DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administrat
Rockville MD 20857

January 6, 2004

Jean Farrell McCawley
Director
Stevens Johnson Syndrome Foundation
P.O. Box 350333
Westminster, Colorado 80035

Dear Ms. McCawley,

Thank you for your letter of November, 2003, to Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research regarding Stevens Johnson Syndrome (SJS).

In your letter you state that you have seen an increase in reporting of SJS in children from the use of ibuprofen. SJS is a well-recognized, rare adverse event of all nonsteroidal anti-inflammatory drugs (NSAIDs), which includes ibuprofen. The Center for Drug Evaluation and Research's Office of Drug Safety queried our adverse event data base and at this time did not find a trend showing an increase in reporting.

Adverse events are not required to be reported to the FDA and it would not be feasible nor enforceable to mandate reporting by consumers in an over-the-counter setting. However, consumers can play a very important public health role by reporting any adverse reactions (as those you describe in your letter) or other problems with products the agency regulates through our voluntary reporting system, MedWatch. If the FDA receives sufficient reports on one particular drug product, showing that there may be an increasing trend of a particular adverse event associated with that product, we would then take necessary actions. We recommend that you advise those calling your organization to telephone our MedWatch Office at 1-800-FDA-1088 or submit the adverse event/problem electronically via the Internet. A link to the Internet voluntary reporting form can be found by going to the MedWatch homepage at *http://www.fda.gov/medwatch/index.html*, and click on "How to Report".

The FDA considers both the seriousness and the frequency of reported adverse events as well as the estimated number of patients who benefit from the drug. Provided that the public health benefit of the product outweighs its known risks, the FDA allows the continued availability of the drug, but often with revised labeling to better describe the risk and provide warnings to the consumer. It is for this reason that the post marketing MedWatch reports are so important and we encourage consumers to submit the reports on their experience to us.

Thank you for your comments and concerns on this important public health issue.

Sincerely,

Steven Galson, M.D., MPH
Acting Director
Center for Drug Evaluation and Research