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October 5, 1971

TO: All Members of the SPI Food, Drug and
Cosmetic Packaging Materials Committee

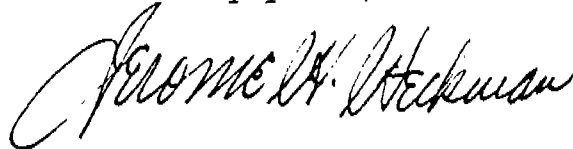
Gentlemen:

Many of you have probably noted the Food and Drug Administration's publication in the September 28 edition of the Federal Register whereby it has indicated its intention to further amend the regulations relating to changes in the "status of GRAS, Food Additive and Prior Sanctioned Substances."

For those of you who may not have picked this item up, a reproduction of page 19089 of the September 28 Federal Register is enclosed herewith. Also enclosed are reproductions of pages 27 through 32 of this week's edition of Food Chemical News since these pages will serve to provide you with (1) an explanation of the motivating purpose behind the September 28 FDA Rulemaking Proposal, and (2) a report on the Congressional hearings regarding the presently pending bill which would provide government indemnification for those injured by the cyclamates GRAS status revocation.

In our opinion, there is no real reason for the Society to comment on the FDA proposal so we shall not plan to file any comments in the absence of our receipt of contrary recommendations from you. On the other hand, if you do have any questions about this situation, please do not hesitate to let us know.

Cordially yours,



Enclosures

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handle constructed of nonconductive material.

38. Section 1518.750 is proposed to be amended by amending paragraphs (b)(1)(i) and (c)(2) thereof. As amended, § 1518.750 would read as follows:

§ 1518.750 Flooring requirements.

(b) *Temporary flooring—skeleton steel construction in tiered balconies.* (1)(i) The derrick or erection floor shall be solidly planked or decked over its entire surface except for access openings. Planking, or decking or equivalent strength, shall be of proper thickness to carry the working load, but shall be not less than 2 inches thick full size undressed, and shall be laid tight and secured to prevent movement.

(c) * * *

(2) For single wood floor or other flooring systems, the floor immediately below the story where the floor joists are being installed shall be kept planked or decked over.

39. Section 1518.800 is proposed to be amended by revising paragraph (a)(4) thereof. As amended § 1518.800 would read as follows:

§ 1518.800 Tunnels and shafts.

(a) * * *

(4) Access to unattended underground openings shall be restricted by gates or doors. Unused chutes, manways, or other openings shall be tightly covered, bulk-headed, or fenced off, and posted. Conduits, trenches, and manholes shall meet the requirements of Subparts M and P of this part.

40. Section 1518.859 is proposed to be amended by revising paragraph (e) thereof. As amended § 1518.859 would read as follows:

§ 1518.859 Mechanical demolition.

(e) When pulling over walls or portions thereof, all steel members affected shall have been previously cut free.

41. Paragraph (b)(4) of § 1518.351 (36 F.R. 7368, 9423) is proposed to be amended. As amended, § 1518.351 would read as follows:

§ 1518.351 Arc welding and cutting.

(b) * * *

(4) Cables in poor repair shall not be used. When a cable, other than the cable lead referred to in subparagraph (2) of this paragraph, becomes worn to the extent of exposing bare conductors, the portion thus exposed shall be protected by means of rubber or friction tape or other equivalent insulation.

(Sec. 1, 83 Stat. 96, 97, adding sec. 107 to Public Law 87-581, 76 Stat. 357; sec. 6(b), 84 Stat. 1593, 29 U.S.C. 655, 40 U.S.C. 333)

Signed at Washington, D.C., this 20th day of September 1971.

G. C. GUENTHER,
Assistant Secretary of Labor.

[FR Doc 71-14118 Filed 9-27-71; 8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 121]

CHANGE IN STATUS OF GRAS, FOOD ADDITIVE, OR PRIOR SANCTIONED SUBSTANCES

Proposed Statement of Policy

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-88 as amended; 21 U.S.C. 321(s), 348, 371(a)) and under authority delegated to him (21 CFR 2.129), the Commissioner of Food and Drugs proposes to amend Part 121 by adding the following new section:

§ 121. Change in status of GRAS, food additive, or prior sanctioned substances: statement of policy.

