

October, 1988

Vol. 12, No. 8

## **Diet/Behavior Connection Gains Professional Recognition**

Pure Fac

Newsletter of the Feingold<sup>®</sup> Associations of the United States

*Nelson's Textbook of Pediatrics* is a widely recognized resource for physicians. The most recent edition (published in 1987) contains the following information:

"Food Additives. Naturally occurring chemicals and food additives, particularly the artificial flavors and colors, have been implicated in health problems. It has been estimated that more than 3000 flavors are currently being used, and few children are spared exposure to them in their daily diet.

"Artificial flavors and colors have been associated with respiratory allergic disorders, with urticaria and angioedema, with lesions of the tongue and buccal mucosa, with digestive disturbances, with arthralgia and hydrarthroses, and with headache and behavioral disturbances, including hyperkinesis in childhood."



# "If an Additive is Harmful, Why Doesn't the Government Ban it?"

This is a question frequently asked of the Feingold Association. The following information may help to answer it.

The banning of an economically significant food additive is not a simple matter. It brings into play: the responsibility of government administrators, the private interests of affected industries, and the political philosophy of the White House.

In 1985 the Committee on Governmental Operations/House of Representatives issued a report on several governmental agencies and their part in the regulation of color additives. It is titled, "HHS' Failure to Enforce the Food, Drug and Cosmetic Act: The Case of Cancer-Causing Color Additives." The report criticizes the current administration's actions (and lack of action) concerning several synthetic dyes which have been demonstrated to cause cancer. The agencies involved were: Food & Drug Administration (FDA), Department of Health and Human Services (HHS), and the Office of Management and Budget (OMB).

The industry trade groups working to delay/prevent the banning were: the Cosmetic, Toiletry and Fragrance Association (CTFA), the Certified Color Manufacturers Association (CCMA), and the National Food Processors Association (NFPA).



The Feingold Associations are grateful to all of you who have provided much needed donations through your United Way or Combined Federal Campaign.

In many areas, participants are allowed to designate a non-profit group (such as ours) as the recipient of part, or all, of their contributions.

This is the season the United Way and Combined Federal Campaign will be contacting their members. Please keep us in mind when you make out your pledge cards. If we can assist, leave a message on our answering tape and we will return your call. The number is (703) 768- FAUS.

The Committee cites instances of government agencies and the office of the Vice President ignoring the counsel of qualified scientists and lawyers, and improperly allowing the industry to influence their actions.

This report documents the period between 1960, when Congress passed legislation concerning the safety of food dyes, to May of 1985. During those 25 years, little progress was made to remove six of the dyes demonstrated to be carcinogens (cancer-causing agents) and it was not until July of this year that four of them were finally "delisted" (banned). [See *Pure Facts*, September, 1988.] The most widely used of the six dyes – Red No. 3 – continues to be added to food, drugs, and cosmetics, despite the fact that this is against the law.

Both the Reagan administration and the Department of Health and Human

continued on page 2

The Feingold® Associations of the United States, Inc., founded in 1976, are non-profit volunteer organizations whose purposes are to support their members in the implementation of the Feingold Program and to generate public awareness of the potential role of foods and synthetic additives in behavior, learning and health problems. The program is based on a diet eliminating synthetic colors, synthetic flavors, and the preservatives BHA, BHT, and TBHQ.

## "Reaction Reported to the Dye in Tegretol"

The following letter appeared in the August, 1988 issue of *Archives of Neurology*, published by the American Medical Association.

A 46-year old woman...[who was diagnosed as having epilepsy] was treated successfully with Tegretol. [Later] the manufacturer replaced the original, white tablets with the new pink variety.

The patient noted that within a few hours of ingesting each 200-mg pink tablet, she would experience a constellation of symptoms that would last several hours described as, "feeling uptight, tenseness of the scalp, feeling veins and arteries popping out from the skin, coughing, dry heaves, and a crawling and itchy feeling in the skin, but without rash."

