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HEALTH RESEARCH GROUP

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The Food and Drug Administration has failed to protect the consumer from Red dye #2, disregarding the law which requires it to prohibit the use of additives that may be harmful to health. Red #2 causes fetal death and birth defects in animal tests, and thus poses a serious hazard to human reproduction.

The food industry has continued to use Red #2 in spite of danger signals.

Consumers must therefore protect themselves by boycotting all artificially-colored red food products which contain Red #2. Since almost all artificially-red foods contain this dye, consumers should refuse to buy artificially-red products unless the label clearly states that Red #2 is not used. (At present, most labels merely read: "artificial color added.") Red coatings in pills such as vitamin pills, and lipsticks also contain Red #2, and should be avoided until industry removes the dye.

The Washington Post

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Nader Urges Boycott Of Red-Dyed Foods

By Jack Fuller

Washington Post Staff Writer

Ralph Nader's Health Research Group has urged consumers to stop buying all red foods that contain artificial coloring, claiming that the most common form of red dye used in foods may cause birth defects and genetic damage.

The group warned consumers not to buy red foods unless the labels state that FD&C (Food, Drug and Cosmetic) Red Dye No. 2 has not been used.

Though the Food and Drug Administration (FDA) earlier this month issued a regulation putting a ceiling on the amount of the controversial dye that could be used in food, drugs and cosmetics, the Nader group claims that the FDA broke its own rules in order to weaken the dye regulation and make it ineffective.

An FDA research team of toxicologists had recommended that the FDA limit "drastically" the use of Red Dye No. 2 to food packaging

when the substance would not contaminate the food and to external uses.

Instead, the FDA called upon the National Academy of Sciences for a review of the team report. The report summarized long-term Russian experiments that showed the dye to cause cancer in test animals and its own experiments that showed the dye to cause mutation and birth defects in test animals.

Over the repeated protests of its reviewing committee, the academy subcommittee appointed to study the FDA report recommended that any restrictions on Red Dye No. 2 would be "a premature and unnecessary measure."

The Nader group charged that the academy subcommittee was composed of scientists completely sympathetic with the food industry, which stood to lose its favorite coloring if the FDA researchers' report was accepted.

On the basis of the academy subcommittee report, the FDA decided to apply to Red Dye No. 2 a safety standard limiting the level of the dye in foods and drugs to 30 parts per million and in cosmetics to 1,000 parts per million.

Every year, Red Dye No. 2 is used in about \$10 billion worth of soft drinks, gelatine desserts, baked products, candy, breakfast cereals, gum, pet foods, pill coatings and dozens of other products.

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FOR IMMEDIATE RELEASE

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SNUB RED DYE #2

Consumers should boycott any artificially-colored red foods. Red dye #2 is found in \$10 billion worth of foods, including candies, ice cream, pastry, soft drinks, and popsicles. Virtually every artificially-colored red food contains this dye, and should be avoided unless the label indicates that red #2 is not being used.

FDA has refused to adequately protect consumers from dangerous levels of F.D. &C. Red #2. It has ignored the recommendations of its own scientists that use be drastically curtailed:

It would be prudent to limit drastically the uses of F.D. &C. Red #2 only to indirect or incidental applications involving food; that is limit use of the color to such applications as food packaging where migration to food is nil, color marking of animal feed additives, and to external uses only in drugs and cosmetics.

Soviet scientists in 1970 reported that Red #2 caused birth defects and cancer in animals. FDA scientists obtained similar results from reproduction studies last summer, but FDA higher officials have delayed any action at all for almost a year.

FDA made trivial restrictions on the use of the dye early this week. In deciding to make only token restrictions, FDA denied that there was any evidence of hazard to humans, and said that it was making its restrictions pending completion of safety tests. Although the Color Additives Amendment to the Food, Drug and Cosmetic Act requires scientific proof of safety for all color additives in the food supply, the FDA has consistently disobeyed this law. There is no objective scientific evidence that F.D. &C. Red #2 is safe for use.

FDA tests have shown serious warnings of hazard. Red dye #2 was shown to cause severe reproduction effects in rats, (birth defects, abortions, mutations), deformed embryos in chicks, and was shown to be "one of the most potent" mutagenic compounds ever tested. (Gene mutations) *

FDA tests showed that the no effect level for fetal death in rats was 15mg/kg. As a rule, FDA uses a safety factor of 1/100 (21 C.F.R. 8.34) for determining the safe dose in humans, starting from the no effect level in the test animals.

Thus, under routine safety procedures, the safe dosage level should be .15 mg/kg of body weight daily. This level of the dye in food would allow a 110 lb. woman to drink safely about 2/3 of a can of soda daily. A child would exceed the safe limits if he drank more than a third of a can of soda, as the only source of F.D. &C. Red #2. This is in addition to the artificially-colored red candies, ice cream, synthetic deserts, etc. they ingest, and in addition to the large quantities of lipstick that a woman is likely to ingest.

The FDA announcement came on the tail of an incompetent NAS committee report recommending that no restrictions be made. The NAS report was a complete and irresponsible whitewash of the well-documented hazards of the dye. It admitted that little is known about the safety of the dye but it dismissed all of the tests which agency scientists had performed, in favor of industry tests whose summaries concluded there were no hazards. The NAS committee said no action should be taken because no evidence of harm to humans had been presented it.

Competent FDA scientists know that data of harm to humans is rarely available in cases of substances which have chronic toxicity, since the effects appear some time after ingestion of the substance -- when they are not likely to be associated with the substance. Further, humans are ordinarily exposed to so many substances, that it would be extremely difficult to know what chemicals in the environment cause effects, in the absence of controlled studies. Our society dislikes experimenting on humans with a substance which has been shown to be harmful in animals. Therefore, lack of data on harmful effects on humans is not surprising. We must rely on animal tests to predict dangers, so that humans do not suffer harm.

Birth defects, spontaneous abortions, and genetic mutation are serious problems associated with human reproduction. The recent studies on F.D. & C. red #2 suggest that this most widely used food color may be a contributing factor to the high incidence of these reproductive defects.

No risk should be tolerated for red #2 use because it confers no benefit on the consumer. It is a benefit to the industry only because it adds a false color which makes the product more saleable without improving its quality.

In response to a previous request to remove this potentially hazardous dye from the market, Dr. Charles Edwards, Commissioner of the FDA, replied that it is FDA policy "to base its regulatory decisions on sound science." Sound science, in experiments performed by extremely competent and objective FDA researchers, dictates the removal of Red #2 from the market. Rather than basing regulatory decisions on sound science, the industry-dominated FDA executives case aside concerns for human health and base decision on sound economic factors which promote industry health.

We therefore urge all American consumers to take matters into their own hands and boycott all artificially-colored red products (food and cosmetics).

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*Dr. Marvin Legator, Former FDA Toxicologist