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THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

250 PARK AVENUE · NEW YORK, NEW YORK 10017 · 212/687-2675

September 6, 1973

To: Members, SPI Food, Drug and Cosmetic
Packaging Materials Committee

Re: Attached Minutes

Gentlemen:

We are pleased to attach hereto the detailed minutes of the May 31, 1973 business session of the SPI-FDCPMC.

The reason these minutes are somewhat late in being sent to you is because certain of the documentation was delayed in being edited and approved.

You will be interested to know that Peter Barton Hutt, Esq., our principal speaker from FDA that day, has requested Jerome Heckman, SPI General Legal Counsel, to make the transcript of his presentation publicly available (see Exhibit "A").

By way of a reminder, the next meeting of the Committee is to be held on Thursday, January 10, 1974, again at the Shoreham Americana Hotel. Of course, you will receive a detailed meeting announcement as the time of the business session draws near.

Please be assured of our cooperation.

Charles L. Condit
Staff Vice President

CLC:oms
Encl.

SPI

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

250 PARK AVENUE · NEW YORK, NEW YORK 10017 · 212/687-2675

MINUTES

MEETING OF SPI FOOD, DRUG AND COSMETIC PACKAGING MATERIALS COMMITTEE

Shoreham Hotel
Washington, D. C.

May 31, 1973
8:00 a.m.

Present:

Karl A. Hochschwender, Chairman, Director, Public Affairs, American Hoechst Corporation, P. O. Box 2500, Somerville, N. J. 08876
Willard M. Westveer, Vice Chairman, Product Safety Specialist, The Dow Chemical Company, 2030 Dow Center, Midland, Mich. 48640
Watson B. Ackart, Manager, FDA/USDA Liaison, Union Carbide Corporation, River Road, Bound Brook, N. J. 08805
J. Brian Armitage, E. I. duPont de Nemours & Co., Inc., Plastics Department, Experimental Station, Wilmington, Del. 19898
Ronald R. Arnold, Business Manager, M & T Chemicals, Inc., P. O. Box 1104, Rahway, N. J. 07065
K. J. Auer, Director of Marketing, Celluplastics, Inc., 55 North Street, Fitchburg, Mass. 01420
John A. Avery, Specialist, Quality Control and Analytical Chemistry, General Electric Company, One Plastics Ave., Pittsfield, Mass. 01201
W. C. Bachtel, Supervisor ofMedical & Environmental Labs, 500 S. Main St., Akron, Ohio 44318
John K. Backus, Technical Manager, Mobay Chemical Company, Penn-Lincoln Parkway West, Pittsburgh, Pa. 15205
J. A. Bailey, Technical Group Leader, Diamond Shamrock Corp., P. O. Box 191, Painesville, Ohio 44060
Max S. Bass, General Manager--Chemicals, M & T Chemicals, Inc., American Lane-2C9, Greenwich, Ct. 06830
Robert M. Beverage, Technical Assistant, Dept. of Chemical Control, S. D. Warren Co., Westbrook, Maine 04092
Charles E. Blades, Research Coordinator, Air Products & Chemicals Company, Possumtown Road, Middlesex, N. J. 08846
Norman D. Bornstein, Mgr., Applied Research & Analytical Services, Cryovac Div., W. R. Grace & Company, P. O. Box 464, Duncan, S. C. 29334
Roger G. Boyer, Compound Manager, Pantasote Company of New York, 26 Jefferson St., Passaic, N. J. 07055
R. O. Carhart, Sr. Specialist--Technical Marketing, General Electric Company, One Plastics Ave., Pittsfield, Mass. 01201
John G. Cobler, Associate Scientist, The Dow Chemical Company 574 Building, Midland, Mich. 48640

John O. Cole, Research Division, Goodyear Tire & Rubber Company, Akron, Ohio 44316
Paul F. Cundy, Administrator, Regulatory Compliance, American Can Company, P. O. Box 702, Neenah, Wisc. 54911
L. J. DeCorte, Manager--Technical Labs., Sinclair-Koppers Company, Frankfort Rd., Monaca, Pa. 15061
Lou DeMarco, Applications Engineer--Polypropylene, Diamond Shamrock Corp., P. O. Box 348, Painesville, Ohio 44077
Daniel S. Dixler, Keller and Heckman, 1150-17th St., N. W., Wash., D.C. 20036
Ernest M. Dixon, Medical Director, Celanese Corp., 522 Fifth Ave., New York, N. Y. 10036
R. J. Dowling, FDA Coordinator, Uniroyal Chemical Corp., Spencer Street, Naugatuck, Ct. 06770
George W. Ferner, Research Division, The Goodyear Tire & Rubber Company, Akron, Ohio 44316
Robert P. Fischer, Kerr Glass Manufacturing Corp., P. O. Box 4000, Lancaster, Pa. 17604
D. Fishman, Group Leader, Celanese Plastics Co., Morris Ct., Summit, N.J. 07901
G. Timothy Flint, Sr. Analytical Chemist, The Dow Chemical Company, Bldg. 574, Midland, Mich. 48640
B. J. Garceau, Chemicals Coordinator, ICI America, Inc., Wilmington, Del. 19898
David R. Gaskill, Section Leader, Analytical Chemistry, Mobil Chemical Company, P. O. Box 240, Edison, N. J. 08817
George Gerliczy, Mgr., Market Research & Development, The Solvay American Corp., 609 Fifth Ave., New York, N. Y. 10017
Warren A. Gibson, Attorney, The Dow Chemical Company, 2030 Abbott Rd. Center, Midland Mich. 48640
Robert A. Godfrey, Group Leader, Polymer Characterization, Mobay Chemical Company, Penn-Lincoln Parkway West, Pittsburgh, Pa. 15205
Max Goldfrank, Mgr., Patents & Reg. Compliance, Stein, Hall & Co., Inc., Celanese Corp., 1210 Jackson Ave., Long Island City, N. Y. 11101
Paul R. Graham, Monsanto Company, 800 N. Lindbergh Blvd. St. Louis, Mo. 63166
Francis W. Greenough, Director of Administration, RD&E, Cryovac Division, W. R. Grace & Company, P. O. Box 464, Duncan, S. C. 29334
Joseph E. Hadley, Keller and Heckman, 1150-17th St., N.W., Wash., D. C. 20036
Taylor W. Hanavan, Attorney, E. I. duPont de Nemours & Co., Inc., Market St., Wilmington, Del. 19898
G. Frederick Hanna, Mgr., Regulatory Agency Liaison, Borg-Warner Corporation, P. O. Box 68, Washington, W. Va. 26181
Jerome H. Heckman, SPI General Counsel, Keller and Heckman, 1150-17th St., N. W., Washington, D. C. 20036
Dwight F. Hensley, Director of Marketing, IMCO Container Co., 4240 Blue Ridge Boulevard, Kansas City, Mo. 64133
Alfred E. Horka, President, Plastic Extrusion, Pexco, 78 Turnpike Road, Westboro, Mass. 01581
George W. Ingle, Monsanto Company, 1101-17th St., N.W., Washington, D.C. 20036
Otto S. Kauder, Vice President, Research, Argus Chemical Corp., 633 Court St., Brooklyn, N. Y. 11231
Alfred A. Keller, Market Manager, M & T Chemicals, Inc., Woodbridge Road, Rahway, N. J. 07065