She discontinued the medication independently, and these symptoms ceased. After about one week of freedom from this symptom complex the pink Tegretol was reinstituted at 100 mg/d (one half tablet). With each dose she had a recurrence of the uncomfortable, nervous, and itchy feelings. On stopping the medication under medical direction these symptoms, once again, ceased. Because of the earlier successful and uncomplicated use of the white Tegretol tablets, we speculated that a change in the production of the tablets was responsible for her unusual symptoms.

We were able to provide the patient with a supply of the original, white Tegretol tablets. After starting at 100 mg/d, the dosage has been slowly increased to 200 mg three times a day with no untoward effects.

**Comment** – The pattern of clinical response to the white, then pink, and finally, white Tegretol tablets makes a compelling scientific argument for implicating some component of the new, pink Tegretol tablets in causing the toxicity. Anecdotal reports of altered clinical status associated with the introduction of the new Tegretol tablets have also recently appeared in the epilepsy lay press. Management in this woman may require the availability of the old, white Tegretol tablets or other, perhaps generic, preparations.

Ivan S. Login, MD Departmant of Neurology University of Virginia School of Medicine

## Seizures, Tegretol and Dyes

The child who suffers from both seizures and hyperactivity faces a difficult choice.

For many years, the treatment of choice for most of these youngsters has been Tegretol (carbamazepine), available in an uncolored white tablet. When synthetic dyes (Red No. 3 and Red 40) were added to the drugs, families following the Feingold Program were alarmed. Although carbamazepine is available in the generic form, this is not identical to Tegretol, and cannot be used with success by all children.

(The April, 1987 issue of *Pure Facts* describes the behavioral disturbance suffered by one teenager as a result of the addition of red dye to the drug.)

More recently, a liquid form of Tegretol has been introduced, but it is unacceptable because it contains Yellow No. 6, and "flavoring".

Pure Facts has been in contact with the manufacturer of Tegretol, CIBA Geigy (best known for their drug Ritalin), in hopes of finding a solution. A recent conversation with a company spokesman was promising.

White Tegretol is still being manufactured in Switzerland, the company's home base, and if there is sufficient demand for it, CIBA Geigy would make an effort to have this available for families in the U.S.

FAUS has agreed to collect data on the number of individuals who believe they require Tegretol in the uncolored form, and to pass this information along to the company. Please assist us in this by contacting FAUS as soon as possible if you have such a need.

You can write to Pure Facts at P.O. Box 6550, Alexandria, VA 22306; or call our answering tape (703-768-FAUS) and leave your name and phone number, along with a brief message.

#### Additive, from page 1

Services received sharp criticism from the House Committee for taking authority away from the FDA. Later, two unprecedented Executive Orders gave virtually total control of the regulations of food additives to the Office of Management and Budget – an agency under the direct control of the President. The removal this summer of four of the cancer- causing dyes was the result of a law suit against the government, not action on the part of the FDA.

# The following is taken from the Congressional report.

#### Background

The 1960 Color Additive Amendments to the Food, Drug, and Cosmetic Act allowed for "provisional listing" or interim approval of color additives that were already in commercial use, pending the completion of studies to determine whether they were safe for their intended use. Additives found to be "safe" were to be "permanently listed," i.e., approved. Provisionally listed color additives not shown to be safe were to be removed from the market. The law imposes upon industry the burden for establishing that color additives meet... high safety standards.

Until 1981 the FDA controlled the regulation of food additives.

Although the Color Additive Amendments give the [FDA] discretion to determine whether a color additive has been shown safe for continued use, the law limits that discretion for any color additive found to be a carcinogen. Once agency scientists have concluded that a dye causes cancer in man or animal, its continued marketing is prohibited by the Delaney anti-cancer clause contained in the Amendments.

The Color Additive Amendments provided industry 2 1/2 years from their date of enactment on July 12, 1960, to demonstrate the safety of provisionally listed color additives. The Secretary [of HHS] was authorized, however, to postpone this "closing date" for "such period or periods as he finds necessary...if in his judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific *continued on page 3* 

#### Additive, from page 2

investigations necessary for making a determination as to listing such additive."

