# FOOD DRUG COSMETIC LAW JOURNAL

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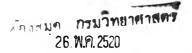
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# FOOD DRUG COSMETIC LAW JOURNAL

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# REPORTS

# TO THE READER

The Journal's first article is concerned with the adequacy and safety of our food supply, specifically it deals with an approach to the toxicological evaluation of food substances. Sherwin Gardner, acting Commissioner of Food and Drugs of the Food and Drug Administration, discusses the problem of toxicology in relation to reliable investigation. The article "An Approach to Toxicological Evaluation," which begins on page 640, was presented before the Grocery Manufacturers of America, Inc., Technical Committee on Food Protection in Anaheim, California, on June 8, 1976.

Twentieth Annual Educational Conference of the FDLI and the FDA. The following papers were presented at the 20th Annual Educational Conference of the Food and Drug Law Institute and the Food and Drug Administration, which was held in Washington, D. C. on December 7th and 8th, 1976.

John T. Walden, Assistant Commissioner for Public Affairs, Food and Drug Administration, shows in his article. "FDA With a Capital 'L'," that the FDA is one of the most acces-

sible and open agencies of government. His article, which begins on page 649, covers several aspects of FDA concern in the areas of legislation, litigation, labeling, laboratories and animal feed.

In his article "Consumer Interests—Do We Get the Foods We Want?," William V. Whitehorn, presents food as an area of primary public concern. Mr. Whitehorn's presentation focuses on increasing consumer involvement with the problem of nutrition labeling and emphasizes the need for adequate public information regarding such issues. Mr. Whitehorn, whose article begins on page 656, is Assistant Commissioner for Professional and Consumer Programs in the Food and Drug Administration.

In "The Network of Consumer Information" beginning on page 664, H. J. Barnum, Jr., presents a review of the network which supplies the consumer with information about food, drugs, cosmetics, and devices. Mr. Barnum, President of Barnum Communications, Inc., concentrates on sources, routes and receivers of information.



# Food Drug Cosmetic Law

# An Approach to Toxicological Evaluation

# By SHERWIN GARDNER

Mr. Gardner Is Acting Commissioner of Food and Drugs of the Food and Drug Administration.

YOUR INVITATION could not have come at a more opportune time, for I have been considering a subject that I hope may be of interest to you. It is a subject that, I believe, goes to the core of the challenge facing the Food and Drug Administration (FDA) as a regulatory agency and to you as experts in food technology, R & D and quality control. Indeed, it is important to everyone concerned with the adequacy and safety of our food supply. Specifically, it is the approach to toxicological evaluation of food substances. There are two general areas that are of interest:

- (1) the "how to do it"—involving lab standards, protocols, GCPs, etc.—and:
- (2) the how to approach it—involving administrative, political, social and economic factors (in short, the policy and philosophy).

Whether one's training is in engineering, science, or management, a fundamental issue is measurement of things with which we are concerned. The approach to measurement, employed by these professions, is a continual search for reliably measuring just one factor or variable.

The famous experiments conducted in the Hawthorne plant of the Western Electric company highlight what can happen when more than one variable is being measured—the engineers thought they were measuring the ratio between productivity and specific changes in working conditions. As Dr. Elton Mayo later discovered, they were actually measuring something entirely different: group dynamics, as well as, perhaps, the relationship between working conditions and productivity.

This difficulty in determining precisely what is being measured faces each of us as we seek to interpret data. It is particularly difficult when interpretation of data involves regulatory decisions, decisions that may be limited to a single product but which can involve an entire industry or region of the country.

To us in the FDA, the necessity of assuring that data and decisions stem from proper and precise measurement is not a theoretical matter, it is vital to our business.

# The Paul Principle

In the scientific area, decision making is complicated by something I call the "Paul Principle".

We have all heard of the so-called "Peter Principle" which holds that by some irresistible force of nature, individuals in large organizations tend to rise until they arrive at their "level of incompetence". While I suppose the FDA, as all large organizations, exhibits a certain amount of the Peter Principle, what really confounds us is Peter Principle's first cousin: the Paul Principle.

Instead of the incompetent moving above levels where they once performed adequately, as in the Peter Principle, the Paul Principle reflects the fact that in a rapidly changing scientific environment scientific facts tend, over time, to become outmoded and, therefore, incompetent at levels where they once performed adequately.

For example, science continually produces new and more reliable safety-testing methodology. The methodology often makes past judgments about safety subject to question. This, of course, is the price we must pay for progress.

If the activity of the Paul Principle is both welcome and inevitable, then the question that arises is, how can we be sure that new data, in regard to the safety of a chemical—a food additive, a drug, a cosmetic substance, is scientifically valid?

# Reliable Investigation and Measurement

The way, I suggest, is to assure that the evidence is derived from reliable investigation and measurement before we act. Frequent-

ly, that is easier said than done. There are many factors urging a rush to make judgments. The importance of many substances to individual health and to economic health is profound. The ability of the information media to communicate problems and concerns about these matters to over 200 million people instantaneously is both wondrous and frightening. Combine subject importance with speed of light communication and you have a situation in which reliable measurement of an effect assumes more significance than usual, while at the same time failure to measure reliably also becomes more damaging.

In view of this kind of pressure, when the safety of a chemical substance is called into question, it is vital to know that the question stemmed from toxicological data that reflect the reliable measurement of an effect. We need evidence of the influence of a specific dose to a specific organism, rather than a varying dosage of chemical "X" mixed with unknown impurities administered under varying circumstances in differing periods of time in an uncontrolled environment to mice of unknown genetic background.

Playing pool with "twisted cue on cloth untrue with elliptical billard balls" may be fine for Gilbert and Sullivan but it doesn't provide an acceptable approach for rigorous scientific method.

When we hear that a chemical produces a given kind of pathology, it would be good to know that the pathology was not the product of failure of the temperature control in the laboratory, juggling of the experimental and control animals, sloppy record-keeping, excess dosage, or the many other uncontrolled or unknown variables that poor science is heir to.

# Evidence of Impeccable Quality

We must make decisions on the basis of evidence of impeccable quality—which is another way of saying that we must be sure that we are *measuring just one thing*, basing our critical conclusions through attending to the tune, not the static.

In regard to food, drugs, cosmetics and other substances consumed purposely or involuntarily by people, the process of reliably measuring just one thing is complicated by the fact that it involves the convergence of three issues.

The first involves techniques of toxicological testing. Just how good are the tools and methods used to determine toxicity?

The second involves expectations of safety and protection. What should be the toxicological standards employed to insure safety of foods and drugs?

The third involves an allocation of burdens. What is the proper division of labor involved in evaluating toxicity?

## Division of Labor

Let us take these one at a time. The division of labor presently used, and which has seemed satisfactory, involves a petitioner-petitionee relationship. The party making the petition, be it for a drug or a food additive, has the burden of proof. Philosophically and conceptually, this is appropriate.