Peter P. Klemchuk, Technical Manager, CIBA-GEIBY, Ardsley, New York 10502
William A. Knapp, Consumer Product Safety & Toxicology, Allied Chemical Corp., P. O. Box 1057R, Morristown, N. J. 07960
George P. Koo, Polymer Materials Scientist, Stanford Research Institute, 333 Ravenswood Ave., Menlo Park, Calif. 94025
Jack L. Lawing, Attorney, Eastman Chemical Products, Inc., Kingsport, Tenn. 37662
Clyde W. Leaf, Staff Consultant, Central R&D, BASF Wyandotte Corp., 1609 Biddle Ave., Wyandotte, Mich. 48192
Donald D. McCollister, Mgr., Product Registration Section, Government Reg. Relations, The Dow Chemical Company, Midland, Mich. 48640
Frank E. McTigue, Research Supervisor, Hercules, Inc., Polymers Department, Hercules Research Center, Wilmington, Delaware 19899
G. F. Macke, Specialist, Product Development, General Electric Company, Plastics Department, Lexan Lane, Mt. Vernon, Ind. 47620
Joel Markowitz, Quality Assurance, Dart Industries, Inc., Chemical Group, W. 115 Century Road, Paramus, N. J. 07652
Robert M. Miller, Medical Department, Hercules, Inc., 910 Market Street, Wilmington, Del. 19899
Robert J. Mitchell, Degussa, Inc., 2 Penn Plaza, New York, N. Y. 10001
Stacey J. Mobley, Attorney, E. I. duPont de Nemours & Co., Inc., 1007 Market St., Wilmington, Del. 19898
Kenneth Morgareidge, Food & Drug Research Labs., P. O. Box 107, Waverly, N. Y. 14892
Bernard G. Murray, Staff Manager, Color Division, Ferro Corp., 4150 E. 56th St., Cleveland, Ohio 44105
Jack B. Murray, Jr., Attorney, Patent & Trademark Dept., Allied Chemical Corp., P. O. Box 1057R, Morristown, N. J. 07960
M. V. Noble, Contracts Manager, E. I. duPont de Nemours & Co., Inc., Film Department, 1007 Market St., Wilmington, Del. 19898
S. F. Peirce, Marketing Manager, Plastic Container Div., Continental Can Company, 633 Third Ave., New York, N. Y. 10017
J. K. Peterson, Manager, Technical Coordination, USS Chemicals, Division of U. S. Steel, 600 Grant Street, Pittsburgh, Pa. 15230
Jules Pinsky, Manager--Development, Mearl Corp., 217 North Highland Street, Ossining, N. Y. 10562
Dale A. Pribanic, Product Engineer, Packaging Materials, B. F. Goodrich Chemical Company, 6100 Oak Tree Boulevard, Cleveland, Ohio 44131
Donald W. Pugh, Section Leader, U. S. Industrial Chemicals Company. P. O. Box 218, Tuscola, Ill. 61953
Lorence Rapoport, Director of New Products R&D, Olin Corp., Film Department, P. O. Box 200, Asheville, N. C. 28768
George A. Richter, Jr., Rohm and Haas Company, Independence Mall West, Philadelphia, Pa. 19006
Edward T. Russell, Jr., Assistant House Counsel, Foster Grant Co., Inc., 289 N. Main Street, Leominster, Mass. 01453
Robert E. Rutherford, Director of Registration & Labeling, Gulf Oil Corp., 439 Seventh Ave., Pittsburgh, Pa. 15237
F. A. Sacks, Applications Engineer, Diamond Shamrock Corp., P. O. Box 191, Painesville, Ohio 44077

J. S. Schaul, Development Associate, Celanese Plastics Company, P. O. Box 1000, Summit, N. J. 07901
E. F. Schultz, Dow Chemical USA, Plastics Production Department, Bldg. 433, Midland, Mich. 48640
William W. Sederlund, Manager for Product Assurance, National Starch & Chemical Corp., 1700 West Front St., Plainfield, N. J. 07922
Dwight M. Sheets, Supervisor, Regulatory Affairs--Chemical Products, Shell Chemical Company, One Shell Plaza, Houston, Texas 77002
Matthew E. Smith, Owens-Illinois, P. O. Box 1035, Toledo, Ohio 43666
C. J. Spiegl, Manager, Analytical Chemistry & Toxicology, Continental Can Co., 7622 S. Racine Ave., Chicago, Ill. 60620
Robert P. Steward, Group Counsel, Olin Corp., P. O. Box 200, Pisgah Forest, N. C. 28768
E. J. Temple, Monsanto Company, 101 Granby St., Bloomfield, Ct. 06002
Don F. Thompson, Research Chemist, Amoco Chemicals, Naperville, Ill. 60540
Melford F. Tietze, Foor & Drug Attorney, ICI America, Inc., Wilmington, Del. 19899
Judith A. Tins, Coordinator of Toxicological Information, Celanese Corp., 522 Fifth Ave., New York, N. Y. 10036
P. J. Vanderhorst, E. I. duPont de Nemours & Co., Inc., 1007 Market St., Wilmington, Del. 19898
Nicholas A. Vonneuman, Attorney, Air Products & Chemicals, Inc., 5 Executive Mall, Wayne, Pa. 19087
George F. White, Jr., Director of Technical Services, Reynolds Metals Co., 10th and Byrd Streets, Richmond, Va. 23219
Norman G. White, Consultant, Armstrong Products, 4111 Grennoch Lane, Houston, Texas 77025
Ronald M. Wilson, Technical Service Representative, Emery Industries, Inc., 4900 Este Avenue. Cincinnati, Ohio 45232
Einar T. Wulfsberg, American Paper Institute, 1619 Massachusetts Ave., N. W., Washington, D. C. 20036
L. W. Ziemlak, Administrative Director of R&D, Foster Grant Company, Inc., 289 N. Main Street, Leominster, Mass. 01453
Daniel D. Zimmerman, Celanese Plastics, Morris Court, Summit, N. J. 07901
Charles L. Condit, Secretary, Staff Vice President, The Society of the Plastics Industry, Inc., 250 Park Avenue, New York, N. Y. 10017

Principle Speaker

Following an 8:00 a.m. breakfast, Chairman Hochschwender was pleased to introduce Peter Barton Hutt, Esq., Assistant General Counsel of the Food, Drugs, and Product Safety Division of the Department of Health, Education and Welfare, Food and Drug Administration. Mr. Hutt structured his presentation around ten principle questions posed by members of the Committee through Mr. Heckman and delivered prior to the day's session to Mr. Hutt for study.

During and at the end of his formal presentation, Mr. Hutt asked for and responded to questions from the floor.

[Please note: Attached hereto as Exhibit A is a taped version of Mr. Hutt's presentation which he has reviewed prior to our incorporation of the Exhibit in these Minutes. In editing the actual transcript of his presentation, Mr. Hutt made one substantive change of considerable importance in his presentation. The change is reflected on pages eleven and twelve of the transcript. In effect, what is involved is that Mr. Hutt has now indicated that FDA intends to continue requiring Environmental Impact Analysis Reports in all Food Additive Petitions although it is by no means contemplated that Environmental Impact Statements will be necessary with respect to most petitions. It will be noted that Mr. Hutt inserted an entire paragraph to draw a clear distinction between EIARs and Environmental Impact Statements.]

BUSINESS SESSION

Chairman Hochschwender called to order the general business session at 9:45. This was, of course, a deviation from the agenda which had been distributed with the Secretary's meeting announcement in order to accommodate Mr. Hutt's change in scheduled appearance.

The Chairman asked for the usual self-introductions, and following that, requested that those signing in at the day's meeting should also state their staff affiliation at their companies.

Minutes of Last Meeting Approved

There being no corrections or additions to the Minutes of the last meeting held in Washington, D. C. at the Shoreham Hotel on December 15, 1972, Chairman Hochschwender declared them approved as written and circulated.

Aims and Objectives of Committee

Dr. Hochschwender announced that Jerome H. Heckman had prepared an informative paper on the aims, objectives and purposes of the Committee which paper was used as a basis for incorporating the information in a recent edition of "NEWSBRIEFS," SPI's basic membership publication which is sent to all Voting Representatives of the Society, and many others. The issue dated March, 1973, Volume 2, Issue 3 included the FDCPMC story.

[Please note: The Secretary is attaching a copy of the presentation as it appeared in NEWSBRIEFS as Exhibit B.]

Report of SPI General Counsel

Chairman Hochschwender, in introducing Mr. Heckman, noted that it is traditional for the Committee to hear a report from Counsel at each meeting on those items which Mr. Heckman feels should be brought to the attention of the session.

In his opening remarks, Mr. Heckman asked members of the Committee to interrupt him following each of the unrelated subjects he discussed to enable him to answer any questions that might be posed relative to a particular discussion.

Mr. Heckman then proceeded to discuss a variety of matters including the proposed rulemaking for PVC liquor bottles; the involved and confusing subject of Environmental Impact Statements and Environmental Impact Analysis Reports; the status of the Ramsey proposal (which was discussed earlier by Mr. Hutt); and other matters as they arose at the day's session.

[Please note: Attached hereto as Exhibit C is the complete formal presentation by Mr. Heckman; it has been post-edited to include answers to many of the questions which were raised during the morning's business session.]

As a result of Mr. Hutt's presentation at the morning's session, Mr. Heckman said that he and his staff will make a so-called list of "assignments" given to the Committee by Mr. Hutt during his presentation. This listing will be prepared after reviewing Mr. Hutt's formal presentation and thinking over the many items which he suggested the SPI Committee undertake to handle.

During the lengthy discussion on the proposed rulemaking to ban PVC as liquor bottles, Mr. Heckman said that if individuals would like to obtain an insight into the type of information which was prepared in connection with the effort to have the Bureau of Alcohol, Tobacco and Firearms of the Department of the Treasury approve PVC bottles, they might do so by obtaining copies of BATF's Final Impact Statement and the so-called Bailie Associates Report. This can be done by contacting the following office:

National Technical Information
Service
U. S. Department of Commerce
5285 Port Royal Road
Springfield, Virginia 22151

and asking for one or the other of two documents--EIS-AA-73-0477-F-1 or EIS-AA-73-0477-F-2. Requests should include checks for $3 for each of the documents desired.