#### **FDA Authority Reduced**

Prior to May 11, 1981, the Secretary of Health and Human Services (HHS) delegated to the Commissioner of Food and Drugs the authority to perform all of the functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act. As of that date, however, the Secretary "reserve[d] the authority to approve regulations of the Food and Drug Administration" under certain circumstances.

Over the past two years, the Secretary has reserved the authority to review FDA recommendations to remove from the market several cancer-causing color additives used in foods, drugs, and cosmetics. To date, the Secretary has approved none of these recommendations.

Dyes found to cause cancer are prohibited by the Color Additives Amendment Act of 1960

That ten color additives remain provisionally listed testifies to the numerous closing date extensions that have been granted in the 25 years since the Color Additive Amendments were enacted.

#### The Dyes as Carcinogens

FDA scientists have definitively concluded that six of the ten color additives remaining on the provisional list – FD&C Red No. 3, D&C Red No. 8, D&C Red No. 9, D&C Red No. 19, D&C Red No. 37, and D&C Orange No. 17 – caused cancer in appropriately conducted animal studies. [Note: FD&C means the dye is permitted to be used in food, drugs and cosmetics; D&C refers to dyes allowed only in drugs and cosmetics.]

In an August, 1982, memorandum, Mr. Emil Corwin of FDA's Press office wrote:

"At the meeting today to brief the Commissioner on the status of provisionally listed color additives, Sandy Miller [Director of FDA's Bureau of Foods] said we are moving toward a ban of most of them....When all the reports are in, Sandy said, we can expect a lot of flack, since the colors are economically important and, for most part, irreplaceable....Because of the sensitivity of the problem (economic impact), we are to keep mum until the end of October, when we can expect a public announcement." [It did not materialize.]

January 12, 1963 was to be the deadline for industry to prove the safety of the synthetic dyes.

#### **Delaney Clause**

Urging HHS Secretary Heckler to continue FDA's longstanding tradition of interpreting the Delaney clause "as an absolute ban" on color additives "which have been determined to cause cancer by appropriate tests in man or animal," on March 16, 1983, then FDA Commissioner Arthur Hull Hayes, Jr. forwarded to the Department a recommendation that the Secretary remove Red 19 from the provisional list. Dr. Hayes' memorandum informed the Secretary that her decision on his recommendation "is important to the industry, not only because of its impact on Red 19 but because of its impact on upcoming color additive decisions as well." By that time, FDA was poised to recommend termination of the provisional uses of other carcinogenic color additives....Commissioner Hayes described the "urgency" of the situation: "...Red 19 can stay on the provisional list until April 29. After that date, unless we permanently approve it, it can no longer be used."

On April 4, 1983, Commissioner Hayes' recommendation to ban the remaining uses of Red 19 was approved by Assistant Secretary for Health, Edward N. Brandt, Jr., and forwarded to Secretary Heckler's office.

# The FDA recommended the banning of many dyes, but the Secretary of HHS took no action.

...On April 29, 1983, however, another two-month extension of the provisional listing for the external uses of Red 19 and 37 was granted [by FDA].

#### Legal Counsel

In August of 1983...Mr. Philip Derfler, the HHS Office of General Counsel attorney principally involved in the regulation of color additives, wrote that permitting the continued listing of Red 3 was *legally indefensible*. Mr. Derfler recommended that the provisional listing for Red 3 be terminated on its then upcoming closing date of October 2, 1983.

Dr. Sanford Miller, Director, FDA's Bureau of Foods, wrote in an October 3, 1983, memorandum to then Acting FDA Commissioner Novitch: "As a result of our continuing scientific evaluation, the Bureau of Foods has concluded that it would be scientifically unsound, on the basis of the available data, to permanently list D&C Red Nos. 19 and 37 and D&C Orange No. 17..."