It is a division of labor that has provided us with the safest food and drug supply of any nation in the world. It also happens to be a division of labor that is being accorded increasing criticism. For, as you are well aware, such a system rests on a large amount of trust, in the sense that it is simply impossible for the government to carry its review of test data provided in support of an application to the ultimate, by doing the whole business over to see if it flies.

Senator Nelson, among others, has proposed a different way of doing business, that is by having a third party conduct the tests on the assumption that third parties, somehow, are above the temptation to cut corners.

Personally, I do not believe that merely changing who employs researchers would automatically provide better data. What is needed is a system for assuring that research meets contemporary standards of ethics, and that it is sufficiently rigorous so that it is reliably measuring just one thing.

While I am convinced that government should not assume industry's burden of testing food substances, as I will develop in a moment, this kind of separation does not necessarily have to mean divorce.

We can cooperate while maintaining a strict division of labor and responsibility. And I believe that some form of cooperation is necessary for two interrelated reasons. Society faces a rather stringent resource problem in the area of highly competent researchers and first-class facilities. To cite a constraint often overlooked, we simply do not have time to squander. Questions raised about substances already in the food supply must be answered promptly. Similarly, we

ought not delay the introduction of new and potentially beneficial substances because the nation's overburdened research capability means that the best speed we can make is a dull plod.

# **Expectations Concerning Protection**

Let us turn now to the second point of view I cited earlier—that of society's expectations concerning protection. If society ever arrived at a common agreement about its standards of expectation, many of its safety problems would fall into place like the last couple of pieces of a highly patterned jig-saw puzzle.

Some would set a very extreme standard, indeed. They would simply prohibit the use of many substances, such as colors and preservatives. That is, of course, one option.

It is not very helpful to oppose the use of individual substances on this thesis. If this is to be the basis for action, then Congress will have to be persuaded to change the law—and that is certainly one option that should be explored. But until it is, the consumer deserves the best approach we can devise to resolve safety questions.

Much of the contention that enlivens our days at the FDA involves precisely this subject—standards. It is important to recognize and understand what we can do. We can establish operational standards for risk (as a practical matter we must do so in order to establish criteria and objectives for scientific studies). Sooner or later we have to agree on how to do testing. Are fifty animals enough, or 5,000 or 50,000? What really can be called "good evidence" and what fails the test?

The National Cancer Institute (NCI), in particular, has been involved with the problem of proper standards for the conduct of bioassays. It recently published a document, "Guidelines for Carcinogen Bioassay in Small Rodents" that conveys what NCI considers to be satisfactory protocols. I expect this document will be of considerable importance to the FDA as we devise toxicology standards to carry out our function. Certainly our own regulations governing Good Laboratory Practices (GLP's) will be influenced by ideas from this and other sources.

# Techniques Used in Toxicology

Let us look now at the third point of view, or link in the chain leading to proper scientific conclusions—the tools and techniques involved in toxicology.

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Unless these tools and techniques are above reproach, there is simply no way to generate precise scientific evidence; no way that shuffling the division of labor is going to do more than subdivide confusion; no way that expectations are going to be met. Standards—no matter how high and allocation of resources—no matter how well devised, are insufficient without good methods and tools.

So, I want to spend a moment looking at tools. Perhaps the best way to begin that look is by saying that we in the FDA are keenly aware of the too often unmet need to measure just one thing reliably. Not only are we aware of it, we are making what I believe to be a significant contribution to responding to that need. I am referring now to an important "tool" for determining the proper standards to be used in toxicological research: the National Center for Toxicological Research (NCTR).

NCTR is one of the nation's finest tools for reliably measuring just one thing. It has honed the elimination of extraneous variables to a fine edge. By being confident of what variable it is in fact measuring, it is making important progress in understanding the incredibly complicated science of carcinogenity, mutagenesis, teratogenesis and estrogen mechanics.

The NCTR has evolved very rapidly from a facility concerned with biological warfare to a facility concerned with modern toxicology of foods and drugs. If you have not visited the NCTR recently, previous impressions should be abandoned as obsolete. The FDA has invested a major portion of its research budget in the NCTR, and we are proud of the outcome.

### Chemical Substances

I believe that what the NCTR is doing and how it is doing it is of considerable potential importance to your industry, but before I tell you how, let me make one observation about the chemical industry and the toxicity of basic chemical substances.

A chemical that proves to be suspect may be a minor item in the product mix of a single chemical company. Because it is used in dozens, perhaps hundreds of processed foods, what is a minor ripple in the production mix of a chemical company may translate into a financial and public relations disaster for an entire industry for which the chemical is but one of many raw materials or ingredients. Thus, the interest of users in the toxicology of chemicals is at least as compelling as that of the company that produces them.

The companies that produce chemicals are by no means unaware of their own need to gather precise toxicological data. It is for this reason that the chemical industry decided to join together to establish the Chemical Industry Institute of Toxicology (CIIT).

# Toxicological Problems

I also read with approval of the highly relevant proposal made last year by Dr. John Kirshman of General Foods at a Conference on Chronic Toxicity Testing and the Food Industry. Dr. Kirshman urged that toxicological problems be tackled by a group or consortium representing the drug, food, cosmetic, petrochemical and other consumer product industries.

These actions and proposals on the part of responsible industry segments and representatives are indicative of a picture that is beginning to emerge. It is a picture of a society increasingly concerned about standards that determine the degree of protection. It is a society increasingly concerned with the adequacy of the testing being employed to assure those standards are in fact being met. And it is a society that is examining how best to allocate the scarce resources of scientific talent, money and especially time to assure that tests of the highest quality are performed with the least amount of wasted effort.

It is within this context that I would like to pose several questions:

The NCTR was established to serve the FDA and EPA's needs but also, and quite specifically, to serve as "a national resource." It seems logical to ask whether there is some appropriate role that the NCTR and the FDA can play in providing the food industry and perhaps others with the kind of excellence in toxicology that Dr. Kirshman was seeking through his proposal.

Let this not be construed as a "position wanted" advertisement. I am not soliciting work for the NCTR. My intent is rather to explore with you and with others concerned with the issues I have mentioned on how this nation best might use the resources available to it in this area.

## Role of NCTR

If the NCTR is to be involved, what might that role be? Should it be viewed as a kind of referee or supreme court of toxicology—seeking to determine which of conflicting findings is the most reliable measurement? We might look at and be guided by experiences in this area. A couple of years ago, the question of Red No. 2 safety turned

to the findings of embryo toxicity produced by gavage administration. The question was whether or not the gavage feeding method would produce data relevant to human consumption and, if so, what would the findings be? We put the question to an *ad hoc* committee of scientists—they concluded that gavage testing would be useful and the NCTR along with other laboratories conducted the tests. That successful experience was overshadowed by subsequent events—yet, it should not be overlooked as a model for the future.