Mr. Heckman made special note of the fact that the FDA proposal in connection with polyvinyl chloride was really an affirmation of the prior sanctioned status of the resin for all uses except as a container for alcoholic beverages. Even in this connection, it should be noted that the exclusion of sanction for use with "alcoholic foods" is merely a proposal, not a final regulation.

At one point during the discussion of the PVC bottle situation, Robert M. Miller, Hercules, Inc., moved on behalf of the Steering Committee, which met the previous evening, that:

> "WHEREAS it is anticipated that the Food and Drug Administration may ultimately publish a "Notice to Manufacturers and Distributors" whereby it will require Environmental Impact Analysis Reports for all plastic bottles for food use, and
>
> "WHEREAS the SPI Food, Drug and Cosmetic Packaging Materials Committee has reviewed such a Notice and considered this matter in its many aspects; and
>
> "WHEREAS the feeling of the Food, Drug and Cosmetic Packaging Materials Committee is to the effect that it would be more logical for those directly concerned with the marketing of plastic bottles to define the resins warranting the extensive type of attention this Food and Drug Administration Notice will require, and
>
> "WHEREAS the Plastic Bottle Division and the Public Affairs Council of the Society have heretofore dealt effectively with an Environmental Impact Statement requirement imposed by the Bureau of Alcohol, Tobacco and Firearms of the Department of the Treasury;
>
> "NOW, THEREFORE BE IT RESOLVED that a recommendation be made to the Plastic Bottle Division and the Public Affairs Council that they undertake leadership and organize such group efforts as may be necessary to comply with the Food and Drug Administration Notice, it being understood that the members of the Food, Drug and Cosmetic Packaging Materials Committee will certainly lend all possible technical and other assistance requested in this connection."

Paul Cundy, American Can Company, seconded the motion.

During a discussion of the Resolution, Mr. Heckman explained that the Steering Committee feels that the SPI Food, Drug and Cosmetic Packaging Materials Committee is so broadly-based and representation thereon is involved in so many different unrelated resins and polymers, that it would be much the better part of judgment for the SPI Bottle Division to consider this particular matter at the present moment since it will probably relate only to bottles at the beginning although a broadening to other packaging materials has been "promised or threatened," as you see fit. It was explained that the Steering Committee was making its recommendation that the Bottle Division deal with the problem since

this would allow those with the best marketing knowledge to indicate what resins or other materials should be covered by efforts to develop Environmental Impact Analysis Reports, instead of leaving the question to our Committee which might otherwise undertake such a massive effort in some directions of no real marketing significance. */

The motion by Mr. Miller was passed unanimously.

Report of Daniel S. Dixler, Keller and Heckman

Dr. Dixler reported on several technical matters on behalf of Mr. Heckman, following the practice which was started at the last meeting of the Committee.

Of the four items on the agenda, he dismissed with very brief comments the subject of FDA Extraction Guidelines and FDA Toxicological Guidelines saying that, as was announced at past meetings, these matters are still being considered by FDA; and, according to it, the Guidelines will be issued in due course. As a matter of fact, he pointed out that, at the morning's breakfast session, Mr. Al Holtz, FDA, reaffirmed that the status of these two items was relatively static at the present moment.

Dr. Dixler then dealt with the regulatory proposals for colorants for plastics and for asbestos-free talc.

[Please note: Attached hereto as Exhibit D is Dr. Dixler's report.]

During the course of Dr. Dixler's discussion, there was some discussion from the floor in connection with chromium oxide green, phthalocyanine green and quinacridone red. These colorants were proposed for use with polyolefins only, and in the comments which had been filed earlier on behalf of SPI, it was requested that these colorants be permitted for use in all otherwise permitted plastics. FDA personnel had reported that there was no technical reason why this could not be done, but administratively the request set forth in the comments would not be adopted because the presently-proposed regulation was responsive to a Petition. Consequently, FDA has indicated it would only change

*/ Since the time of the meeting and as a result of several conferences between Mr. Heckman and Mr. Hutt, it is now understood that the Food and Drug Administration will probably proceed in a much different way than was indicated in the FDA internal draft Notice circulated under cover of Mr. Heckman's letter of May 22, 1973. Mr. Heckman was able to convince Mr. Hutt that the Notice as drafted would impose an impossible logistics burden on the plastics industry and that it would be more reasonable to approach the matter by requesting Environmental Impact Analysis Reports one at a time on families of resins or products considered of particular significance.

It is now anticipated that the first request for broad EIAR treatment will be issued in the near future and will relate only to resins intended to be used for "carbonated soft drinks and beer" or similar beverages. Actually, even though such a Notice has not yet been formally published, work on such an EIAR is well underway under the auspices of a special group set up within the Public Affairs Council of the Society.

the proposed wording in response to either an amendment by the original Petitioner, or in response to a new Petition. The simplest procedure would be for the Petitioner to amend his Petition; and Mr. Heckman requested a Petitioner's representative in the Committee to consider the matter and report back to him as to what the Petitioner decided in this connection.

Committee on Food Additive Regulation of Furnace Black (COFREB)

Chairman Hochschwender then called on George W. Ingle, Monsanto Company, who was appointed at the last meeting to head up a Task Force to study furnace black and matters relating thereto, noting he would prefer that Mr. Ingle make the report at this time since it is so obviously related to the subject of colorants in general.

Mr. Ingle delivered the following report.

> "COFREB is a partial acronym for the [sub]Committee on the Food Additive Regulation of Furnace Black Pigments.
>
> "The project was authorized at the last meeting of this Committee, to identify and establish one or more 'furnace' type carbon black pigments in compliance with FDA criteria for safety in plastics in food-contact. The urgency of this project reflects the demise of gas-type channel black pigments, due to environmental concerns in their manufacture. Channel blacks have been essential in formulating colored plastics for utilitarian purposes in food-and-drug contact, aside from other uses more decorative in nature.
>
> "Two meetings have been held, the second yesterday. In spite of the fact that all furnace blacks have absorbed carcinogens, their levels--for carefully selected and colorimetrically desired types--are so low that the probability is very high for demonstrating 'no migration' by highly sensitive analytical methods required by FDA.
>
> "COFREB is now drafting a complete protocol for review and acceptance by FDA. It must be emphasized that the dollar costs of the required analyses, their high premium on relatively scarce analytical competence at the required PPB levels, and FDA's attitudes towards carcinogens, make this a difficult project.
>
> "Interest in cooperative work has been expressed by The Cosmetic, Toiletries and Fragrance Association, the Rubber Manufacturers' Association, and the Man-Made Fiber Producers' Association. The National Paint, Varnish and Lacquer Association has not yet replied.
>
> "We hope to report more tangible progress at the next meeting."

Reports on Liaison with Other Organizations

Chairman Hochschwender pointed out that it is customary to hear status reports on those activities within other associations which relate to the interests of the SPI Committee and then called for such reports.

Pharmaceutical Manufacturers
Association and U. S. Pharmacopeia

Watson B. Ackart, Union Carbide Corporation, who has been responsible for the liaison on behalf of the Committee with PMA, and the status of the U. S. Pharmacopeia activity, presented the following report:

> "The December 15, 1972 report of this subcommittee stated that our procedures for testing polyolefin containers for oral dosage forms had been under consideration by the U. S. Pharmacopeia Advisory Panel on Containers and had made good progress through their Task Group on Plastic Containers of which Jules Pinsky is a member. Some problems were encountered with the Chairman of the Advisory Panel which appeared to have been resolved.
>
> "Recently some high level reorganizations in the U. S. P. and the National Formulary have resulted in the initiation of a cooperative effort by the two in the area of drug containers and packaging and some of the people previously involved have resigned. I am told that the current thinking involves the development of new procedures and that our work is no longer under consideration. I have written both to Dr. W. H. Heller of the U. S. P. and Dr. J. V. Bergen of the N. F. for status reports and my letters have not been acknowledged. There appears at this time to be little that we can do to reactivate their interest in our procedures.
>
> "Last week, however, I received a phone call from a packaging expert at Parke-Davis whose ultimate aims appear to parallel our own. I sent him a copy of our report and hopefully we may be able to get back in through the efforts of the pharmaceutical people where the whole thing started.
>
> "We propose now to discontinue our efforts to stimulate the U. S. P. to adopt our procedures as such but there appears to be some hope that we can work indirectly toward ultimate publication."

At this point, Dr. Ackart called upon Jules Pinsky, The Mearl Corporation, to discuss the U. S. P. matter since he is directly involved in these activities.

