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### Eczema Drugs Elidel and Protopic May Be Linked to Cancer Risk

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March 11, 2005 – The U.S. Food and Drug Administration (FDA) has warned healthcare professionals and patients via public health advisory of the potential cancer risk associated with use of pimecrolimus cream (Elidel, made by Novartis Pharmaceuticals Corp.) and tacrolimus ointment (Protopic, made by Fujisawa Healthcare Inc.), according to an alert sent yesterday from MedWatch, the FDA's safety information and adverse event reporting program.

The warning was based on recommendations made by the FDA's Pediatric Advisory Committee during its Feb. 15 meeting.

Tacrolimus ointment and pimecrolimus cream are topical immunosuppressant calcineurin inhibitors. They were approved in December 2000 and 2001, respectively, for the treatment of eczema.

Since the approval of tacrolimus, the FDA has received 10 reports of serious adverse events associated with its use in children younger than two years, and 17 reports of cancer (including non-Hodgkin's lymphoma and skin cancer) in all age groups.

Pimecrolimus cream has demonstrated a similar adverse event profile; 54 serious adverse events (many of them skin-related) have been linked to its use in pediatric patients younger than two years. Eight cancers have been reported in all age groups, with half of these occurring in pediatric patients aged two years and older.

Although causation has not been established, results of animal studies have also linked topical or oral exposure to these drugs with the development of cancer in three different animal species (mice, rats, and monkeys).

The FDA notes that these studies were conducted at doses higher than those normally used by patients, and that the risk of cancer increased with increased drug dose and duration, possibly leading to systemic exposure. Systemic exposure to tacrolimus through tablets/injection (to prevent rejection of liver or kidney transplants) is known to carry a risk of skin cancer and lymphoma.

Because studies of 10 years or longer may be required to determine the presence and extent of cancer risk in patients using these topical products, the FDA has recommended that pimecrolimus cream and tacrolimus ointment be used only for second-line, short-term, and intermittent treatment of atopic dermatitis (eczema) in patients unresponsive to or intolerant of other treatments. The FDA notes that use of pimecrolimus and tacrolimus topical products is contraindicated in children younger than two years. Clinical studies have shown an increased incidence of upper respiratory infection in this population upon exposure, and effects on the developing immune system are unknown. Their use in immunocompromised adults and children is also contraindicated.

To minimize the possibility of systemic exposure, pimecrolimus and tacrolimus topical products should only be used for short periods of time and at the lowest effective dose.

Adverse events related to use of pimecrolimus cream or tacrolimus ointment should be reported to the FDA's MedWatch program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, online at [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or by mail to 5600 Fishers Lane, Rockville, MD 20852-9787.

#### Kommentar:

Die neuen topischen Immunmodulatoren für die atopische Dermatitis werden ja – nicht zuletzt in der Folge der massiven Propaganda und teilweise Fehlinformation der Herstellerfirmen – viel zu oft bereits als first line treatment und bei Kindern unter 2 Jahren eingesetzt. Diese Warnung der FDA muss sehr ernst genommen werden. Wir dürfen nicht schwerwiegende Folgekrankheiten in Kauf nehmen, um harmlose und durch gute Patienten-/Elternführung meist vermeidbare Nebenwirkungen (der Stereoiden) zu vermeiden! UL.