Having raised the question, let me suggest what some of the considerations might be while stopping just short of an answer. We are at a point where fundamental risk-benefit questions are being raised. They are raised by consumers, the Congress, scientists and industry. They range from "Why colors at all?" "Why substance X?, What does it do for the consumer?" to "If there's a suspicion of anxiety (read cancer-causing, mutagenic, teratogenic), why permit its use until we're sure?"

### Public Examination of Standards

The concerns behind such questions are strong incentives for a more deliberate public examination of standards to be employed for safety evaluation. The NCTR, together with our Toxicology Advisory committee, could be helpful in several ways—from protocol design, to identification of issues heading experimental illumination and to participation in a collaborative test program.

A fair guess would be that we have just seen the tip of the iceberg. While recent attention has been focused on Red No. 2 and cyclamates, other substances also are likely to become of concern. The GRAS review, work of individual investigators and development of new substances all are potential sources for new safety issues.

The question is not should the government become involved with evaluating food substances—it already is:

- (1) it is developing new standards,
- (2) it is developing new methods,
- (3) and it is resolving safety questions when others are unable to do so.

A more appropriate question is how the approach to safety evaluation can be changed to provide a more coordinated and collaborative approach—one that would be in the public's interest by resolving

controversies promptly, and one that would conserve public and private resources.

If we are to examine collaborative approaches, then other questions will need to be answered—

- (1) What sources of nongovernmental funds would be available to the NCTR and the FDA?
- (2) How might such funds be provided so objectivity of the work was not compromised?

There are a number of other questions I could raise, but my purpose at this point is not to cover the conceptual waterfront, but to stimulate some thinking about how we can apply the best knowledge with the least lost motion to the solution of public health problems. Part of that thinking involves an assessment of who is doing what and how—this in order to determine if and where improvements can be made.

Providing food and providing for the safety of food are tasks too important to be damaged by a kind of toxicological Babel. We need answers, we need correct answers and we need to find the shortest possible point between the safety question and its correct answer.

If there is some additional constructive role that the FDA, through the NCTR can play in this process, I want you to know that we are willing to explore it. [The End]

# INGREDIENT LABELING RULE FOR COSMETICS PARTIALLY STAYED

In response to an order from a federal appellate court, the Food and Drug Administration has stayed the November 30, 1976 effective date for complying with the requirement in 21 CFR 701.3 that cosmetic labels bear a declaration of ingredients. The regulation was effective as to labeling ordered after May 31, 1976 and as to all cosmetic product packages labeled after November 30, 1976. The stay applies only to the November 30 date. As a result of the stay, labels not complying with Reg. § 701.3 that were ordered before May 31, 1976 may continue to be applied to cosmetic packages until the stay is ended.

# FDA With a Capital "L"

# By JOHN T. WALDEN

Mr. Walden Is Assistant Commissioner for Public Affairs, Food and Drug Administration.

FOR THIS DISCUSSION ONLY, I will spell "Food and Drug Administration" ("FDA") with a string of capital "L's". The first "L" in FDA is for "Leadership." Dr. Schmidt resigned as of Dec. I and Sherwin Gardner, Deputy Commissioner, is acting Commissioner of Food and Drugs and will continue as such until the new administration names Dr. Schmidt's successor. (Meanwhile, the work goes on and I do not see the hiatus that others are predicting.)

# Focus of FDA Leadership

A continuing focus of FDA leadership is along three parallel tracks: order, accessibility and openness. By order I mean orderliness of operation. A whole "book" of procedural regulations has been issued to this end. They are "how to" procedures: how to petition the Agency; how to ask for, how to conduct and how to participate in various kinds of hearings, etc.

A second "book" of new procedural regulations defines and clarifies enforcement procedures—including recalls, regulatory letters, criteria for prosecution and use of publicity. Except for one portion, the administrative procedures are all published and all final. The enforcement procedures should all be published in final or as proposals by the year's end.

Rules now in effect make the FDA one of the most accessible and open agencies of government. Each of our 60-plus advisory committees and 500-plus advisors must discuss and decide in public session on the advice they give the Agency. They must do this to the absolute extent allowed by law. This policy of maximum openness is in place a full two months before the new sunshine law will make such procedures mandatory.

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The FDA's Freedom of Information (FOI) regulations have been revised after an extended shake-down cruise. The revisions will be published this month. There are refinements but no basic changes in what already is among the most extensive and liberal FOI policies in the executive branch.

During 1976, the Agency continued to live by the "Public Calendar"—a system whereby all top policy makers report weekly and publicly on all meetings with regulated industry.

One welcome result is that my job of answering press and consumer charges of "secret deals" has been considerably reduced.

# Legislation

The second "L" in FDA is for "Legislation." The biggest legislative production of the year was the Medical Devices law. The biggest current job for FDA is putting the new law to work:

- (1) In the classification of medical devices—the job is well along, about 2,500 product classifications have been made.
- (2) In the registration of device manufacturers—the deadline is Dec. 31 and there are 2200 registrants. (We still have some "holdouts.")
- (3) In setting rules for the investigation and development of new devices—a public hearing will be held in February.
- (4) In promoting preventive regulations through Good Manufacturing Practices—these are still some months away.
- (5) And, finally, in setting procedures for device standards and for pre-marketing approvals—both have high priority for 1977.

I will not dwell on the many legislative proposals on specific new regulatory authorities still hanging fire. Far more pertinent and more immediate are the legislative issues that deal with the reorganization, relocation, redefinition and, in a word, the reform of the FDA.

Legislators pushing reorganization generally are either "lumpers" or "splitters." The splitters want to divide the Agency at least by two. The lumpers want to make us one with others in a new bureaucracy to be called the CSA. (The initials stand for Consumer Safety Administration but after January, CSA will likely be, in many minds, first remembered as the Confederate States of America.)

It is anybody's guess what the result of all the reform-reorganization talk will be; it is a pretty good guess that the talk will result in changes. (For what it is worth I think the lumpers have the edge.)

# Legislative Oversights

Legislative oversight continues. Congressman Bumpers has called us to a December 15 hearing to explain our fluorocarbon-vs.-the-ozone policy. Congressman Moss may want to talk early next year about antibiotics in animal feed and about a ban on nitrofurans—if for no other purpose than to ask why the FDA still has made no final decision.

Senator Nelson may turn his attention from fat pills to food and color additives; while Congressman Fountain may well dig deeper into the FDA use of advisory committees.

One of the surest bets has to be that Senator Kennedy will return to the FDA drug review process. I say this because the Department of Health, Education and Welfare (HEW) Drug Review Panel is still trying to produce a report and when it does the ball will bounce back into Kennedy's court.

## Litigation

The third "L" is for "Litigation." First in our minds, if not in our hearts, is Laetrile. I cannot even keep up with the court maneuvers on this one. I do know that honest Laetrile believers as well as the purveyors of false hope for profit are well organized and vocal. They are before the courts, before the Congress and before the TV cameras.