Dr. Pinsky made the following statement:

"Apparently, because of internal political difficulties of the U. S. Pharmacopeia, that organization is now setting up a program of its own on packaging. The first thing it will look at is a tentative procedure for moisture and oxygen permeability in containers for solid oral dosage forms. This is being handled by a joint USP-NF panel. I am a member of the Advisory Panel (containers and packaging). The NF drew up some methodology under a Dr. Grady and said it had contacted the appropriate PMA Committee Chairman. They will have the FDA run some tests on this methodology, and 'several industrial firms review and try to test therein.'

"The next thing they say they will investigate is unit dose packages and establishment of suitable standards and test procedures for them. The USP will handle that rather than the NF. The people apparently to contact on this are Dr. Daniel Banes, Director of Drug Standards with USP, and Dr. John Bergen, Director of the National Formulary. I will leave a copy of this methodology with Mr. Condit. I do not think that they are even reading the past Minutes of the Advisory Panel, let alone what SPI has submitted, so I guess if the SPI methodology is going to be considered it will have to be reintroduced.

"If there are no questions on that, I will talk about the liaison with the CTFA. Dr. Norman Estrin from the CTFA has advised that his organization is much concerned with the proposed FDA regulation of PVC bottles for alcoholic products. He has asked if there is a problem for the CTFA since many of the cosmetic and toiletry preparations contain ethanol in the proportions found in distilled liquors. He further stated that CTFA would be happy to engage in a joint research study with SPI.

"I telephoned him that our Committee did not believe the CTFA had an immediate problem since the proposed FDA regulation applies only to alcoholic foods so far. I further noted that a special SPI committee had been initiated which had received assurance by the PVC manufacturers that they will provide material which will be acceptable to the FDA with regard to alcohol extraction. He thanked me and asked me that I put such details in a letter to him which I have done. I ask that, in the future, information be funneled to them faster than they hear it from other groups so they will feel that we are contributing something to allay their concerns."

Attached hereto as Exhibit E is a copy of a U.S.P. memorandum to the Advisory Panel on Containers and Packaging which Dr. Pinsky asked be attached to the Minutes as representative of the present methodology being considered by U.S.P.

Manufacturing
Chemists' Association

George W. Ingle, Monsanto Company, gave a status report on MCA's FDC Chemicals Committee. It follows:

> "The recent (May 17) meeting of this Committee may prove notable more for its ultimate effects than for other accomplishments. The Chairman was authorized to appoint a Steering Committee to reappraise the objectives and to propose a restructuring of this Committee to reach these objectives. The present aim is to have greater impact on FDC matters, more appropriate to MCA's spectrum of interests, and in liaison with other trade associations with related goals.
>
> "A major present activity is supporting the Consumer Information Subcommittee of MCA's PR Committee, by revising MCA's considerable literature on the safety of food additives, and by providing technical spokesmen for radio and television programs on this subject."

PCB Report

Norman D. Bornstein, W. R. Grace and Company, delivered the following report on PCB's:

> "The Minutes of our last Committee meeting outlined the program undertaken by ASTM F-2 to develop a methodology to determine the PCB content in plastic polymeric packaging films. There is really nothing further to report other than the first round robin phase of the program is well underway and the results will be evaluated within the next month at a task group meeting."

SPI Market Development Committee
of the Plastic Bottle Division

Matthew E. Smith, Owens-Illinois, who has acted as liaison between the FDCPMC and the Market Development Committee of the Plastic Bottle Division since this liaison was established, noted first that he is no longer a member of the Market Development Committee. He then stated, and it was noted that there is general agreement on this point, that there really is no further necessity for this special type of liaison because (1) the Market Development Committee of the Bottle Division is presently concentrating on matters having nothing to do with

the food and drug laws, and (2) Mr. Heckman is now attending all Plastic Bottle Division meetings so there is a sort of built-in liaison on a continuing basis.

Under the circumstances, it was noted that this particular liaison report will not be called for by future agendas but any problems which require coverage will still be handled and the FDCPMC, as well as the Market Development Committee and the entire Plastic Bottle Division will be kept posted on food and drug problems by Mr. Heckman's office.

Cosmetic, Toiletry and Fragrance Association

Dr. Hochschwender said that this is a new liaison reflected by the agenda at the suggestion of Jules Pinsky, Mearl Corporation, prompting Dr. Pinsky to deliver the following report by way of a letter dated May 29, 1973 to Dr. Hochschwender.

> "Dr. Norman Estrin of CTFA has advised that his organization is much concerned with the proposed FDA regulation of PVC bottles for alcoholic products.
>
> "Dr. Estrin has asked if there is a problem for the CTFA, since many of the cosmetic and toiletry preparations contain ethanol in the proportions found in distilled liquors. He further stated that the CTFA would be happy to engage in a joint research study with SPI.
>
> "I telephoned him that our committee did not believe that the CTFA had a problem since the proposed FDA regulation applies to 'Alcoholic Foods.' I further noted that a special SPI Committee had been initiated which had received assurance by the PVC manufacturers that they will provide material that will be acceptable to the FDA with regard to alcohol extraction.
>
> "Dr. Estrin thanked me, and requested that I send him a letter noting such details, which I have done."

Phthalates

Paul R. Graham, Monsanto Company, delivered an interesting and informative illustrative presentation on the phthalate situation and gave the Secretary the following written report:

"In late 1970, Dr. R. J. Rubin at Johns Hopkins University disclosed that di-2-ethylhexyl phthalate was extracted by human blood stored in PVC bags. He revealed that DEHP tended to accumulate in the lung, liver, spleen and abdominal fat. Considerable speculation beyond these facts appeared in the lay press pointing to problems of inhalation from automotive interiors and associating DEHP with the 'shock lung syndrome' exhibited in Viet Nam. Among others, the University of Tennessee reported further work on the toxicology of phthalates.

"In September 1972, the National Institute of Environmental Health Sciences sponsored a meeting, at Pinehurst, North Carolina, bringing together academic, regulatory and industrial representatives to present all available data. The phthalate issue which was 'hot' prior to the Pinehurst meeting now appears to be low key and balanced. No rush for alternatives to phthalates has resulted from the Pinehurst meeting.

"The Society of Plastics Engineers RETEC meeting, held at Monticello, New York, tended to further alleviate concern and provided additional perspective. It was reported that, regardless of their routes into the animal body, DEHP and butyl phthalyl butyl glycollate are metabolized readily resulting in low levels of long-term accumulation. Phthalates were shown to be readily biodegradable and not refractory compounds such as DDT. The sources of phthalates which are known to be in the environment were not discussed.

"This conference did not answer all of the questions being asked about phthalates. It did strongly reinforce our historically accepted conclusion that they are relatively safe when introduced orally. The question still remains as to their effects when injected via other routes such as intravenously, intraperitoneally or by inhalation. Strong opinions were expressed by both Rubin and Autian that DEHP should not be used in blood bags.

"This report describes the status of the phthalate issue including the postures being taken by the various governmental, academic and industry groups in regard to both toxicology and environmental problems. This presentation also provides specific technical information regarding the permanence properties (volatility and migration resistance) of various plasticizers, including phthalates, which have become important considerations in the tendencies for external plasticizers to enter the human body or the overall environment. Specific emphasis is placed on the degree of plasticizer volatilization from the automotive upholstery or the extraction from the PVC blood bag. Data showing that phthalates are biodegradable are also presented."

Report of Medical Devices Standards Subcommittee

George A. Richter, Rohm & Haas Company, and Chairman of the Task Force on Medical Devices Standards, gave the following report by way of a communication dated May 22, 1973 to Mr. Condit:

> "As projected at the December 15, 1972 meeting of the SPI Food, Drug and Cosmetic Packaging Materials Committee, MDSS members met with ASTM representatives on February 21, 1973 to explore the possibility of developing within the ASTM structure consensus standards for plastic materials to be used in medical devices and to determine how MDSS can best cooperate in the execution of such a program. A report on this meeting (dated March 2, 1973) was forwarded to you.
>
> "It was decided at the February 21 meeting that a new ASTM subcommittee would be formed under ASTM Committee D-20 to develop standards for plastics used in medical devices. MDSS members (and other interested SPI members) are invited to become members of this new ASTM subcommittee which will also, of course, be open to other interested and qualified persons. I understand that this subcommittee could be so structured that SPI would have a vote as a corporate entity. At first, the subcommittee would logically be concerned with standards for definitions, recommended practices, methods of test and classifications. At this stage, a balanced subcommittee membership (e.g., a minority of producers) would not be mandatory. If, at a later date, the subcommittee becomes involved with the development of standard specifications, committee balance would be required.
>
> "Mr. Hulse requested our recommendation for chairman of the new ASTM subcommittee. A limited effort to develop such a recommendation has not yet been successful. In the absence of such a recommendation, I understand that ASTM will seek a chairman under standard procedures. In a recent conversation, Mr. Hulse said that Dr. DeMerre of the Office of Medical Devices (FDA) has expressed an interest in accepting the chairmanship of the new subcommittee. The Steering Committee should consider how to react to this new development.
>
> "Mr. Hulse has suggested that the subcommittee be formed sometime during the next ASTM meeting in Philadelphia scheduled for June 24 to June 29. Attached to this report is a memo from Mr. Hulse to Mr. Peter Thoma, Chairman D-20, regarding formation of the new subcommittee.