(a) Regulations promulgated under section 409 of the Federal Food, Drug, and Cosmetic Act give no implied or explicit guarantee that any substance named therein will continue in a particular status.

(b) The decision to use a particular GRAS (generally recognized as safe), food additive, or prior sanctioned substance in a food is a voluntary one. Proper economic planning for the decision should recognize that the substance and the food containing the substance may subsequently become unmarketable because the substance has become newly recognized as posing a hazard to the public health.

Interested persons may, within 30 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare (Room 6-88, 5600 Fishers Lane, Rockville Md. 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum of brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated September 23, 1971.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.
[FR Doc. 71-14294 Filed 9-27-71; 8:50 am]

Public Health Service

[42 CFR Part 75]

PREPAID MEDICAL SERVICE PLANS

Subpart A—Authorization for Issuance of Prepaid Medical Service Contracts by Carriers

Notice is hereby given that the Administrator, Health Services and Men-

tal Health Administration, with the approval of the Secretary of Health, Education, and Welfare proposes to amend Subchapter F of the Public Health Service regulations by adding a new Part 75 and a Subpart A of that part as set forth below. Subpart A would provide for the issuance of authorizations under Title IV of Public Law 91-515 to enable certain carriers to issue contracts for prepaid medical services.

Inquiries may be addressed, and data, views and arguments relating to the proposed regulations may be presented in writing, in triplicate, to the Administrator, Health Services and Mental Health Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20852. All relevant material received not later than 30 days after publication of this notice in the FEDERAL REGISTER will be considered. All comments received will be available for public inspection in Room 6A30 at the above address between the hours of 8:30 a.m. and 5 p.m., Monday through Friday.

Notice is also given that, in the light of the public interest in the speedy implementation of the statute, it is proposed to make any regulations that are adopted effective upon publication in the FEDERAL REGISTER (9-25-71).

It is proposed to amend Subchapter F of Chapter I of Title 42, of the Code of Federal Regulations by adding a new Part 75 as follows:

PART 75—PREPAID MEDICAL SERVICE PLANS

Subpart A—Authorization for Issuance of Prepaid Medical Service Contracts by Carriers

Sec.

- 75.1 Statutory provisions.
- 75.2 Definitions.
- 75.3 Applications for authorization.
- 75.4 Issuance of authorizations.
- 75.5 Services to be provided by medical group.

AUTHORITY: The provisions of this Subpart A issued under 80 Stat. 379; 5 U.S.C. 301.

§ 75.1 Statutory provisions.

The applicable statutory provision, Title IV of Public Law 91-515 (84 Stat. 1309), reads as follows:

SECTION 401. (a) The Secretary of Health, Education, and Welfare may, in accordance with the provisions of this section, authorize any carrier, which is a party to a contract entered into under Chapter 89 of title 5, United States Code (relating to health benefits for Federal employees), or under the Retired Federal Employees Health Benefits Act, or which participates in the carrying out of any such contract, to issue in any State contracts entitling any person as a beneficiary to receive comprehensive medical services (as defined in paragraph (b) of this section) from a group practice unit or organization (as defined in paragraph (c) of this section) with which such carrier has contracted or otherwise arranged for the provision of such services.

(b) As used in this paragraph, the term "comprehensive medical services" means comprehensive preventive, diagnostic, and therapeutic medical services

The Purina Trout Chow had been previously involved in a seizure (See FOOD CHEMICAL NEWS, Sept. 27, Page 24).

Other recalls on the Food and Drug Administration's weekly list involving PCBs included: (1) Fishmeal in bulk being recalled voluntarily from users in the Southeastern States by South Pacific Proteins, Inc., Darien, Conn., from meal processed at the East Coast Terminal, Wilmington, N.C.; and (2) Meatmeal in bulk being recalled voluntarily from a single retailer in Springfield, Ill., by National By-Products, Inc., Mason City, Ill., from meal manufactured by Penn Tallow Co., Pittsburgh, Pa.

The list also included several voluntary recalls by Haver-Lockhart Laboratories, Kansas City, Mo., from wholesalers in the United States and Canada of Neo-plus products, which contain neomycin plus triple sulfas, which had been found "probably not effective" in the review of pre-1962 veterinary products conducted for FDA by the National Academy of Sciences.

