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INTERNAL CORRESPONDENCE

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Dr. A. B. Steele
Dr. N. L. Zutty
New York, New York

Date: March 20, 1974

Originating Dept.: Research & Development

Answering letter date:

Dr. J. J. Brezinski - SC
Dr. C. U. Dernehl - NY
Dr. W. F. Gorham - BB
Mr. R. E. Gulick - NY
Mr. R. J. Hanna - SC
Mr. N. H. Reinking - BB
Mr. R. N. Wheeler - SC
Mr. W. L. Wood - NY

Subject: Food Chemical News Summary of FDA-SPI Meeting

This excerpt from Food Chemical News, March 18, 1974 is attached for your information.

W. B. Ackart

WBA/km

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FOOD CHEMICAL NEWS

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HIGHLIGHTS of the news

PVC prior sanction may be revoked, with Petitions required to show lack of VCM migration from packaging. Page 23

NITRITE smoked fish ban may be proposed by FDA. USDA to further limit nitrates. Consumers urge label warnings. Page 20

FOOD SURVEILLANCE positions retained by GMA, NCA. Moss-Hart proposals, Administration bill hit. "Independent arbiter" of confidentiality suggested. Page 7

CIVIL PENALTIES would be set by FDA, not the courts, under Justice Dept. proposal. FDA direct access to courts opposed. Industry hits strict criminal liability. Page 3

SACCHARIN tumor induction in rats formally reported by FDA. Canadian researcher says it is not a carcinogen. Page 28

CPA bill amendments urged by White House in letter to Holifield. Page 37

USDA MICROBIOLOGICAL guidelines will include sampling plan. Page 17

MEAT, POULTRY inspection budget increase supported at hearing. Page 39

USDA nutrition labeling, net weight proposals attacked by firm. Page 26

COLOR ADDITIVE provisional listings extended. Three cosmetic colors deleted from list; two are added. Page 30

FTC accepts "prime responsibility" for childrens' ad content. Page 33

SELENIUM Order expansion requires Petitions, FDA says. Page 34

EMERGENCY PERMIT regulation language changes sought by NCA. Page 19

DRAINED WEIGHT proposal opposed by foreign governments, firms. Page 18

LEAD-IN-MILK FDA data made available to Consumers Union. Page 24

SALMONELLA causes another recall of chocolate Easter bunnies. Page 36

PAPER, paperboard manufacture retention aid resins approved. Page 31

DIALIFOR tolerances set for raisins, animal feed ingredients. Page 31

BACITRACIN METHYLENE DISALICYLATE OK-ed for use with amprolium, ethopabate, roxarsone. Fenthion clearance expanded. Page 32

LOUIS ROTHSCHILD, Jr., Editor and Publisher, 420 Colorado Bldg., 1341 G St., N.W., Washington, D.C. 20005

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Associate Commissioner for Compliance Sam Fine discussed the upcoming April 1 public hearing on iron in flour and bread (See FOOD CHEMICAL NEWS, March 11, Page 46), indicating that there will be a pre-hearing conference, and that a possible date for that is March 25. Fine said FDA is "determined" that the hearing will not be a "circus," but will be "an orderly proceeding" sticking to the issue of safety.

Additional appearances have been filed for the iron-in-bread hearing (See FOOD CHEMICAL NEWS, March 11, Page 29) by Dr. William H. Crosby, of the Scripps Clinic and Research Foundation; Consumers Union's Dr. A. Karim Ahmed; Cooley's Anemia Blood and Research Foundation for Children's Edward D. Paradiso, Nunzio D. Cazzetta, Carmine Geonie, and Dr. Edward C. Zaino; and Order Sons of Italy in America's Dominic R. Massaro.

Crosby, a hematologist who has been one of the staunchest opponents of increasing iron levels in bread, is being represented by consumer advocate Anita Johnson, who requested that FDA move the public hearing from the Parklawn Building to FDA's Washington FOB 8 building.

Cooley's anemia is an iron binding disorder, which is also known as "Mediterranean anemia."

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FDA MAY REVOKE PRIOR SANCTION FOR PVC FOOD PACKAGING

The Food and Drug Administration is considering a proposal to revoke the "prior sanction" for use of polyvinyl chloride in food packaging because of the possibility of migration of vinyl chloride monomer.

The new proposal to make PVC a "food additive" would replace the pending proposal which would formalize the "prior sanction" for general food packaging under §121.2009, but ban its use for packaging alcoholic beverages.

The agency had previously informed the Society for the Plastics Industry that more data is required on PVC and vinyl chloride monomer migration to food (See FOOD CHEMICAL NEWS, March 4, Page 25), but this was mainly in the context of alcoholic beverages. Industry had previously informed FDA that new processing of PVC would reduce migration of the monomer (See FOOD CHEMICAL NEWS, Oct. 22, Page 26; and Dec. 24, Page 22).

FDA's doubts about PVC packaging, especially for fatty foods, were conveyed to SPI representatives in a recent meeting in Washington.

Agency officials noted that testimony before the Occupational Safety and Health Administration had indicated monomer migration to foods, especially fatty foods, and that FDA has found that regulatory agencies in other countries have found vinyl chloride in food.

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FDA-ers say that the new-process PVC might take care of the problem, but that "trade secret" considerations have prevented the investigations that are needed. It is probable that firms will have to file Food Additive Petitions, in which they will have to demonstrate that vinyl chloride monomer migration meets a specific limit.

MASTER FILES!

A way must be found to limit the amount of vinyl chloride monomer to less than the sensitivity of the most sensitive method available, FDA-ers say. Current methods are sensitive to 50 p.p.b. Officials indicate that PVC will have to meet both tests for residues and an end-test on the package itself.

There will also have to be toxicological work, FDA-ers say, in order to establish a no-effect level for vinyl chloride.

There are now a number of clearances for PVC as a "food additive" under the Subpart F indirect Food Additive Orders. These probably will be reviewed. FDA-ers say there is information that PVC used in can coatings under §121.2514 for resinous and polymeric coatings does not result in vinyl chloride getting into the food.

OUR resins - via Continental Can & American Can - WBC

FDA GIVES C-U ACCESS TO LEAD-IN-MILK DATA

The Food and Drug Administration and Consumers Union are continuing their faintly acrimonious correspondence about lead in canned evaporated milk, despite the fact that both parties are agreed that lead levels have successfully been reduced (S e FOOD CHEMICAL NEWS, Feb. 4, Page 40).

The latest letter was from FDA Commissioner Schmidt in response to a letter from CU's George A. Pollak.

The agency said that CU is entitled under the Freedom of Information Act to the FDA test data and to a summary of results submitted by the Evaporated Milk Association. It is understood that CU has been unable to obtain EMA's results, since FDA lacks the Association's raw data.

Noting that CU's second survey showed lead levels within the agency's guideline, as did the FDA and EMA data, Schmidt noted that "industry is obligated to monitor its own production and report any lots exceeding the FDA guideline of 0.5 p.p.m.," and that "none has been reported nor have we found any lots exceeding the guideline."

Pollak had written that the tests relied upon by FDA had involved composite samples rather than single cans, and Schmidt said that "the investigators at the Albert Einstein College of Medicine did analyze 15 single cans of evaporated milk which they purchased in 1972 and 1973," finding the highest lead content 0.22 p.p.m. and the average 0.11 p.p.m.

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