"Mr. Charles L. Condit has forwarded to me a booklet entitled 'Biomedical Uses of Polymeric Materials' by George P. Koo of Stanford Research Institute. This booklet is intended to serve as background for a new research project at Stanford Research Institute which SRI hopes will lead to more ready acceptance of plastic materials for packaging drugs and for design and construction of new medical devices. SRI is seeking sponsors for the program at $6,000 per client. The new ASTM subcommittee may wish to consider whether a cooperative effort with SRI should be explored."

Report of Technical Information Subcommittee

Willard M. Westveer, Vice Chairman of the Committee, The Dow Chemical Company, presented his usual report on recently issued Food Additive Regulations.

[Please note: Attached hereto as Exhibit F is the detailed report by Mr. Westveer.]

Report of Lawyers' Advisory Committee

Taylor W. Hanavan, E. I. duPont de Nemours & Company, Inc., Chairman of the Lawyers' Advisory Committee, presented the following detailed report:

"Karl, thank you very much for allowing me to speak out of turn in connection with the Legal Advisory Committee Report.

"With respect to Item 12(a) on the agenda, the Toxic Substances Control Act, there are two major bills pending in Congress dealing with this problem. The first, in the House of Representatives is H.R. 5356, and the second in the Senate is S. 426. There are other bills in the House and the Senate on this subject but H.R. 5356 and S. 426 represent the bills of principal interest.

"H.R. 5356, Toxic Substances, was introduced in the House by Congressman Moss and is essentially the same bill that was enacted by the House last year on this subject. H.R. 5356 provides that EPA may by rule prescribe test protocols and the results to be achieved for any substance or class, substances where the administrator finds that such testing is necessary to protect against an unreasonable risk to health or the environment. In addition, pre-market screening is required for all new chemical substances or new uses for old chemical substances which the administrator finds are likely to pose a substantial danger to health or environment. Substantial

danger means 'an unreasonable risk of death, severe personal injury or illness, or severe harm to the environment.' The House bill goes on to exempt from coverage foods, drugs, cosmetics, products subject to the FDA Act, or unreasonable environmental risks that could be reduced or prevented by other federal laws such as the Clean Air or Water Acts. Thus, the House bill would come into play only where other laws are not available.

"The DuPont Company, the Dow Chemical Company, MCA and SOCMA supported H.R. 5356 in House hearings earlier this year.

"The Senate version presents several different problems. The Senate version requires EPA to establish test protocols and the results to be achieved for all chemicals unless, in the judgment of EPA, a particular chemical or class of substances is of no unreasonable environmental or public health threat. Thus, the Senate bill is all encompassing since it requires a judgment by EPA as to all chemical substances with any negative judgment as to environmental effect subject to challenge in court. In addition, the Senate version requires pre-market screening of new chemical substances or new uses for established chemical substances for those chemicals for which protocols have been established. Unlike H. 5356 which imposes a higher level of risk (substantial danger) for those substances for which pre-market screening would be required, the Senate version applies the same standard of risk for the need for a test protocol and for pre-market screening.

"The legislation at the moment is drifting. We think by mid-June there should be Senate action. We anticipate there will be some toxic substance legislation enacted by Congress this year.

"One of the problems that has arisen in the legislative interplay is that there are efforts to amend H.R. 5356 to give EPA the option in the area of air and water to operate either under toxic substances legislation as enacted or the Clean Air or Water Acts. Industry is opposing this and we hope for a House bill like the one which was endorsed by industry in testimony earlier this year.

"The second item on the agenda is the Consumer Product Safety Commission. We've mentioned this in previous reports but basically, the law provides for a President-appointed Commission to establish a federal clearing house for consumer product toxicity information and to establish

safety standards for articles used in or around--and I quote this because of its significance--'the household, school, in recreation or otherwise.' As a lawyer the 'or otherwise' is a very impressive phrase in that it covers everything else that the other three words, 'household,' 'school,' or 'recreation' do not. The standards that could be established may relate to product performance, design, construction, composition and other related characteristics. Under this law, the Commission has authority to ban products posing an unreasonable risk where a reasonable standard is not feasible. It also has authority to peremptorily ban products presenting an imminent hazard.

"In addition, the Consumer Product Safety Commission has been assigned responsibility for administration and enforcement of the Federal Hazardous Substances Act, as amended; the Poison Prevention Packaging Act; the Flammable Fabrics Act; and several other related laws. On May 14, the Commissioners, duly nominated and approved by Congress, were sworn in. There have been administrative directives transferring certain groups from FDA and other agencies to the new Commission and the law is now fully operable.

"The next item on the agenda is the Consumer Protection Agency. Last year there was considerable legislative activity which we reported though no laws were enacted. In this new session, the Senate has been quite active and S. 707 and S. 1160 have been introduced and have been the subject of hearings. S. 707 would create an independent Consumer Protection Agency to represent consumer interests with authority to intervene as a party in formal agency proceedings and to participate in informal activities. It would grant the Agency standing to obtain judicial review of any agency action reviewable under law and to participate or intervene as a party in any federal court civil proceeding. The Agency would be empowered to request certain information from businessmen in interests deemed necessary by the Agency, to insure consumer health and safety, and to prevent consumer fraud. If a businessman did not comply with the request, the Agency could petition the appropriate federal court for a subpoena to require production of the information. It would establish a three-member Council of Consumer Advisors in the Executive Office to coordinate and make recommendations on consumer matters.

"Another bill which was sponsored by Senator Allen, S. 1160, incorporates the amicus curiae aspect of his former bill in 1972. Thus, it would restrict the Agency's participation to formal agency proceedings and court cases and then only in the amicus curiae capacity. There are other bills pending but they are not considered to play a major role.

The Administration is supposed to testify against S. 707. There's an apparently delicate problem that the Senate Committee holding hearings thinks they have extended an invitation to the Administration to testify. It is, apparently, the White House's position that if there was an invitation, it was so ambiguous that it was not the kind of invitation that they wanted.

"Right now the bill is dormant and there's a juggling going on as to when this thing is going to get active again and there's some serious problem as to whether the Administration will testify one way or the other. At the moment, the problem is dormant. The legislative prediction is that there may well be some form of legislation along the lines covered by either of these two bills this year but what final form it will take at the moment is, at most, uncertain.

"On the question of devices and device legislation, the situation legislatively is somewhat different from last year in substance, but in form it looks the same. The bills that were in issue last year which we discussed in previous reports have been reintroduced but the actual agreed upon legislation has not as yet made an appearance. We understand that the industry-FDA agreed upon legislation will be introduced by way of amendments to the basic legislation that has already been introduced this year. In this regard, I'll defer to the latest information of the Device Subcommittee.

"This concludes my report. It's primarily legislative at this time. As Jerry [Heckman] mentioned, the Morgan case, of course, from a litigation point of view is most significant in terms of the Freedom of Information Act and the question of trade secrets. When this decision will come down is speculative."

Next Meeting

In line with the intentions which were announced at the last meeting, Dr. Hochschwender stated that he would like to set the date of the next meeting each time well in advance so that members of the Committee could be alerted and be able to mark their calendars. He then added that the Steering Committee, at its previous day's session, decided that the next meeting of the Food, Drug and Cosmetic Packaging Materials Committee would take place on Thursday, January 10, 1974.

There being no further business, Chairman Hochschwender declared the session adjourned at approximately 2:30 p.m.

Respectfully submitted,

Charles L. Condit
Secretary

TRANSCRIPT OF PRESENTATION
BY PETER BARTON HUTT
TO SPI, FOOD, DRUG AND COSMETIC
PACKAGING MATERIALS COMMITTEE
May 31, 1973

(HOCHSCHWENDER) May I have your attention, please. We're running against a very tight schedule so I am going to make my introduction very short. I think you all know why we're here this morning. We have the unusual situation where we had invited our speaker to come to lunch which would have been nice for him and for us, but he is under the pressure of having to be at a Congressional hearing later this morning and was so very kind to agree to come here for breakfast. He has brought with him two gentlemen from the Food and Drug Administration who would, perhaps, when I call your names please stand and be recognized. Mr. Albert Rothschild, Assistant to the Director of the Division of Food and Color Additives; and Mr. Albert Holtz, chemist from the Division of Chemistry and Physics. And now without further ceremony I'm going to introduce to you Peter Barton Hutt, Esquire, the Assistant General Counsel of the Food, Drugs and Environmental Health Division, Department of Health, Education and Welfare; in common parlance, FDA's General Counsel.

