



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

SEP - 4 2001

Mr. John E. Freudenberger, President
National Reye's Syndrome Foundation, Inc.
426 North Lewis Street
P.O. Box 829
Bryan, Ohio 43506-0829

Re: Docket No. 98N-0337
Comment 11

Dear Mr. Freudenberger:

This is in response to your letter of April 16, 2001, expressing concern that certain aspirin manufacturers are placing the dosage directions on the front of the immediate container label, and the warnings on the back of the immediate container label. In addition, you state that the label of the outer carton, containing the immediate container, lists the product warnings after the indications and dosage. You believe that such labels give priority to use of the products over the health and well being of the consumers. You ask that the FDA reevaluate the labeling by all producers of over-the-counter drugs to determine if the health and welfare of the general public is being met.

As you are aware, the regulations governing the "Drug Facts" labeling format and content for all over-the-counter drugs are prescribed in §201.66 of the Food and Drug Regulations (21CFR 201.66). The regulations became effective on April 16, 1999. However, the applicable implementation date for internal analgesic, antipyretic and antirheumatic drug products is the date specified in the final monograph or, if a monograph has not been finalized as of May 16, 2002, then the product must comply as of the first major labeling revision after May 16, 2002 or by May 16, 2005, whichever occurs first (see 65FR38193, copy attached). Thus, aspirin products will have to comply with the "Drug Facts" labeling regulations at the implementation date.

Please note that the subject "Drug Facts" regulations are applicable only to the outside container or wrapper of the retail package or the immediate container label if there is no outside container wrapper (see § 201.66(c)). Accordingly, an immediate container label that is in compliance with all other relevant labeling requirements, need not comply with "Drug Facts" labeling, if the immediate product container is enclosed in an outside box/wrapper with proper "Drug Facts" labeling.

98N-0337

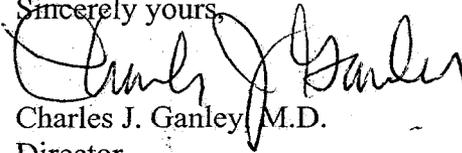
LET8

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Freudenberger
Page 2

If you have any questions, please call Walter Ellenberg, Ph.D., Regulatory Health Project Manager, at 301-827-2222.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Charles J. Ganley". The signature is fluid and cursive, with a large initial "C" and "G".

Charles J. Ganley, M.D.

Director

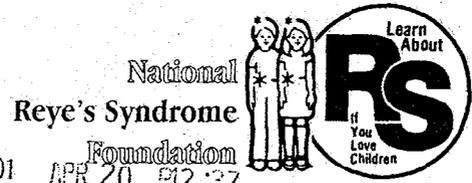
Division of Over-the-Counter Drug Products

Office of Drug Evaluation V

Center for Drug Evaluation and Research

Attachment

Mr. John E. Freudenberger, President
National Reye's Syndrome Foundation, Inc.
426 North Lewis Street
P.O. Box 829
Bryan, Ohio 43506-0829



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National Headquarters

National Reye's Syndrome Foundation, Inc. April 16, 2001
426 North Lewis Street
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Bryan, Ohio 43506-0829

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James C. Crawford, Trustee
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Stephen Pumm, Trustee

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Cincinnati, Ohio

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San Francisco, California

Director of Development:

Susan Landversicht

Docket No. 98N-0337
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, Maryland 20852

To Whom It May Concern:

I am writing to you on behalf of the National Reye's Syndrome Foundation's Board of Directors. In 1999 when the Food and Drug Administration established standardized content and format requirements for the labeling of OTC human drug products, we commended your efforts. It is with grave concern that I write today regarding a labeling tactic that we feel is contrary to the health of the general public.

At our Annual Meeting in 1999, we had the privilege of having Debra Bowen, M.D., Deputy Director, Office of Drug Evaluation 5 of the Food and Drug Administration, as our guest speaker. Dr. Bowen discussed the labeling requirements and the need to aid the consumer in making an informed decision about the purchase and use of medications. Our understanding of the new label was that the warnings on products would take preference over the dosage directions so the purchaser would know the risk in taking a particular medication prior to its use.