In preparation for what could mushroom into a legal confrontation over the whole system of new drug clearances, the FDA, early next month, will publish a statement reaffirming the new drug status of Laetrile. We also will bring together and expand the administrative record on this subject and take this record back to court in defense of our case. Much more will be heard about Laetrile in 1977, in the courts and elsewhere.

# Labeling

The fourth "L" is for "Labeling." The record here is a good one. The most far-reaching initiatives are in patent-package labeling for prescription drugs. We are proposing to require that dispensers of oral contraceptives (OC's) provide a special brochure to women each time they fill a prescription. The new patient brochure is unique in the depth and detail of language about risks and benefits. The mandatory brochure would be backed up by a revised, patient label in each package of pills. Also, new physician labeling for OC's are being issued as a final order to be effective within 120 days.

A similar new labeling proposal for estrogenic drugs was published in September and the Agency is now preparing physician and patient labeling for intrauterine contraceptive devices. The IUD labeling should be issued in final form this month.

Late in November, the Agency proposed a first-of-a-kind label warning on most of the aerosol products containing a type of flurocarbon gas known to cause damage to the ozone. It should take 4-6 months to implement. An eventual ban is in the works.

Litigation is still under way but the FDA, nevertheless, is now requiring that cosmetic manufacturers prove claims of superior safety for so-called hypoallergenic products. We intend that the regulations shall apply to all cosmetics making claims of relative safety.

# Ingredient Labeling

Full ingredient labeling for all cosmetics is now being phased in. Within the past few days, a court deferred a November 30 deadline for such labeling, but we do not expect any real delay in compliance.

The most innovative developments in food labeling continues to be "drained weight" for canned foods and the September proposal to require percentage of main ingredient labeling on baby foods.

The National Canners Association responded last month to the FDA's drained weight proposal with its own "solid content" labeling and the FDA will evaluate this idea along with its own plan.

We expect the results of a professional cost analysis of the drained weight idea this month. This will be made public when received.

Percentage of main ingredient labeling for baby foods is intended as the forerunner of similar regulations for other classes of food. Before Christmas, we expect to order sales restrictions and mandatory labeling to meet the obvious need for consumer protection when buying hearing aids. We also plan, in the days immediately ahead, to restate our proposal for requiring blood and blood-product labeling to identify those from paid donors and those from voluntary donors.

We think both physicians and patients have a right to know the source of transfusion blood as well as the relative risks of hepatitis—a risk up to 10 times higher with blood from paid donors.

### Laboratories

The fifth "L" is for "Laboratories." By laboratories, I mean the major new FDA program to expand surveillance of animal research

done by the food and drug industries in developing pre-marketing product safety data.

Kennedy hearings, growing out of the FDA's own investigations, have identified and broadcast the fact that some of this research is less than dependable and, in some cases, less than honest.

The combination of FDA investigations and Congressional hearings resulted in 16.4 million dollars in new money and nearly a 10% increase in FDA manpower with which to mount a more intensive data surveillance program. We call it the Bio-Research Monitoring Program and despite this horrible name the program is important, intensive and of top priority. Under the program, we are moving immediately to substitute an orderly system of surveillance for the sometimes non-existent programs of the past. Already, we have found enough problems to propose withdrawal of a major new drug and to consider prosecution of some manufacturers and some test laboratories.

At least 40 other animal lab investigations are now getting started. I think we must expect further regulatory actions and possible prosecutions.

This is the short-term picture. The more positive long-term result of the Bio-Research Monitoring Program to date is the Good Laboratory Practices Regulations. Published for comment on November 19, the FDA will hold public hearings in the spring, followed by final regulations.

## Leftovers

The next to last "L" is one I shall call "The Leftovers." The recent decision to deny Parke, Davis & Co. permission to continue marketing diphenhydramine as an over-the-counter (OTC) cough medicine tops the list of "leftover" issues. Within recent days, there have been multiple seizures and a temporary injunction which stopped further seizures as well as further distribution of Benylin. Watch almost any space for further developments.

The twin issues of bioequivalence and bioavailability are just barely leftover. Final regulations should be signed this month. They will appear shortly thereafter in the Federal Register. The new regulations mean that in the immediate future all new drug applicants must prove bioequivalence and bioavailability. The regulations have major implications for government reimbursement for drugs and the generic-vs.-brand-name controversy. I recommend Dr. Crout for further enlightenment.

During November, the Agency permanently approved 20 provisional color additives for use in drugs and cosmetics. Leftover are 52 food, drug or cosmetic colors still on the provisional list. Despite past hopes and repeated promises, these will not be finally decided for two to four more years.

Animal studies on the last of the red dyes, No. 40, continue. A consumer group says the data now supports a ban and the FDA to-day named an FDA-NCI review group which will meet December 16-17.

The GRAS review continues and the concept evolved into a broader program for cyclical review of safety data for all food and color additives. The Bureau of Foods has hired 20 people and is recruiting and training them. The system is a reality.

Then, there is the leftover program of ingredient labeling for alcoholic beverages. The Department of Justice is now trying to decide whether to appeal as the FDA wants or to accept a lower court decision that rules the FDA out of bounds in trying to impose such labeling. If Justice decides against appeal, then your favorite booze will likely continue without ingredient labeling until and unless the Congress gets into the act.

A relatively new leftover is the issue of the new X-ray system known as the "CT" scanner. The FDA's problem is to decide if regular X-ray emission standards can be revised to serve or if we need a whole new set of standards. A very stale leftover is the so-called Sensitivity of Method regulation. We now project a regulation by December 31.

But this will not end the matter. This is no more or no less than a continuing effort to deal with the sticky fact that our technology for measuring anything in anything has gotten ahead of our ability to interpret the health implications of such exquisite measurements. The entire concept of method sensitivity may eventually butt directly against the Delaney clause and the butting could be explosive.

### Animal Feed

I have already mentioned the Agency's prolonged wrestling match with the issue of antibiotics in animal feed. It has been studied and re-studied and, at this moment, is before the FDA National Food and Drug Advisory Committee. Their recommendations are due in January and the issues will be discussed in detail in one of your workshops.

Another meaty leftover is DES as a growth promotant in food animals. About two years ago, a judge told us we had to grant a hearing on our latest proposal to ban the drug for this use. On November 26, the Agency decided that such a hearing is justified. Further decisions on that hearing will be decided, beginning January 5, 1977, at a prehearing conference.

The final "L" is really an alliterative phrase that goes like this: "Loud and Likely to get Louder." This refers to issues and events likely to make the most noise during the new year.

My personal predictions for this category are:

- (1) The future of the fat pills. Dr. Crout, in November, committed the FDA to a decision based on data due at any moment from the Drug Enforcement Administration.
- (2) The Benylin Case. It may well touch the whole OTC Review—our use of advisory committees and drug marketing generally.
- (3) The Laetrile Confrontation. This noisemaker has a real big clacker.
- (4) The regulatory reform and reorganization circus, the greatest show on earth—complete with cannons as well as clowns.
  - (5) Bio-medical research monitoring. It cannot be done quietly.

