measure out exact doses.
- Long-acting, continuous application to the site of pain until the delivery platform is removed.
- Not messy to apply and odorless on the skin.
- The non-occlusive/breathable technology reduces potential for skin irritation.
- Avoids potential eye contamination that can occur with creams and ointments applied directly to the skin.
- More efficiently uses monograph analgesic active ingredients.
- Delivery platform is water resistant, insuring that drug formulation does not wash off.
- The foam pad provides the pain area with a comfortable cushion.

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PRODUCT RATIONALE (Cont'd)

Ointment

The active ingredients capsaicin (0.075%) and menthol (4.0%) in concentrations established in the monograph, are incorporated in a non-aqueous system consisting of Bees Wax, Cocoa Butter, Microcrystalline Wax, Petrolatum and Sterol Alcohol. The ointment is solid at room temperature and slowly melts at body temperature.

Adhesive

The acrylic adhesive Duro-Tak 387-2587/87-2587 (Appendix 2) is transferred by contact to the perimeter of the film foam laminate platform. There is no adhesive in the center of the platform where ointment is applied in parallel stripes.

Platform

Film foam laminate of polyurethane is a safe soft pliable substance, which contains numerous vacuoles, which allow the free passage of water vapor and air. Only the periphery is covered by adhesive, allowing for breathability of the "loose" portions of the platform while delivering the ointment. At no time does ointment come in contact with adhesive, and when applied to the skin the platform has all the physical and dynamic properties of a band-aid.