On October 4, 1983 FDA announced the two-month extension of the closing date for Red 3....FDA officially concluded on November 29, 1983, that Red 3 is an animal carcinogen. That same day, however, FDA announced another two-month extension of the closing date for Red 3.

# Each new FDA Commissioner tried to have the dyes removed.

On December 20, 1983, FDA briefed [Assistant HHS Secretary] Dr. Brandt on its recommendations to terminate the provisional listing of the six carcinogenic color additives as well as to publish a proposal to revoke the food uses of Red 3.

By mid-January 1984, FDA...had prepared a decision memorandum urging Secretary Heckler to ban all six carcinogenic color additives. On February 3, 1984, however, the closing dates for all six carcinogenic color additives were extended for an additional two months.

On March 30, 1984, Acting FDA Commissioner Novitch sent to the Department a decision memorandum recommending that Secretary Heckler terminate the provisional listing of all six carcinogenic color additives and begin rulemaking proceedings to revoke the permanently listed food and drug uses of Red 3. Dr. Novitch strongly argued for speedy Secretarial approval and implementation of his recommendations.

Another two-month extension of the closing dates...was granted on April 4, 1984.

#### FDA Commissioner Young

Upon his assumption of duties on July 16th, 1984, FDA Commissioner Frank E. Young, at the request of Secretary Heckler, began re- reviewing the science surrounding FDA's regulation of the carcinogenic color additives. Two weeks later, the closing date for *continued on page 4* 

#### Additive, from page 3

the six carcinogenic dyes was again postponed for two months.

[Addititonal two-month extensions for the six cancer-causing dyes were granted on: October 2, 1984, December 3, 1984, February 1, 1985, and April 2, 1985.]

Based on Dr. Young's own statements, the [Congressional] committee must conclude that continued public exposure to the carcinogenic color additives is indefensible on policy as well as legal grounds.

#### The Legality

The general safety clause of the Color Additive Amendments...requires that provisionally listed color additives be shown to be safe to remain on the market. The law places the burden on industry for proving the safety of these additives.

#### Government lawyers pointed out the illegality of the agencies' actions.

A color additive will be considered "safe" only if "there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive." [Taken from the Code of Federal Regulations, the guidebook for FDA.] In the past, FDA had even concluded that FD&C Red No. 2-a color additive that might be an animal carcinogen - had not been shown to be "safe" within the meaning of the law and, therefore, had to be removed from the provisional list. To require that a presumptively unsafe dye be removed from the market while additional testing is conducted is consistent with Congress' mandate in the Color Additive Amendments that the primary consideration underlying the regulation of color additives be public safety.

The Food, Drug, and Cosmetic Act requires that industry prove that a provisionally listed color additive is safe – not that FDA prove that it is unsafe.

#### Red No. 3

Because FD&C Red No. 3 is the only one of the [six] carcinogenic color additives permitted in food, it may present a greater public health risk than the other carcinogenic dyes. Dr. W. Gary Flamm, Director, Office of Toxicological Sciences, Center for Food Safety and Applied Nutrition, testified that, based on exposure es-

4 Pure Facts/October, 1988

timates, all the uses of Red 3 were calculated to pose an upper level human cancer risk in the neighborhood of the 1 cancer in 100,000 population range, ten times higher than the 1 in 1 million risk that is normally deemed to be "acceptable" by Federal health and safety regulatory agencies.

# Red No. 3 has been granted temporary extensions for 28 years.

Former Acting Commissioner Novitch and former Assistant Secretary Brandt have regarded Red 3 as presenting a greater cancer risk than the five other carcinogenic dyes.

Despite this, in late 1984 FDA Commissioner Young recommended that the Secretary ban all of the carcinogenic color additives *except* Red 3....Until this case...FDA has "never agreed to extending the provisional list for a carcinogen so that new toxicity data could be developed and evaluated."