### Artificial Sweeteners

Finally, we face the continuing saga of the artificial sweeteners:

- (1) Abbott is unhappy with FDA's latest ban on cyclamates and demands a hearing;
- (2) Canadian studies, due in mid-1977, will likely lead to new decisions about saccharin:
- (3) and on aspartame, the FDA this month reconfirmed its support for third party authentication of questionable safety data. The work has not yet begun.

With all this, I come out where I came in. Transition or not, I see little peace or quiet or inactivity in the FDA's immediate future.

[The End]



FDA WITH A CAPITAL "L"

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# Consumer Interests— Do We Get the Foods We Want?

# By WILLIAM V. WHITEHORN

Dr. Whitehorn Is Assistant Commissioner for Professional and Consumer Programs in the Food and Drug Administration.

AS 1 PREPARED FOR THIS TALK, I was impressed by the nature and the complexity of the questions posed for this afternoon's discussion. These questions are not answered easily. They deal with attitudes, value judgments and imperfect quantitations. They cannot be answered by rules, regulations or legalisms.

But I am very pleased that they have been given a place in this conference since, unless they are considered, the best interests of the public cannot be served.

As the Director of the Office of Professional and Consumer Programs for the Food and Drug Administration (FDA), much of my time is spent gathering information on consumer attitudes and perceptions on a wide variety of FDA-regulated activities. In the conduct of this job, I have access to a highly competent staff of consumer experts—the FDA Consumer Affairs Officers, located throughout the country. Much of what I say reflects their input as well as that of the other channels of communication the Agency actively maintains with consumer advocates and consumer leaders across the country.

I am addressing you not as a rule-maker, but as one who has the responsibility for the various programs which represent the educational component of the Agency's regulatory activities. Today, the FDA firmly believes that protection of the public health can be achieved realistically on a wider scale by education, information and involvement of the public. The Agency is actively pursuing ways of increasing public participation in its decision-making processes. For

instance, there are currently 55 consumer representatives on the FDA's advisory committees. On a regular basis the Commissioner and his top staff meet with consumer advocates in Washington, D. C. as well as in other major cities to discuss with them important and timely health issues. The National Advisory Food and Drug Committee, the top advisory committee to the Commissioner, has particular consumer representation.

# Primary Public Concern

From all these sources, it is clear that food is an area of primary public concern.

Today, shoppers confront a food supply that no longer is taken for granted as being healthful, safe and good simply by virtue of its being marketed. Consumers are bombarding the FDA with their inquiries, complaints and demands concerning the quality and safety of their food. Yet, with these demands comes the perplexing question—how much protection does the consumer want, need and can afford?

The simplicity of this question belies the complexity of the response. Take, for example, the question of how much protection consumers want. With conclusive scientific evidence now available that cigarette smoking and alcoholism are not only "hazardous to your health" but are contributing significantly to permanent body damage—or, in the extreme, to death—consumers continue to drink and smoke in increasing numbers. Moreover, many of these same people vehemently oppose any governmental interference with their right to do themselves bodily harm if they so choose. Consumers want to know, "How much risk exists?" At the same time, they want to retain the right to take risks, if they feel the benefits are great enough.

On the other hand, when it comes to foods, an increasingly vocal segment of our population is demanding that the government guarantee a 100 percent safety coefficient, which, of course, is neither realistic nor practical. Foods themselves are chemically composed. Even the ordinary potato is made up of at least 150 different chemicals, and some of these chemical constituents are known to be toxic. In actuality, there are toxicants present in naturally produced foods that would raise serious questions by the FDA if offered as food additives. Does this mean that we should do without the benefit of these foods because of the potential risks? Obviously not. At what point, then, do the

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risks outweigh the benefits? How much risk is acceptable, at what price? Who decides?

Understandably, the consumer desires the highest food standards possible, until the nagging reality of cost enters the picture. In general, shoppers with a higher socioeconomic status and education level are more willing to pay an additional cost for greater protection in relation to food quality. Poverty level consumers strive to have enough food to keep themselves and their families alive and reasonably healthy. They often cannot afford the luxury of protection to the same degree as the more wealthy.

# Highest Quality Safety Standards

FDA has the responsibility of protecting all consumers by setting the highest quality safety standards that are scientifically feasible and that are also economically reasonable. However, we realize that often there are times when we are unable to satisfy all the people we serve.

The Agency, on the other hand, does not have jurisdiction over food quality nor does it even have a reliable definition of food quality. It cannot determine how or which foods are processed, nor can it determine the ingredients or the preservatives which go into these foods. As the law presently stands, that is industry's domain.

But, we at the FDA must concern ourselves with increasing constituent criticism from a society that expects more and more from its public institutions. Consumers expect the FDA to guarantee the safety, purity and wholesomeness of food. These quality expectations are certainly the ultimate goals of us all. When one considers the fact that there are 200 million American citizens each consuming 1.420 pounds of food a year, one realizes the difficulties in achieving consistent quality—whatever the ultimate measure of quality happens to be. A large majority of Americans eat not only to satisfy their bodily needs, but also as a form of social entertainment and pleasure. In fact, with so much of our daily and social activity revolving around food and the pleasure of eating, food aesthetics and taste often are given more consideration than food quality and quantity. This demand for food to be appealing to the eye, smell and taste underlies another benefit-to-risk and benefit-to-cost situation-food additives and food colors. There is an increasing public awareness and suspicion

of these substances, which, on the positive side, preserve, aesthetically increase the appeal of food products and keep costs down. On the negative side, many of these additives and colors, throughout the years, have been found to contain, or were suspected of containing, carcinogens or toxins. They were, therefore, removed from the market or were listed permanently, depending upon the FDA's assessment of the proof of safety and the courts' upholding of the Agency's judgment. Consumers rightfully expect a product which is safe, clean, fresh and, in this sense, wholesome. It is the FDA's responsibility to assure the consumer of this.

# Food Labeling Regulations

While the Agency cannot determine the composition of foods produced, it does have the responsibility to see that the foods under its jurisdiction are labeled properly. Because shoppers today are flooded by thousands of food choices, they need to know, and are demanding to know, the identity and nutritional value of what they are eating. Ideally, this additional knowledge will eventually lead to rational decisions enabling the consumer to eat better and to pay less for food products. The FDA recently has implemented a program of food labeling regulations. Its purpose is twofold: (1) to provide the consumer with better nutrition information on labels in a standardized way; and (2) to make all information on food labels more comprehensible to the public. During the past year, the Agency has held approximately 600 seminars and workshops to describe the various packages of regulations that have been issued by the FDA this year. These workshops have included a broad group of "multiplier people"-nutrition educators, teachers, extension agents, dieticians and other professionals—who deal with the problems of hunger and malnutrition and who in turn react with the consumers and the public. The emphasis has been upon explaining the aims and methods of the nutrition education program of the FDA and how nutrition labeling, dietary supplement regulations and various other regulations contribute to consumer education.

