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August 5, 2005

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

RE: FDA's "Drug Watch" for Emerging Safety Information
Docket # 2005D-0062

To Whom It May Concern:

The National Eczema Association applauds the FDA for being concerned with patient safety with regards to drugs that are on the market. Patients and physicians need accurate and rapid access to key information so they can make intelligent decisions about their healthcare.

We hope that the information provided will be fair and balanced. There has to be a context of relative risk and benefit. When identifying potential risks we do not want to create unwarranted consequences that result in under treatment and adverse events due to lack of therapy.

When adverse events are placed on the drug safety website the data needs to be continually updated for risks and benefits for physicians and patients, as this information is constantly evolving. Raw data without analysis over emphasizes the risks over benefits and is confusing to the public. It will not be accurate if only one side of the equation is cited.

The "related" and "possibly related" risks are the only parts that should be reported and they need to be constantly compared to benefit. "Not related" risks should not be reported. There needs to be some type of filter to make this happen. It would be beneficial to establish some type of formula to plug in these risks and benefits to be consistent and fair in reporting this information to the public. There needs to be thoughtful interpretation.

Risk of "no treatment" plus "benefits with treatment" has to be continually compared and reevaluated against "risk of treatment." Patients with atopic eczema many times will suffer more immensely from no treatment than from possible risks of treatments.

Please contact our association for any other information.

Sincerely,



Vicki Kalabokes
CEO

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