Timetables for final regulatory action on Red 3 have already been repeatedly pushed back to accommodate new industry testing. ...again in March 1984, the industry sought an extension to [the last deadline] to permit yet additional toxicity testing:

[In March of 1984, the Executive Vice President of the National Food Processors Association wrote to FDA on behalf of the NFPA and the Certified Color Manufacturers Association. He stressed that a new extension would allow adequate time to decide the safety of the dye.]

"The proposed new closing date will provide adequate time for completion and evaluation of further studies now in progress or promptly to be initiated, and for FDA to make an informed determination as to the appropriate status of Red No. 3 under the color additive provision of the Federal Food, Drug, and Cosmetic Act."

The risk from Red dye No. 3 is ten times higher than what the government considers acceptable.

Despite the unqualified conclusion of FDA scientists that none of the data submitted by industry proves [the latest] hypothesis, the provisional listing for Red 3 was again extended for two additional months on April 2, 1985.

#### Department of Health and Human Services

There is no indication in the record...that any of FDA's three sets of recommendations to delist carcinogenic dyes has ever "officially" reached the Secretary's [HHS Secretary Heckler] desk for her concurrence.

On October 5, 1984, former Assistant Secretary [of HHS] Brandt testified before the subcommittee that in the preceding week he had learned that his and FDA's recommendation to remove Red 19 from the provisional list had not yet reached the Secretary's desk. Now, more than two years after her office first received it, the Secretary still has not acted on this recommendation.

# The continued use of Red 3 violates both government policy and law.

[Criticizing the influence of the industry in HHS decisions regarding the additives, the committee's report notes,] No FDA personnel were invited to attend what, in the regulatory history of the carcinogenic color additives, proved to be a critical meeting between Dr. Brandt [Assistant HHS Secretary] and CTFA representatives on May 1, 1984. It was as a result of the arguments presented to him by industry representatives at that meeting that Dr. Brandt urged, without first consulting FDA's scientists, consideration of CTFA's proposal to delay regulatory action.

OMB

The Office of Management and Budget Improperly Interfered with the Department's Enforcement of the Delaney Anti-cancer Clause

The Secretary's approval of FDA's recommendations to delist the carcinogenic color additives would not necessarily have resulted in their removal from the market, because she is not the only Government official who has asserted authority to review FDA regulations. Once major FDA regulations clear the Department, they often may not be published in the *Federal Register* unless and until they are cleared by the Office of Management and Budget.

Since 1981, Executive Order 12291 has authorized the Director of the Office of Management and Budget (OMB) to assess the costs and benefits *continued on page 6* 

## **Dear Pure Facts**

"My child's pediatrician suggested the diet before we get on a medication. The problem I have encountered is the use of butter instead of a lower fat substitute. My husband has to be on a low cholesterol diet and this presents a problem."

You will be happy to learn that Hain Safflower Oil Margarine has recently been researched and found acceptable for use on the Feingold Program.

For many years Hain was an independently owned company distributing their products through health food stores. Pet, Inc. now owns the Hain line of foods, so you may find them more readily available in some supermarkets. Representatives at Pet have told *Pure Facts* that they do not intend to make substantial changes in Hain products, which have great appeal to consumers who wish to avoid certain food additives.

You can reduce the amount of butter by trying this delicious honey butter spread.

## **Honey Butter**

In a blender container, combine: 1/3 to 1/2 cup vegetable oil 1/2 cup honey 1 stick butter

Blend until smooth; store in the refrigerator. It is delicious and will stay soft and spreadable.

## **To Our New Members**

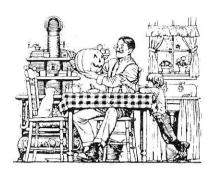
We're glad you found our program and hope you have already experienced success.

Please check your foodlist and see if Sorbee Gummy Bears are included. This candy has recently been changed and now contains synthetic dyes and flavorings; be sure to delete it from your foodlist. The Sorbee hard candies and lollypops are still acceptable.