It would be incorrect to say that nutrition labeling thus far has been an unqualified success. The FDA fully recognizes that nutrition labeling will not be an effective device until shoppers know what the nutrients are, where to get them, and how much of them need, or need not, to be eaten. Techniques to communicate this message effectively

are being explored constantly. Statistically, however, we do know from a comprehensive FDA consumer nutrition knowledge survey that approximately two-thirds of the shoppers interviewed in the 1975 Bureau of Foods shopping survey have seen nutrition labeling, although only one-third of them affirmed that they actually used it. One significant factor was the definite increase in the use of this information as the educational level of the consumer rose. Younger shoppers, college-educated individuals and mothers with children under 18 years of age had a greater tendency to utilize information on food labels.

A 1975 "Redbook" nutrition survey conducted by the Gallup organization portrayed a more optimistic outlook in relation to consumer usage of food labeling. This was a national study of women shoppers which revealed that 56 percent read and used food labels to decide what food they would purchase for their families. The poll also indicated a trend towards a greater desire for nutrition labeling. In 1971, 39 percent of the women surveyed desired more information on nutrition. A substantial increase is indicated by the fact that in 1976, five years later, 50 percent of the women interviewed expressed a desire for more nutrition information and most of them expressed a willingness to pay an extra three cents per item for increased nutrition labeling.

## Consumer Awareness

Especially during these times of escalating food costs, shoppers must analyze their priorities in relation to nutrition and costs for the food purchased. Consumer awareness is essential in this regard as it is possible with the necessary knowledge to eat better for less money. In the 1974 portion of the shopping survey conducted by the FDA, 57 percent of the shoppers interviewed replied that it is possible to cut food costs and still serve their families nutritious meals. Not surprisingly, the individuals who responded in this manner tended to be younger and relatively well educated in the realm of nutrition.

When analyzing the results of the surveys mentioned, we can conclude that there are beneficial effects from nutrition labeling and that the younger, better educated shoppers tend to use it more. The goal, however, is clear—How can the Agency better educate all consumers to use label information so that more nutritious food can be bought at the lowest possible cost?

In addition to nutrition labeling, the FDA is concerned with net and drained weight labeling, ingredient labeling, baby food labeling and the labeling of the percentage of the characterizing ingredients in foods with a common or usual name. People on restricted diets, shoppers who are anxious to cut costs while maintaining the nutritional quality of their meals, mothers who buy prepared infant food and the average shopper, are all dependent on the FDA to help guarantee the accuracy of the label information. Many consumers today feel that this is not enough and remain critical of the FDA because the Agency has not made it mandatory that industry disclose the percentage of ingredients in standardized foods as well as the nutritional value of this processed food on the label. The mere listing of ingredients in the order of content may be misleading and, in many cases, is considered as such by the consumer. This is again an example of the Agency's lack of jurisdiction in this area. If the public really wants this information, it must take steps to see that the appropriate laws are enacted.

# Consumers' Choices

It is my belief that food regulations have a very limited effect on consumers' choices. Ideally, we do not want consumers to eat anything that would be detrimental to their health. Realistically, we know that consumers do not and will not have their food habits dictated to them by a regulatory agency. The FDA does not attempt to restrict consumers in their choice of foods. We are dedicated to providing the public with information about proper nutrition so individuals can knowledgeably make their own choices. Indeed, if an individual desires to exist by eating nothing but convenience food, the option is his. Convenience foods are available in the marketplace because there is a demand for them.

It is the FDA's responsibility to insure that food consumed is healthful, safe, free from contamination and adulteration and accurately labeled. But, again, simple words lead to complex questions. There is no absolute definition of safety.

As technology becomes more sophisticated, our previous perceptions of what is safe become obsolete and the benefit-to-risk question again presents itself. To offer one well-known example: cyclamates, once deemed safe, now are banned as a food additive.

To consumers, such as diabetics and dieters, who previously counted on cyclamates as an artificial sweetener, rather than saccharin, which left a bitter after-taste, this move could be interpreted as limiting the consumer's choice. Some people believe that the FDA does not have the right to act "arbitrarily" in this way. The other school of thought insists that the FDA is obligated to ensure the safest possible products for the consumer. Ultimately, we cannot do either, yet we do attempt to work towards the latter.

When I began this discussion, I referred to the complexities of the questions the panel was asked to consider. Now, after perhaps increasing the confusion, let me return to the theme for this panel— "do we get the foods we want?"

# Variety of Foods Available

One need only visit the average supermarket to see the enormous variety of foods available to the American public today. In addition to the general food sections, there are other sections devoted entirely to ethnic gourmet foods such as Chinese, Mexican, Italian, Greek and Japanese. From this observation, it is obvious to me that the food industry is responding in its way to what it thinks the consumer wants. Accordingly, if any new product does not sell at a profitable rate, it is speedily removed from the shelves. This devotion on the part of the food industry to the culinary wants of the American public goes deep indeed. The results of the millions of dollars spent on carefully designed marketing and promotional campaigns reveal information on what brand X items Mrs. Jones will serve her family, how often and even what Mrs. Jones is willing to pay for the brand X 's lining our favorite supermarket shelves. But can we determine by variety and numbers of food items available in the supermarkets whether or not the consumer really is getting the food he wants? I think not. Let me quote from the Nutrition Foundation, 1969-1970 Report:

"The food supply in the United States is among the finest in the world. The amount produced is adequate for everyone to achieve good nutrition, and the food is of the highest quality. At every step, producers, processors, distributors and government agencies take great care to maintain this quality for the consumer....

<sup>&</sup>quot;... notwithstanding the high quality of the food supply, poor eating patterns and lack of understanding of the basic principle of nutrition are prevalent among all socioeconomic levels of the population."

On the same subject Dr. Briggs, University of California, Professor of Nutrition, had this to say:

"The typical American diet is a national disaster. There is much malnutrition in this country among rich and poor alike. It shows up in many different ways—hunger and outright nutrient deficiencies, high incidences of anemia, increased infection, underweight and overweight, severe dertal problems, reduced growth, needless problems in pregnancy, shortened life-spans and even in behavioral and mental problems in children and older people."

We must learn more about what the public thinks about the questions we are considering today. And we must involve the public in our deliberations and decisions

The Nutrition Foundation Report which applauds the American food supply on the one hand and Dr. Briggs' statement concerning the national diet on the other, suggests that there may be definite differences between the food we want and the food we need. Perhaps in order to have a meaningful discussion of the issues raised by the question "do we get the foods we want?" we need first rephrase the question to read "do we get the foods we really need?"