(HUTT) Good morning to all of you. I agreed to come this morning on the grounds that I would not have any prepared remarks, but I would be happy to answer any questions that might arise. So, Jerry [Jerome H. Heckman, Esq., SPI General Counsel] took me up on that and I have a letter that was hand-delivered to me two days ago with a series of ten questions, presumably ones that some of you have given to him. What I'd like to do is simply run down those ten questions. Rather than reading each one, I will summarize it, and give you whatever comments I can. If I happen to give the wrong answer, my colleagues in the back of the room will, I'm sure, correct me, and, if I don't answer it completely, I'm sure Jerry will stand up and tell me I haven't answered it.

Now, at the end of each one of these brief discussions, I would like you to ask any additional questions or make any comments you wish because I'm sure that otherwise you will forget them by the time we get through all ten of the questions. So here we go.

The first question, and I will not read it specifically, but will summarize it. Jerry's first question related to our prior sanction regulation which was published on May 15. He pointed out that in the comments there was a suggestion that we include the so-called Lehman list, published in 1956 and which--

although I did not realize it, Jerry, until I got the letter--apparently has been amplified upon in the Society's publication entitled "GMP Criteria for Plastic Resins, Prior Sanctioned Under the Food Additives Amendment of 1958." And he asked why this, the Lehman list, wasn't included in the regulation which we did publish in final form and, second, how it might be included.

Well, the reason it wasn't included is very simple. In order to include anything in any of our regulations, it must be published for comment. Now we had not included in the original proposal any mention of the specific Lehman list and, therefore, we could not have included it in the final regulation. We were remiss, Jerry, in not pointing that out in the preamble to the final regulation. I frankly wasn't aware you had made the suggestion in the comments.

In any event, the way to get it included is to submit a request that it be published in the Federal Register as a proposal for inclusion under the new Subpart. The regulation, which I have here somewhere, does provide, as I'm sure you know, a rather simple procedure. It simply says: "The Commissioner will publish in this subpart all known prior sanctions. Any interested person may submit to the Commissioner a request for publication of a prior sanction supported by evidence to show that it falls within section 201(s)(4) [--that's the prior sanction provision--] of the Act." So, to make a long story short, write us. That would apply obviously to all prior sanctions. Any questions on that one or was that one very easy? Jerry?

(HECKMAN) In cases where people do not choose to make that request that, of course, does not really affect their prior sanction status.

(HUTT) No, it does not affect the prior sanction status. A prior sanction cannot be revoked. As we have said in the Federal Register, a prior sanction exists once it was given prior to 1958 and nothing can change it. We can invoke other sections of the Act to limit it--namely the adulteration provisions of the Act--but we can't revoke a prior sanction and publication is merely public notice of what happened prior to 1958.

Well, let's go on question number two. I hope I can get away this easily on all of them. A question has been raised about the legal justification for the change in the title of the Subpart F.

Jerry, I honestly don't remember what it was before. It reads "Prior Sanctioned Food Ingredients." I think it referred before specifically to packaging ingredients. Well, there was

some concern among some of you here, apparently, that we intended to somehow exclude packaging ingredients. I think we made the answer here quite clear by our proposal on PVC bottles. We are not excluding packaging ingredients. We intended the word or the phrase "food ingredients" to include direct and indirect food ingredients. This really is all that was intended--we wanted a broader term to encompass, in short, both food packaging as well as the direct food ingredients. Any further questions on that issue? I see none.

A third question. Some prior sanctioned, GRAS and cleared food ingredients are now presently covered by cross-reference, in either general or specific ways, in indirect food additive regulations. Does the adoption of the new Subpart E in any way affect the propriety of continuing to use prior sanctioned direct additives in food contact surfaces which are indirect additives?

The answer is no, once again. Subpart E is intended to give public notice and not--if I can put it this way--to have any substantive effect upon the prior sanction unless we specifically are trying to limit it through use of the adulteration provisions of the Act--again, the best example being the PVC proposal that has now been published. Now, there is one thing, though, that I would caution you on. [Some people have concluded that if ingredient A, whether it's a direct or indirect additive, had a prior sanction for one use, it can be used for all uses, and that is not true.] A prior sanction is for a specific use. Now if it is--let's say ingredient A is prior sanctioned as a direct food ingredient--someone might well conclude that although it isn't prior sanctioned for packaging use it would be generally recognized as safe for packaging use, and that presents a different issue. But you cannot take a prior sanction or, indeed, GRAS status for one particular use and necessarily project it across the board to all uses. That requires separate analysis in each individual case depending upon the ingredient, what is known about it, etc. Jerry, did I answer that one?

(HECKMAN) Yes. The only thing you might take into account is that under §121.2500, which is the Good Manufacturing Practices Regulation for indirect additives, it does say that if something has been found safe for use in or on foods, by some means or another, it can be used in packaging materials.

(HUTT) Yes, but that shouldn't be interpreted, necessarily, to apply to all prior sanctions. Prior sanctions are quite different. [If it's generally recognized as safe for use in food, then, clearly, it would be generally recognized as safe for packaging use.] But a prior sanction is quite different from a concept of general recognition of safety because general

recognition of safety applies now, whereas a prior sanction was back prior to 1958 when, perhaps, we didn't know very much about it.

All right, question number four. We've been advised about FDA's intention to notify manufacturers and distributors of a requirement for Environmental Impact Analysis Reports for plastic bottles for food use. Would you please comment on the genesis, intended scope and purpose of this draft notice. Among other things, there is great interest in knowing how broadly this notice is to be interpreted as regards substances which might, with or without the knowledge of a petitioner, be used as adjuvants in the manufacture of plastic bottles. We would appreciate recommendations you may make on how a responsible reaction can be made to this Notice. I've got lots of recommendations on that, Jerry. It would also be of interest to the Committee to know why only plastic bottles were singled out whereas there are other types of containers such as glass and paper. There may be an element of discriminatory treatment involved, particularly since environmental impact analysis reports require, in part, allusion to alternatives and, therefore, demand something in the nature of comparative analysis between types of containers.

Well, this is obviously a notice that is in draft form which is currently circulating within the Food and Drug Administration to determine what we should do about it. I will give you the genesis of it which is very simple. A manufacturer submitted a petition before the regulation became effective but it was not acted upon as of the moment that the regulations became effective; that is, the environmental impact regulations that we have published. The issue arose in FDA--are we now required to look at this particular petition under the environmental impact regulations? Moreover, the question raised was somewhat broader than that because the environmental impact law, NEPA, the National Environmental Policy Act, became effective two or three years ago. We simply, frankly, have not implemented it adequately. We have been derelict in not having implemented it for the last couple of years.

Indeed, as some of you may know, in the area of our PCB regulation we went ahead and implemented it before we put out a final regulation.

So, the answer came back on this particular petition--yes, if NEPA was indeed applicable, then we had to make that analysis which is required under the law, and we determined that this was a significant application and therefore we had to look

at it. Well, the company came back and said, "well, we don't have any difficulty in submitting an analysis report, but the fact remains that this is discriminatory because we have all these containers, plastic bottles, and everything out there already made by people who happened to do it just a few months ahead of us. Why are you going to hold us up from marketing for six months or a year while you go through this? Why don't you instead go ahead and approve our regulation with the stipulation that you would look at this on a broad-scale basis?"

We thought that was, frankly, eminently reasonable. I might add that it was a member of this group here and there may be a representative here who made that argument to us. I won't single out who it was, but this is, I think, a far better way of approaching it.

Now all of you, I'm sure, would be interested to know that the Council on Environmental Quality's guidelines to implement NEPA specifically state that the law is to be applied retroactively back to day one--back to 1776--wherever possible. Certainly in the situation we have with constantly evolving indirect and direct food additive regulations, it is quite possible because they are amended quite frequently. As a result, we are searching--and I emphasize we are still searching because no final decision has been made--for a means of requiring industry to go back in order to submit Environmental Impact Analysis Reports on total packaging systems or individual ingredients, whatever may be applicable, and to, in effect, bring all of our indirect and direct food additive regulations into compliance with NEPA.

Now, I have given you the genesis and the scope of what we intend to do and the purpose for it. As to exactly how we will do it, I can't give that to you this morning, because I don't know, nor do my two colleagues in the back of the room know, because no decision has been made. This is something we're looking at. We are considering one possibility of simply putting a notice in the Federal Register that would give a certain period of time--we had thought perhaps 90 days, Jerry Heckman thought perhaps 180 would be a little more realistic--for environmental impact analysis reports to be submitted to FDA on all plastic bottles. That's one way of doing it. I don't know, Jerry, if you have any better ideas or if anybody here has any better ideas. But this is something that we have been given to do--that we've got to do in one way or another. The real question is, if we've got to do it one way or another, what's the best way to do it? I have described the problem and I will now turn to all of you for the answer.