If you wish to contact the manufacturer concerning this unfortunate change, you can write to: Sorbee, 9990 Global Road, Philadelphia, PA 19115.

# Halloween!

Check your *Feingold Handbook* and Calendar for hints on dealing with this junk food holiday.



## **Pumpkins!**

Instead of carving your pumpkin this year, how about using paint, marker or crayon to provide it's face? This is a great project for younger children. What's more, the pumpkin does not grow "peach fuzz" on the inside, and after Hallowe'en is over, you can use it for cookies, cake or pumpkin bread.

from the Feingold Association of Southern California

One family writes: "We discovered a trick last Halloween that made our jack-o-lantern a little bit different, and make lighting it a lot safer.

"Instead of making the first cut around the stem on top, cut your opening around the bottom. No more reaching down inside to light the candle. Simply lift the pumpkin by its stem, leaving the bottom and the candle exposed, ready to light."

## **Pumpkin Cookies**

Cream together: 1 cup **butter** and 1 cup **sugar** 

Add and mix: 1 cup cooked pumpkin, 1 egg, 1 teaspoon vanilla.

Sift together and add: 2 cups flour,1 teaspoon baking powder, 1/2 teaspoon baking soda, 1/2 teaspoon salt, and 1 teaspoon cinnamon

Drop onto a cookie sheet. Bake at 375 degrees for 15 minutes. *Feingold Association of* 

Southern California

# Vampire Alert

The synthetic dyes in a "Frothing Blood Capsule" caused a severe reaction in a teenaged boy last Halloween. The following account appreared in *FDA Consumer*, the magazine of the Food & Drug Administration.

"A physician reported that a 13year old boy had apparently suffered an epileptic-type seizure after biting on a Frothing Blood Capsule containing imitation blood. According to the boy's mother, her son had used the capsule to complete his vampire costume for a Halloween party and had the reaction the next morning. He had a similar reaction a year earlier, she said, after spraying his hair with red spray color.

"Lab analysis found three illegal color additives in the imitation blood: amaranth (formerly FD&C Red No. 2), pomceau 4R, and carmosine. However, it was not determined if any of the colors might have caused the boy's reaction. FDA received no other complaints about the product."

### White Grease Paint

2 teaspoons white shortening

- 5 teaspoons cornstarch
- 1 teaspoon white flour

Glycerin (This can be purchased at a drug store.)

Blend the shortening, cornstarch and flour with a rubber spatula.

Add 3 to 4 drops of glycerin to make a creamy consistency.

For red coloring, add some beet juice to a small amount of the grease paint.

## Brown Grease Paint (for outlining)

1 teaspoon white shortening

2 1/2 teaspoons unsweetened cocoa Blend; apply to the face with a soft paint brush.

When the festivities are over the grease paint can be removed with any of the following: additional white shortening, cold cream or baby oil.

The Feingold® Associations do not endorse, approve or assume responsibility for any product, brand, method or treatment. The presence (or absence) of a product on a Feingold foodlist, or the discussion of a method or treatment does not constitute approval (or disapproval). The foodlists are based primarily upon information supplied by manufacturers, and are not based upon independent testing.

Pure Facts/October, 1988 5

#### Additive, from page 4

of most major proposed or final agency rules.

[However] since Secretary Heckler has never approved any of FDA's recommendations to ban the carcinogenic color additives, no draft *Federal Register* notices delisting them and denying their petitions for permanent listing were submitted to OMB under the Executive Order.

That FDA recommendations to delist carcinogenic color additives have never cleared the Department [HHS], however, has not deterred OMB from extensive involvement in the regulation of these dyes. In fact, because OMB personnel are the only Government officials on record as urging Secretary Heckler not to accept FDA's recommendations to delist carcinogenic color additives as violative of the Delaney anti-cancer clause, it is likely that OMB played a major, if not pivotal role, in the continued, unlawful marketing of these dyes.