In June 2000, it was brought to our attention that although the Bayer Corporation and other aspirin manufacturers did as required and placed the warning indicator for their products at the top of the back label on their over-the-counter medications, they placed the dosage directions on the FRONT of the label! The box containing the bottle of aspirin still lists the products warning after the indicators and dosage. Once again, giving priority to the use of their products over the health and well being of the consumers.

Prior to the warning label on salicylate containing products, many lives were lost to Reye's Syndrome. Over the years the number of cases has diminished, but the disease has not been eradicated. We know that most laypersons and medical professionals do know not to

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(ODEI#2832)

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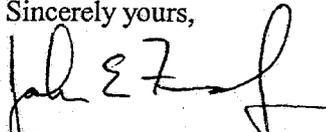
Docket No. 98N-0337
Food and Drug Administration
April 16, 2001
Page 2

give aspirin to children, but many do not remember why. There are fewer individuals who know that Reye's Syndrome also kills adults. Most of our adult cases result in death because it is assumed that they are beyond the age of Reye's. We are working diligently to educate the general public with our limited resources, but are daunted by the greater effect the drug industry has through their powerful use of advertisements.

While the aspirin manufacturers are promoting newfound uses for their product, we feel they have not acted prudently in alerting the general public to the possible dangers of their product as well. In the article, "FDA To Overhaul Drug Warnings," published by the Associated Press in December 2000, was a statement that acknowledged that, "too few doctors today even read vital drug warnings." If our doctors do not take the time to be informed, they will not forewarn their patients. The FDA most assuredly has the responsibility to act in the best interest of the consumer. The consumer must have this important information presented in the way it was intended in the original guidelines established by the FDA in 1999. The warnings for all dangers and side effects must be prioritized over and above the dosage so the consumer can make a wise and informed choice.

We ask that you reevaluate the labeling by the aspirin companies and all producers of over-the-counter medication to determine if the health and welfare of the general public is indeed being met. We do not want to witness an increase of Reye's Syndrome because of the narrow focus of pharmaceutical companies.

Sincerely yours,



John E. Freudenberger
President

Enclosure

JEF/sl



National Headquarters

National Reye's Syndrome Foundation, Inc. May 3, 2001
426 North Lewis Street
P.O. Box 829
Bryan, Ohio 43506-0829

*a disease that affects the liver and brain

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Bennett A. Shaywitz, M.D.
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M. Michael Thaler, M.D.
San Francisco, California

Director of Development:

Susan Landversicht

Dr. Walt Ellenberg
Division of Over-The-Counter Drugs
Food and Drug Administration
5600 Fisher's Lane, HFD 560
Rockville, Maryland 20852

Dear Dr. Ellenberg,

It was a pleasure talking with you yesterday. We appreciate the interest the Food and Drug Administration is taking regarding our concern of the labeling by the aspirin manufactures.

I have enclosed a bottle of Bayer Aspirin. You will find the warning indicator for their products at the top of the back label on their over-the-counter medications and the dosage directions on the FRONT of the label! The box containing the bottle of aspirin still lists the products warning after the indicators and dosage. The copy of our letter you received gives in greater detail our concerns.

Thank you for your telephone call. I look forward to hearing from you regarding the FDA's decision on the aspirin product warning labels.

Respectfully,

Susan Landversicht

Susan Landversicht
Director of Development

Enclosure

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 9/10/01

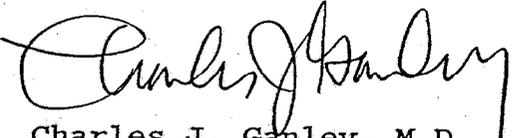
FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 98N-0337/

TO: Dockets Management Branch, HFA-305

The attached material should be placed on public display under the above referenced Docket No.

This material should be cross-referenced to Comment No. 211


Charles J. Ganley, M.D.

Attachment