An FDA-initiated recall was being carried out in Puerto Rico by Masti-Kure Products Co., Norwich, Conn., of Dr. Garcia Poly Neo Formula mastitis treatment, distributed by Dr. A. Garcia Bird, Div., M. Rio Pedras, Puerto Rico, because the penicillin content was subpotent. FDA said it contained 77.9% of declared potency.

Meanwhile, FDA cleared recently the following New Animal Drugs:

- (1) §135b.39 was issued Sept. 21 to clear sodium thiamylal injection as an anesthetic in dogs, on veterinary Rx legend. Sponsor of the new regulation is Phillips Roxane.
- (2) §135c.41 was issued Sept. 21 to clear sulfamethoxypyridazine tablets and §135c.42 to clear acetyl sulfamethoxypyridazine oral suspension for use in dogs and cats for sulfasusceptible gram-positive and gram-negative bacterial infections, on veterinary Rx legend. The sponsor is Parke, Davis.
- (3) §135c.47 for ampicillin trihydrate capsules, veterinary, was amended Sept. 22 to clear use in cats for treatment of sensitive gram-negative and gram-positive organisms, on veterinary Rx legend. The change was proposed by Squibb.

In other activity, FDA finalized Sept. 30 a list of 703 NADAs of 222 manufacturers proposed for revocation as a result of NAS findings that the products were not effective (See FOOD CHEMICAL NEWS, May 3, Page 19).

GRAS STATUS CLARIFIED BY CYCLAMATE INDEMNITY HEARINGS

Cyclamate indemnity hearings last week before a House Judiciary subcommittee triggered a public review of the uses and possible abuses of the "generally recognized as safe" list.

The day before the hearings, on Sept. 28, FDA spelled out its disclaimer against manufacturer and processor reliance on the GRAS list (See FOOD CHEMICAL NEWS, Sept. 20, Page 7). FDA said in the Federal Register notice:

"The decision to use a particular GRAS food additive or prior sanctioned substance in food is a voluntary one. Proper economic planning for the decision should recognize that the substance and the food containing the substance may subsequently become unmarketable because the substance has become newly recognized as posing a hazard to the public health."

The FDA disclaimer in the Federal Register took the form of a proposed addition to the food additive administrative regulations, with 30 days allowed for comments. The proposed new regulation also said, "Regulations promulgated under §409 . . . give no implied or explicit guarantee that any substance named therein will continue in a particular status."

The "disclaimer" statement takes on added significance in light of FDA's current review of GRAS substances (See FOOD CHEMICAL NEWS, July 5, Page 9).

Alan T. Spiher, Jr., who is in charge of FDA's GRAS review, told a meeting of the Tennessee Dietetic Association in Gatlinburg, Tenn., last week that after the review, the information will be reviewed by a group of "distinguished scientists" who will recommend a status for each substance among one of the following categories:

- "1. Continued GRAS status.
- "2. Food additive regulations.
- "3. Discontinue use until further studies done.
- "4. Insufficient information for final decision without chronic toxicity studies."

He said that when the review is completed, FDA should have "as adequate a scientific basis for the use of GRAS compounds as we do for food additives."

During the indemnity hearings, Food and Drugs Commissioner Charles Edwards told members of the Claims subcommittee that although the GRAS list "is an administrative compilation of current scientific beliefs" (rather than a formal approval mechanism), the list "has at no time carried on its face the warning that the listed substances . . . could at any time be found unsafe and consequently delisted." He continued:

"And, indeed, the list appears to have been relied upon as an official assurance that listed substances were safe in fact."

This was as close as FDA came to endorsement of the cyclamate indemnity payments, although Administration representatives from the Department of Commerce endorsed the measure. Estimating that indemnity payments would total from \$100 to \$120 million, to be determined in subsequent Claims Court cases, Commerce General Counsel William Letson said:

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"Clearly, commercial users of cyclamates had little or no reasonable basis prior to HEW's action in October 1969 for believing that cyclamates would be found to be carcinogenic and thus be declared to be totally unsafe for use in consumables. Their reliance on the GRAS list was, therefore, justified."