Let me ask, would it be easier in your judgment or would it be in effect more difficult to pick out the "plastic of the month" and put a notice in the Federal Register the first day of every month--boys, this week it's polypropylene! I have doubts, frankly, that that would be any easier and, indeed, you might find that it would be far more burdensome to do it that way, but I would like your judgment on that.

(HECKMAN) As a matter of fact, that's a matter that we intend to discuss at this meeting and if you will allow us to do it, we'll try to come up with some recommendations. One of the problems is a simple matter of logistics--how much work can the same people do all at the same time? If we're going to be required to do this, if we could do them seriatim instead of all at once, at least there would be an opportunity to do a decent job on each one.

(HUTT) Okay. Now, the other question is do we intend to leave out glass, paper and the other things. The answer is no. But when we will get to them, we just aren't sure. Do we have any indirect glass regulations, incidentally? Do we, Al?

(HOLTZ) Not that I know of.

(HUTT) Okay, well, that's somewhat difficult therefore to get a handle on. If we have no regulations on glass, obviously we can't ask for environmental impact analysis reports on glass.

(HECKMAN) Glass may not be applicable but we might suggest that you start with others instead of plastics.

(HUTT) Well, don't hold your breath. It's a good suggestion, but I don't think you ought to rely too heavily on it. Yes sir?

(INQUIRER FROM AUDIENCE) You're talking about food use of plastics containers. I don't know myself, but a lot of the same containers are used for furniture polish, household ammonia and so forth.

(HUTT) We have no jurisdiction over those.

(INQUIRER FROM AUDIENCE) I know you have no jurisdiction but that's part of the whole environment.

(HECKMAN) By the nature of the problem you're, in effect, providing a handle whereby all of those issues will have to be brought to bear.

(HUTT) I'm sure that's true, but obviously we don't intend to get into something that only, I would suppose, the Consumer Product Safety Commission could really get into. You might suggest that to them. The gentleman in the back.

(INQUIRER FROM AUDIENCE) Considering that plastics play such a minor role in the food packaging compared to glass or metal, why have you decided to start your retroactive study of environmental effects with plastic bottles?

(HUTT) Because the issue arose first with plastics and we agreed to approve this particular petition and, indeed, to go ahead on all other petitions as they come through as a routine matter, without trying to look at each one on an environmental basis, as we are required, as long as we do it on an across the board basis until we catch up.

(HECKMAN) A comment. Given the opportunity to do this in a reasonable way, with time to prepare the statements so that we don't have to try to rush around and do 90 of them all at once, this could turn out to be a plus for plastics. That might be remembered too--every now and then the chance comes along to establish yourself in a way that others don't have a chance.

(INQUIRER FROM AUDIENCE) FDA is now being asked by NEPA, in effect, to enter into areas other than the safety and effectiveness of these products.

(HUTT) We aren't being asked--we're being required. Yes, I would have to state this--and when I've said this I've shocked many people--NEPA was, in effect, an amendment of the Federal Food, Drug and Cosmetic Act. It added a dimension to the Food and Drug and to all our laws and regulations that none of us and I'm sure none of you realized at the time it was being enacted. In effect, if we conclude that there is an adverse environmental impact, that now becomes a determination that could be dispositive of whether we approve a petition or not.

(INQUIRER FROM AUDIENCE) What coordination is there between EPA and FDA to make sure that the items on which FDA might be spending its time from an environmental standpoint are really significant to the overall picture and would be significant in the eyes of EPA?

(HUTT) As a matter of fact we've talked--certainly on the PCB's, for example--very closely and they helped develop our environmental impact statement on PCB's as well as did CEQ. The second environmental impact statement that we filed was just

recently on selenium in animal feed and I don't believe we had time on that one because we had to do that too quickly to talk to CEQ. But, I doubt that anyone would dispute that adding selenium to all animal feed is not a significant environmental happening, if I can put it that way. In the future, obviously, we will consult with EPA and CEQ and any other government agencies that might be involved so I really don't think that's much of a problem.

(INQUIRER FROM AUDIENCE) I believe your draft notice is to be directed at bottles. Does that mean you are not at this time looking at other forms of plastics for food packaging?

(HUTT) I believe the proposal was to start with the bottles.

(INQUIRER FROM AUDIENCE) How would you define bottles?

(HUTT) How would you define bottles? You're the experts so maybe you can help us. That's something you might also consider--should we break it down that way or should we handle all of the containers at once? I guess Jerry says I'm running behind schedule, I better move on. If you can hold your question maybe we can get it later.

A number of indirect food additive regulations refer back to GRAS substances now listed but subject to the ongoing FDA GRAS list review. FDA has already proposed to delist some of these direct additive GRAS items because it is believe they are no longer being employed. SPI intends to comment. Will it be sufficient for us to simply request a continuation of the listing or will something more be required? Would you please comment so that it will provide guidance for future situations where delisting of GRAS items might be contemplated.

Obviously, the reason we put the proposal in the Federal Register and asked for comment on the delisting of some of the now existing GRAS determinations in 121.101, but which the NAS found were no longer being used by anybody in food was to get comment. Now there are two or three types of comment I suppose we could get. There may be some manufacturers still using them as direct food additives. We've gotten some of those comments. There are, I know, some uses in animal feed and pet food and we've gotten comments on that. Now, the third category would be yours where they're used in indirect food additive or food ingredient use and obviously your comment should be made on that basis. What we would intend to do if we find it's a perfectly valid comment and if we find that there is documented present use

is to put a limitation in 121.101 to indirect use. Now, I would suggest that you do more than just simply say keep all those on so that we can use them in indirect food additive use. You should provide us with information in as much detail as you can as to what type of packaging material they are used in--again you don't have to be terribly specific, but at least give us some general idea--and the levels of use so that we can have something on which to base our final action. You can get this information very simply by a survey. Any questions on that? The gentleman in the back.

(INQUIRER FROM AUDIENCE) If a material has been generally recognized as safe in the past but is not in current use, I still don't understand why it's being taken off the list. Are these things now considered unsafe?

(HUTT) No, we specifically stated in the preamble to that document that we were not taking them off because of a finding of a lack of safety or anything else from a substantive viewpoint. We are faced in our GRAS list review with going down, literally, thousands of substances and we saw little point in including these along with other items if nobody was using them. Now this doesn't mean something isn't GRAS. It just means that we are not going through and making an affirmation that it is still GRAS.

(INQUIRER FROM AUDIENCE) If a manufacturer wants to use a particular substance that he has used before but that is now delisted, can he use it without getting it put back on the list?

(HUTT) Well, some people in this room would say that he could start using it immediately if, in his conclusion, it was GRAS. He takes the chance that we might disagree with him. Certainly he could come in at the time that he decided to begin using it again and, under our regulations, submit a petition for affirmation of GRAS status. He wouldn't necessarily have to start with a Food Additive Petition. This is simply a bookkeeping measure to be quite honest and nothing more than that. I think we made it quite clear that it was nothing more than that.

(HUTT) Question number six. If I can summarize a rather long paragraph--what ever happened to the Ramsey proposal?

I saw Les Ramsey in the elevator at FOB-8 a couple of days ago and I said, "Les, whatever happened to the Ramsey proposal?" And Les said, "I was going to ask you that question." As far as I can tell it is about as dead as a doornail.

In the 20 months that I've been at FDA I have not heard one mention of it until I got this letter and asked Les about it. Les, I might add, is retiring within a couple of weeks which certainly won't help to revive the proposal. If there is to be anything done along the lines of that proposal or any of its predecessors, it is going to have to be started again. I doubt if the present Acting Commissioner ever heard of the idea and I doubt if the last Commissioner ever really spent more than 30 seconds on it, if that much. In short, I certainly have heard no discussion of it in any Bureau of Foods staff meeting or any Commissioner's staff meeting in 20 months, so that gives you an idea of how current it is.

(HECKMAN) In the comments we filed in the GRAS rulemaking proposal we sort of recited the history of the Ramsey proposal again and in the preamble it was indicated that Food and Drug thought this was a matter that should be given active consideration.

(HUTT) Yes, but that just simply summarizes that, at this moment, it is not being given active consideration and has not been for two years.

(HECKMAN) Is it your suggestion that we request that it be reactivated or how would you suggest we go about doing this?

(HUTT) I would say this, it is obviously not something that is of an immediate, necessary priority to FDA and, as a result, FDA is not going to reactivate it itself. Now whether you want to or not is up to you, but it isn't a self-generating problem within FDA now.

(HECKMAN) If we seek to reactivate it can we count on getting some attention for it in light of the comment in the last GRAS status rulemaking?

(HUTT) I would say that depends on whether we were looking at saccharin that week or not. Actually, that's really hard to say, Jerry. Obviously no one has decided against it, it simply is that it hasn't been looked at recently. It just has sort of fallen between the cracks and has gone out of circulation or something. I obviously am being very candid with you.