#### **Additional Industry Influence**

As it elevated its case against FDA to the Secretary, CTFA also notified the Secretary that copies of its letter were being forwarded to Mr. C. Boyden Gray, Counsel to Vice President George Bush, and to Mr. Jim J. Tozzi, Deputy Administrator, OMB's Office of Information and Regulatory Affairs.

### "My Mother Loves the Calendar...Maybe There's Hope Yet!"

"The calendar is the best way I have seen to "gently" introduce someone to Feingold.

"It has done an excellent job of providing a wealth of information for the novice as well as the experienced Feingolder. It has even been accepted at the Grandparent's where foodlist after foodlist and newsletters have been 'misplaced'.

"Please send me four more."

Thank you for the donations so many of you have sent in response to our new FAUS School Year Calendar. And we especially appreciate the kind words you have had for this new project.

Another member noted that a hint on the calendar alerted her to the potential reaction her son would have when he visited the dentist that week. ...In his cover letters to Messrs. Tozzi and Gray, [CTFA's] Mr. Kavanaugh protested FDA's proposal to delist [ban] "a number of important color additives used in cosmetic products." From this point on, OMB took up industry's case against FDA proposals to delist carcinogenic color additives.

[As requested by Mr. Kavanaugh] Mr. Tozzi met with CTFA representatives in the spring of 1983 in what was the first of several contacts between the regulated industry and OMB concerning the Department's regulation of the carcinogenic color additives.

Whether an additive is an animal carcinogen is a scientific determination in which OMB, in its assessment of regulatory costs and benefits, has no legal authority to interfere.

Even OMB's former Administrator for Information and Regulatory Affairs, Mr. James C. Miller, acknowledged that cost/benefit anaylsis, the basis for OMB involvement under Executive Order 12291, bears no relevance to administration of the Delaney clause.



## **Pure Facts**

Editor: Jane Hersey

Contributing Editors:

Detroit: Karen Dorries Fort Worth: Carolyn Allen Los Angeles: Colleen Smethers New York: Pat Palmer San Francisco: Lynn Murphy St. Paul: Sue Maldonado

Pure Facts is published ten times a year and is provided to members of the Feingold Associations. It is also available through subscription. Rates are: \$12 per annum in the U.S., Canada, and Mexico; \$16 elsewhere (payable in U.S. currency).

For further information write to: Feingold Association of the United States. Inc., P.O. Box 6550, Alexandria, VA 22306. (703) 768-FAUS.

#### President Reagan's Executive-Orders

... the President's issuance on January 4, 1985, of Executive Order 12498...immensely expands OMB's authority over agencies' regulatory activities. Executive Order 12498 requires Federal agencies to submit to OMB regulatory agendas detailing "all significant regulatory actions of the agency, planned or underway, including actions taken to consider whether to initiate rulemaking requests for public comment; and the development of documents that may influence, anticipate, or could lead to the commencement of rulemaking proceedings at a later date ... " (Emphasis supplied.)

The Committee accused the Office of Management and Budget of acting on behalf of the industry.

If OMB decides that a proposed action is not consistent with the Administration's policies and priorities, an agency generally may not pursue them.

Under Executive Order 12498 as well as Executive Order 12291, OMB is authorized to review agency regulatory decisions only "to the extent permitted by law." Despite OMB's assurance that it has "never tried to press an agency in any way to do anything that a statute did not permit," the committee finds that OMB, acting on behalf of the regulated industry, urged the Department to pursue a regulatory course that was inconsistent with the requirements of the law.

Editor's note: According to an FDA spokesman, D&C Red 37 was delisted (banned) on June 6, 1986.

The last deadline for Red No. 3 expired on August 30, 1988, but this time the provisional listing of the dye has been extended for a year because the agency "still has not made a decision" about Red 3.

## **Science Fair Time**

Do you have a child in search of a science fair project? Our Science Fair Packet may have some useful suggestions. To order it send your name and address to: FAUS Science Fair, P.O. Box 6550, Alexandria, VA 22306.

Please enclose \$3 for each packet.