His statements were challenged sharply by a series of consumer representatives, who charged that industry continued to load cyclamates into more and more foods over a number of years when scientific doubt was growing.

Washington nutrition consultant and consumer advocate Robert Choate said, "Those who would reward the cyclamate users for ignoring repeated warnings of the scientific community are selling the private enterprise food industry down the river." He continued:

"Despite continuing warnings by researchers that the product was of dubious health value, and despite very strong FDA warnings in December 1968 and April 1969, the food industry, particularly California's fruit and vegetable packers, insisted on filling their warehouses with the cyclamated product during the late summer and fall of 1969."

Rep. Sisk (D-Calif.) is a principal sponsor of the indemnity legislation, HR 4265, and the legislation has about 30 co-sponsors, all of whom either testified in behalf of the proposal or submitted statements.

A number of trade associations submitted favorable testimony. These included:

Glass Container Manufacturers Institute - - Washington Counsel Eugene Stewart testified that a variety of bottles and jars were made obsolete by the cyclamate ban, with loss amounting to some \$1.3 million.

National Soft Drink Association - - T. L. Wilson of a Charleston, S.C., beverage company testified as a typical bottler whose business suffered \$7,800 in losses from destroyed product, plant expense, business disruption and depressed prices on dietetic beverages.

National Canners Association - - Milan D. Smith, executive vice-president of NCA, said some 43 companies or cooperatives suffered economic loss (not including profits, which would not be covered by indemnities) of about \$35 million, of which \$2 million would be offset by exports and about \$10 million by tax recovery from the government.

Smith quoted from pre-cyclamate ban statements by advisory groups whose statements were also used by opponents of the legislation. He noted:

"To further emphasize industry's good faith reliance on the GRAS list, the FDA did propose regulations for cyclamates in the Federal Register of April 5, 1969. This was done after all the thenknown scientific data regarding cyclamates

had been weighed. The levels established in the proposal were obviously thought to be safe for human use, as the Federal Register of that date relating to this subject was headed, 'Food Additives: Cyclamic Acid and Its Salts - Safe Usage.' A number of food products, particularly canned fruits, were covered by standards of identity . . . which explicitly recognized the use of cyclamates as artificial sweeteners."

Consumer witness Anita Johnson, representing the Nader-affiliated Public Interest Research Group, noted the same FDA statement in the words:

"In April, 1969, the FDA announced that no adult should consume more than 3.5 grams and no child more than 1.2 grams daily. In fall, 1969, a new study showed conclusively what earlier studies had suggested - - that cyclamate caused bladder cancer in rats."

NCA's Smith told the subcommittee that if the cyclamate ban had issued in April of 1969, rather than in October, most of the processor and manufacturing losses would not have been incurred.

The statement by Anita Johnson also went into earlier cyclamate cautions,, calling attention to statements in - -

1951 - - FDA scientists concluded cyclamate was safe but called attention to unexplained tumors in cyclamate test rats.

1955 - - NAS "warned that cyclamate use should not be expanded . . ."

1962 - - NAS said, "The priority of public welfare over all other considerations precludes . . . the uncontrolled distribution of foodstuffs containing cyclamate."

1967 - - World Health Organization recommended a restriction of cyclamate intake.

1968 - - FDA scientist reported relationship between cyclamates injected into chicken eggs and deformities of embryos.

Miss Johnson said: "It is fatuous to argue that the cyclamate food industry had no warning," adding: The industry had been promoting mass market use of cyclamates when the NAS had warned repeatedly against the uncontrolled distribution of foodstuffs containing cyclamate; when the industry's own labels were required by law to read: 'For use by those who must restrict their intake of ordinary sweets.' On TV Bugs Bunny told mothers that Presweetened Kool-Aid was good to feed children, but on the label, the required warning told only diabetic consumers to use it."

Most processors were prepared for the ban, she said, citing development by Pepsi-Cola of a new diet drink a year before the ban and a statement by a Coca-Cola executive that the company was "taking out insurance" by development of a new diet product. She continued:

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"Those whose business expertise was insufficient to predict the cyclamate ban are now hustling their money more cheaply and directly - - from the Congress."