It is my belief that with proper informational and educational programs the American public will be in a better position to answer that question for itself.

[The End]

# NUTRITIONAL LABELING EXEMPTION ESTABLISHED FOR RESTAURANT FOODS

An exemption from full nutrition labeling requirements has been provided by the Food and Drug Administration for combinations of restaurant foods, such as a hamburger with french fries and a milkshake. According to the new policy, nutritional information may be included in the advertising for and packaging of a combination of foods, as long as such information is displayed at the point of purchase and at the place of consumption. Previously, if any nutritional claim was made for a combination of foods, regulations required that each article of food bear complete nutritional information. It is anticipated that the policy will result in greater availability of nutritional information to patrons of fast food establishments.

CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 41,764

# The Network of Consumer Information

By H. J. BARNUM, JR., M. D.

Dr. Barnum Is President of Barnum Communications, Inc.

A S WE COUNSEL TOGETHER regarding that which consumers should know about foods, drugs, cosmetics and devices, perhaps it would be in order to review the "network" which supplies such information.

Let's begin with the sources of information. In Washington, D. C., there are the Food and Drug Administration (FDA), the Federal Trade Commission, representatives of various professional and business associations, consumer groups, political figures and other representatives of various parts of the federal establishment who from time to time originate information, which in one form or another, and by one route or another, ultimately reaches the consuming public. Beyond Washington, information is generated by a wide variety of sources including the academic and scientific communities, organizations head-quartered outside of Washington, organized medicine and individuals acting either on their own or as representatives of a wide variety of interests in both the public and private sectors of American life.

What are the *routes* over which information travels to consumers? It seems to me the routes of importance are four in number. Let us consider three now, saving the fourth for later discussion:

- (1) obviously foremost, the mass media;
- (2) via health professionals—most notably, physicians; and
- (3) by word of mouth from consumer-to-consumer.

# The Receiver of Information

To complete this brief overview of our information network, let us now consider the *receiver* of information—"the consumer." I have

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just made a serious mistake using the term "the consumer." It is a mistake often made (perhaps even in Washington) because "the consumer" is not a single entity. Rather, the consuming public represents an infinite number of permutations of intelligence, awareness, interest, education, motivation, location, etc. All of these factors may bear heavily upon the ability to receive information and to act upon it appropriately.

It seems a bit previous to discuss "what the consumer should know" as one views an information network, which has only one common denominator—complexity. We have multiple sources generating information which is then carried by a variety of routes to an audience characterized primarily by its heterogeneity. It is a small wonder that there are so many imperfections in the system.

As we study the source, the route and the receiver, we might do well to examine some of the problems and to challenge the reliability of the information network.

# Package Literature

Let us begin in that source area subject to closest regulatory control—the package literature describing prescription drug products. At least one former Commissioner of the FDA and one Director of the Bureau of Drugs have called for widespread revision of the package literature so that the insert covering each product can be the most accurate description of that product, stated in the clearest and most practical terms for the use of physicians not only in drug selection, but also as a basis for the information they pass on to their patients. Despite public statements from individuals high in the management of the FDA, it seems that package inserts for drugs are not yet all they should be. For example, Dr. William O'Brien, of the medical school of the University of Virginia, was quoted recently as describing the current insert for phenylbutazone as "just atrocious" because there are so many adverse reactions listed that it is difficult to tell which are serious and which are not. Package literature of this character is just as wrong, just as bad, just as much a glitch in our system as those inserts of earlier days which were in effect, promotional documents. Over the last decade, we have seen the insert as a continuing battleground over which the issue of promotion has been fought. The federal authorities describe the glass as half empty whereas the manufacturers prefer to describe it as half full. Neither approach is in the hest interest of the public health. Package literature represents a controllable part of our information base. This control should be exercised in the ultimate interest of consumers, not as an instrument either to enhance or to squelch promotion. Benefits and risks should be quantified wherever possible and based on the best and most dispassionate scientific information available. The "promotability" of insert content should not be at issue; scientific accuracy and clinical utility should be. This most important information source simply must be reliable.

### Benefit-to-Risk Ratio

One of the principal benefits of a better body of information for prescription products in the form of package literature would be to pose more clearly, both to physicians and patients, the concept of the benefit-to-risk ratio. This concept simply has not yet met with wide-spread understanding. The fact is: information on health-related products cannot be used properly without an understanding of the benefit-to-risk concept. Despite the shrill demands of those well-intentioned but not so well-informed, we do not live in a risk-free world. Even the bathtub may be "hazardous to health" to those who slip and fall in it.

Next, I will discuss other controllable parts of our information base. All responsible sources should avoid the dissemination of misinformation, incomplete information and premature information. For example, in the absence of clear hazard, I respectfully question if it is either useful or appropriate to use the public press as a means of advising patients taking a prescription drug to discontinue its use, or return to their physicians for alternate therapy, when the effective new drug application status of the drug has been challenged but not yet resolved. It seems to me that such action tends to create fearful and even hysterical responses among consumers. At the very least, it adds to the serious problem of patient compliance.

And whenever information is to be generated or disseminated, may we please pause to consider the merit of plain English? I submit that the average American understands the term "cough medicine" a great deal better than the term "antitussive."

### **Bad** Information

If I seemed to have dwelled excessively in these past few moments on the information glitches in the federal establishment, let me quickly assure you that as many bad examples are to be found among other generators of information, both in the public and in the private sectors. The following are a few examples:

- (1) The cancer cures we read about in the public press and then never hear of again.
- (2) Except for the cancer cure, the press otherwise seems far more interested in Halloween stories than it is in accurate reporting of scientific progress. (Sometimes, it seems that good news is no news.)
- (3) There are lapses in that part of the network in which health professionals figure. Sometimes these health professionals are placed in positions in which they do not wish to be, in which they should not be. Consider for example, the poor pharmacist who gets the question, "Hey doc, what's good for systemic lupus erythematosis?" or the nurse who is told, "But you're a nurse, you should know all about cancer." And, finally, the physician, that victim of the short clock and the long knowledge explosion who is expected to know everything and unfortunately does not and cannot. How about the consumer-to-consumer, word of mouth, part of the network? It is here that we find the amulet, the black box, the rabbit's foot, the old wives' tales and, occasionally, even some useful information.

The problem is, of course, discriminating between the good information and the bad. Where do we draw the line between the right to know and the inability to understand, knowing that we cannot send everybody to medical school?

# Quality of Information

Thus far, we have reviewed sources of information, routes over which information travels, the reliability of both sources and routes and the ability of the receiver to absorb and use the messages flowing over the health information network. We have seen a picture of complexity and imperfection. We are left, I believe, more with the question of how can we improve the quality of consumer information than to consider "what the consumer should know." In this latter respect, I would suggest to you that there is inherent simplicity rather than complexity. Only two points come to mind:

- (1) Consumers should be sufficiently informed to use, with reasonable safety, freely available foods, drugs, cosmetics and devices for those simple uses not requiring the guidance and supervision of health professionals.
- (2) Consumers should have such information as may be useful to their entering into responsible partnership with members

of the health professions for the management of personal health problems, both preventive and therapeutic.