Ruth Desmond of the Federation of Homemakers told the subcommittee that the "food industry had ample opportunity to realize cyclamates were suspect." Referring to the current FDA-sponsored NAS survey of manufacturers on GRAS compounds, she charged:

"From this it would appear that it is not the government nor the taxpayers - - it is industry - - that has been deciding what substances belong on GRAS. The public may believe FDA decides . . . but industry knows better."

She said it is apparent that the GRAS list "is not a sacred document, not even a scientific document."

James Turner, author of The Chemical Feast, testified that it is not accurate to say that cyclamates were widely recognized as being of great value. Repeating warning statements of 1954, 1955, 1956 and 1962, he said, "Between 1965 and 1969, an inexorable march of research began to establish the serious hazards of cyclamate." He continued:

"By the summer of 1969, before the canning season, it was known to the manufacturers of cyclamate that their product might cause bladder cancer. Faced with this threat to their market, Abbott Laboratories did not warn its users but rather sought information from its own test laboratories."

Turner said this fact "shifts the burden of compensation to Abbott."

"Legislative advocate" of the National Health Federation, Clinton Miller, asked the subcommittee to amend the indemnity bill with a specific authorization for consumer suits in the Court of Claims. The court would be authorized to set the amount of damages for injuries sustained by consumers of cyclamates, "including children of consumers."

Commerce's Letson said it is evident that a large segment of the food and drink industry was influenced by the fact that cyclamates were on the GRAS list in responding to a valid market demand for low-calorie products and was caught unaware when the announcement was made that cyclamates were to be removed from the marketplace.

Another important factor, he continued, "is that the losses food processors and soft drink manufacturers suffered because of the ban contained a very substantial multiplier element." Letson explained:

"That is to say, while cyclamates accounted for a very small proportion of the cost of placing the consumer product

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on the market, the entire product - - not just its cyclamate content - - was rendered unmarketable by HEW's announcement in 1969. Moreover, in some instances the loss exceeded the total cost of the product, for there was an additional expense involved in destroying unsalable products. Thus, any product not sold resulted in loss to the manufacturer or processor in excess of the amount of his expenditures on cyclamate additives."

In his statement, Edwards emphasized that the cyclamate case "should in no way serve as a precedent."

"We recognize that reliance upon the GRAS list by individual growers, manufacturers, packers, or distributors, however unwarranted as a technical legal matter, may have caused or contributed to their losses," Edwards' statement continued. "Therefore, in the unique circumstances of this case, we would not object to enactment of legislation compensating these businesses for their losses based on judgments by the Court of Claims."

NCA's Smith outlined the affect on his industry, noting that 43 companies or cooperatives suffered economic losses. Of the 43 canners, 11 represent farmer cooperatives comprising thousands of farmer members and their families, he told the subcommittee, listing them in the following States: Arizona, California, Illinois, Indiana, Maryland, Massachusetts, Michigan, Missouri, New Jersey, New York, Ohio, Pennsylvania, Virginia, Washington, West Virginia, and Wisconsin.

In addition, he said 32 independent canners from Puerto Rico and the following States suffered losses: Delaware, Florida, Georgia, Hawaii, Idaho, Kansas, Maine, Minnesota, Nebraska, Oregon, Tennessee, Texas, and Utah.

"Plant closures may well result, if relief, as provided in the legislative proposal before this committee, is not obtained," the NCA official warned, suggesting that "this would have an adverse effect on the economy with respect to payrolls, outlet for farmers' produce, purchase of supplies, ingredients, etc."

GCMI's Stewart asked for an amendment to make it clear that the losses sustained by the manufacturers of the food and beverages themselves are not the sole losses which are the subject of the legislation, but, rather, that losses sustained by manufacturers and distributors of packaging, labeling, and other materials utilized in the preparation and sale of such foods and beverages are also compensable.

He pointed out that this would include glass containers, labels, and other forms of packaging whose value was destroyed by the Governmental action, and he offered language to carry out the amendment.

Stewart emphasized that permanent marking with ingredients, including cyclamates, of the glass containers and of the closures and packaging cartons for use with food and beverages containing the artificial sweetener "rendered them useless for any other purpose."