I deliberately have left the subject of commercial communications until last, simply because it would have been so easy to put it first. Advertising and the many other modalities of commercial communication often have high visibility in our society. Despite the elimination of many of the objectionable features of our commercial communications in the past, some still persist and must be eliminated. The world of commercial communications must abide by the same high standards we have suggested for other sources of information. It has been said by one famous advertising executive that advertising itself is a multiplier. Honest advertising of a good product multiplies its success, whereas dishonest advertising of a poor product multiplies its failure. Every generator of commercial communications must bear this in mind.

# Advertising

In our free society, we still hold that one has the right to advertise one's wares. One, however, does not have the right to mislead, to abuse or to defraud. Advertising is more accessible to centralized control than most other elements in our communications network. This accessibility carries with it the danger that in our zeal to eliminate evils, we may go too far and thus close down one corner of our free society. If such comes to pass, fault may well lie both with the irresponsible advertiser and the overzealous regulator.

I believe, however, that somehow, like the English, we will muddle through. There is a clear pathway to future progress in giving to the consuming public that information it needs and that to which it is entitled.

The critical points along this way include:

- (1) More responsible *generation* of information at all source levels:
- (2) More responsible *transport* of information by all key links in the network:
- (3) More accuracy, more clarity and more balance in the information conveyed; and
- (4) More real concern for the *public interest* and less self-concern among all who share in the task of informing the public.

If we can bring this about as a reality, not an illusion, that which should reach America's eyes and ears shall. [The End]

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# NEW GRAS CRITERIA ISSUED—11 ADDITIVES AFFIRMED AS GRAS

Criteria for determining whether a food ingredient is not a "food additive" under the Federal Food, Drug and Cosmetic Act but is, instead, "generally recognized as safe" (GRAS) or subject to a "prior sanction" have been defined by the Food and Drug Administration. They were proposed in September of 1974 and comments on the proposal were received through January 6, 1976. The language of the final regulation has been revised in part to reflect comments and objections, but the general impact of the criteria is the same as that proposed.

GRAS status must ordinarily be based upon published literature, but, where the affirmation of the ingredient is requested based on "common use in food," does not require the same quality or quantity of scientific evidence necessary for approval of a food additive. The phrase "common use in food" refers to a substantial history of consumption of the substance by a significant number of consumers in the United States. When GRAS status is granted without specific limits, the regulation will specify the levels of use which served as the basis of the agency's conclusion that the ingredient is GRAS. If use of the substance were then to increase significantly, it may no longer be GRAS. The FDA noted that the limits listed in GRAS regulations are not rigid limitations but are more than a mere aid to good judgment. When an increase in use levels is considered, the manufacturer must assure itself that the substance would still be GRAS.

## Affirmations

The additives affirmed as GRAS concurrently with the issuance of the criteria for affirmation were: benzoic acid and sodium benzoate, acacia (gum arabic), karaya gum (sterculia gum), guar gum, propyl gallate, pulps, dill and its derivatives, garlic and its derivatives, gum tragacarth, gum ghatti, and oil of rue. The FDA has also proposed affirmation of rue as direct human food ingredient and has called for notice of asserted prior sanctions as well as comments on the proposal. Comments should be received by the agency by February 7, 1977. No reports of prior-sanctioned use for any of the affirmed ingredients were submitted in response to proposals to list the substances as GRAS; therefore, the right to assert any prior sanction under conditions different from those provided in the GRAS regulations has been waived.

# **Prior Sanctions**

The procedure for considering the applicability of prior sanctions requires that anyone who asserts a prior sanction of which the FDA is not aware must come forward when the agency proposes a GRAS or food additive regulation after a general evaluation of the ingredient involved. In response to a comment that questioned the FDA's authority to require notification of prior sanctions, the Agency stated that the rule is necessary for the proper functioning of the ingredient review program and that, if the prior-sanctioned use is safe, all users should be permitted to rely upon it.

# ... AND RELAXED LABELING RULE PROPOSED FOR AFFIRMED GRAS INGREDIENTS

The labeling of intermediate mixes containing ingredients affirmed as GRAS would not have to state the concentration of the GRAS ingredient if it provided other information needed by the food processor to independently determine that the contemplated use of the mix will comply with the Food and Drug Administration's GRAS limitations, under a proposed regulation published by the Agency. Comments filed in response to proposed affirmation of various natural ingredients indicated that varying composition makes composition labeling very difficult to determine. In response to these comments, the final GRAS regulations for those substances did not include the composition labeling requirement. However, concern that food processors would be unable to determine what use of the intermediate mix would be in compliance with the GRAS limits led the FDA to propose the substitute labeling. Comments on the proposal may be filed until February 7, 1977.

# NEW COMMISSION WILL OVERSEE PRESCRIPTION DRUG USE

The creation of a Joint Commission on Prescription Drug Use was announced jointly by Senator Edward Kennedy and the Pharmaceutical Manufacturers Association on November 30, 1976. Set up to develop a system for identifying and reporting adverse drug reactions and trends in national drug use, the 18-member group is composed of a coalition of private and public groups, but will act independently of them. The life of the Joint Commission is three years. At the end of this period, it is presumed that there will be a mechanism for permanent data gathering and dissemination of prescription drug use information. Funding for the group in the amount of \$750,000 will be guaranteed by the PMA, which sponsored the creation of the Commission.

CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 41,790

# LAST OF 20 COLORS ARE PERMANENTLY LISTED: 52 STILL PROVISIONAL

On November 30, 1976, the Food and Drug Administration concluded its plans to "permanently" list the 20 color additives which have been on the "provisional" list since 1960 and for which all safety questions have been resolved. The final three colors to be removed from the provisional list and made the subject of specific certification regulations were guaiazulene (previously known as "azulene"), D&C Blue No. 4, and iron oxides. Guaiazulene may be used in externally applied cosmetics, iron oxides are approved for use in all cosmetics, and D&C Blue No. 4 may be certified for use in externally applied drugs and cosmetics.

Still appearing on the provisional list of additives, signifying that the colors are approved for use while further safety data is being gathered, are 52 color additives. The FDA said that there are no significant safety questions concerning the remaining provisionally approved colors, but that it has asked industry to conduct additional studies before the agency decides whether they should be permanently approved or prohibited.

Persons adversely affected by the approval of the three colors named above have until December 30, 1976 to file objections. Unless stayed by the filing of objections, the regulations will take effect January 3, 1977.

CCH Food Drug Cosmetic Law Reporter, ¶41,782—41,784, 6801, 6498, 6621, 6759, 6760, and 7540 Here's your opportunity to bred controver the following cosmetic law internation on him linder paramptly

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