(HECKMAN) The essence of the matter is that we have this continuing problem of deciding what "not reasonably expected to become a component of foods" means. This proposal was an attempt to resolve that problem in part. It's a critical issue for the industry because it comes up every day.

(HUTT) Well, I would say that to the extent it is tied in--at least in the minds of some people--with the NAS Food Protection Committee Report on Toxicological Insignificance, the proposal has, if anything, been hurt rather than helped because the NAS Report has been controversial and has been severely criticized. It has not been accepted by FDA, indeed some of FDA's toxicologists have stated that they flatly would not concur with that report, and, therefore, the concept of toxicological insignificance, at least as set out there, is somewhat troublesome and I would not rely upon it. Now, I'll be the first one to admit I'm not sure I've ever even read the Ramsey proposal. We put that statement in the Federal Register preamble, Jerry, not in the sense that we were going to put it in as a high priority item but simply to say that if this were to be pursued, fine. Someone ought to pursue it, but we are not necessarily going to on our own initiative. I hate to throw a wet blanket over the proceedings so early in the morning but I thought you were entitled to hear it like it is. Any questions or vituperative remarks about what I have said on that one?

(HUTT) Question number seven. Could you comment on the recently adopted Environmental Impact Analysis Reports rulemaking a bit further as regards when such reports can be eliminated because a petition looks only toward amendment of an existing regulation? And then, Jerry points out that our regulations state that on a new regulation--say, a new Food Additive Regulation--an environmental impact analysis report is required. On an amendment to an existing one, it is required if it is a substantial amendment, and it is not required if it is not a substantial amendment. And so he asked the magic question--what is a substantial amendment? He says, for example, if a petition were filed to permit the use of an additive previously allowed for dry foods so that it could also be used for aqueous foods, would this be a substantial amendment?

We must distinguish between an analysis report, filed by industry, and an impact statement, filed by FDA. An analysis report is required for every food additive regulation and amendment, under section 6.1(e) of the regulations. An impact statement is required only where FDA concludes, after reviewing the analysis report, that the amendment is "substantial," under section 6.1(c) of the regulations.

Fortunately Jerry asked an easy question. Look at it this way. If we didn't require an analysis report for aqueous foods, what if it had been a whole separate new petition for the first time and started out with aqueous foods? Obviously I would say that would require an analysis report. The filing of an analysis

report does not mean that the Food and Drug Administration is going to have to file an Environmental Impact Statement. The analysis report may well lead us to the conclusion that there is no significant effect on the environment and therefore that the whole proceeding ends at that stage of the game.

Now, as to the difference between a substantial and insubstantial amendment, I suppose I can give you two examples on either extreme. If you change the specifications of an ingredient in one of the blanket indirect additive regulations, I doubt very much that we would conclude--unless it is really an enormous change in the whole regulation--that this is a substantial amendment. If, on the other hand, the example given here that you are expanding use to a whole new category of foods, then that does appear to me to be a substantial amendment. Let's say you've got an ingredient that is permitted in one of the blanket regulations, but not the other, and you petition to include it in the other. Say it's an ingredient under §2514 and you want to include it in §2526, I doubt that this kind of a somewhat simple procedure would require an impact statement although, again, I can't lay down a blanket rule. But if it's a totally new ingredient intended to have a significant role in any of these regulations, then the answer is "yes"; it undoubtedly would be required.

Everything will require an Environmental Impact Analysis Report but we will not try in any remote way to say that across-the-board everything has to have an Environmental Impact Statement. We're not trying to lay down a blanket rule or, indeed, we would have done that in the regulation itself. Questions on that? Yes sir?

(INQUIRER FROM AUDIENCE) Would it be reasonable to ask if you could expand a bit on FDA expectation with respect to Environmental Impact Analysis Reports?

(HUTT) Well, Jerry says he's going to discuss that later. It's somewhat difficult to do except at length, frankly, because you have to go down the regulations, literally, item by item as we've laid it out in the Federal Register. We are attempting to leave that up to the judgment of the company in the first analysis, rather than try to say we won't accept anything less than ten pages or fifty pages or one page or whatever. We want you to do the job that you think is appropriate. We will then review it for adequacy. We have no preconceived ideas on this, we haven't seen any more of these than you have so, to some extent, it's going to depend on sort of a mutual meeting of the minds over time. All I can do is assure you that we're anxious to work this out. This law--NEPA--wasn't out idea. Frankly, it's going to be very burdensome on us and we are not trying to burden you any more than the law requires.

(HUTT) Question number eight. Must a plastics manufacturer list his products under the Drug Listing Act of 1972 if he has a customer or customers who employ the product for drug containers or such items as syringes where it may have been necessary to establish a Drug Master File for cross-referencing by a drug manufacturer who sought an NDA? That's the first part of this question.

I would say right now, no. That is not intended. I would also be the first one to admit--and I was shocked to recall this when I got this question--it all goes to show you can't write everything in regulation--that nowhere did we make this clear in the regulations under the Drug Listing Act of 1972 nor, indeed, has FDA ever made that clear under the Drug Registration Regulations that have been in effect since 1964. This problem has actually existed since 1964.

Jerry, I would think you might want to consider requesting FDA to clarify this in the regulations. It seems to me it ought to be in there fairly clearly because I'm sure I see the logic behind the question. We clearly take the position under the law that a plastic bottle used as a container for a drug is a "drug" in somewhat the same way that a food container is a "food" under the Act. Therefore, it is subject to the drug provisions of the law and there is no logical reason, unless there's an exemption, why it wouldn't have to be listed and registered but that isn't the purpose of Section 510 of the Act. And it should be clarified.

Now the second question was, is there any circumstance you can think of in which a plastics product manufacturer might be subject to drug listing?

The only thing I could think of is if, for example, a diagnostic product on which we have separate, new regulations were made out of plastic. Then the answer is quite clearly yes, because we have said it doesn't make any difference whether they're drugs or devices. We are requesting people to register their products specifically in order that we can, for the first time, begin to regulate diagnostic products. But that's a quite separate issue and I really don't think this is the rule; it's sort of an exception. Any other questions on this? I think it's an excellent question, I might add.

(HUTT) Question number nine. "The matter of petition processing continues to vex industry." It vexes us, too, I might add. "The complexity of the regulations which have evolved are seriously disconcerting because of the extensive cross-referencing of regulations and the lack of any type of codification which allows for ready comprehension of when a material is covered and when it is not. Can you tell us whether anything is actually being done to simplify and accelerate the review of petitions and to bring about codification?"

Well, this question of review of petitions has been a vexing one since roughly 1958. That's when it started. I am not familiar with anything that is being done that is going to solve this problem in the near future nor, indeed, if I were in charge of solving it would I exactly know how to go about doing it. Therefore, I wouldn't want to give you the impression that anything really is being done to speed it up.

The second part of this is "what about codification?"

Here you run into the usual question of priorities. Would you rather have us codify what's there now and not look at any of the petitions for the next year, or should we keep going on the petitions on which we already have too big a backlog? The answer is obvious. We are required to look at petitions first and, once again, the odds of ever getting around to recodification are relatively poor for that reason unless Congress were to double our budget overnight. Now, there are two possibilities, one of which is in this letter.

The last part of the question is "if FDA is unable to free its own personnel to handle this area could some thought be given to a joint industry-government-university management systems effort towards this end?"

Obviously. In fact you could drop the Food and Drug Administration out of that. You could do it in the industry or with an outside consultant. If it were simple codification there is no reason why FDA would have to be in it at all. The other possibility is there are as you know, at least two private cross indices--the Food Chemical News Guide and CCH. I think you would probably find that we use those in FDA as much as you do outside. The answer is, until we recodify and index ourselves, you're just going to have to use a private source for that information. That's not a happy answer, but that's, again, a fact of life. We just don't have the people and the time to do it. If industry wants to do it, we'll be just delighted and we'll give you every bit of help that we can. Any questions on that?

Now the last question is one of these complex ones that starts out, fortunately saying "this question is probably more directed toward the technical people at FDA but is being submitted for your consideration and perhaps reference to them. In the food additive regulations there are a rather substantial number of provisions allowing for the use of coating materials on a variety of substrates. Assuming the substrate is acceptable, is there any reason still extant for not combining the coatings regulations so that they could cover all basic substrate materials such as cellophane, metals, paper and all regulated GRAS or prior sanctioned plastics?"

Well, obviously, this was not exactly my bag so I had my secretary call Dick Ronk and say "what do I say on this one?" And Dick gave me a little handwritten note which I will read to you. I think I understand it. If I don't, my two colleagues are in the back of the room to clarify what I have obscured. "Up to the present time,"--this is Dick Ronk's note and he probably doesn't know it's being published but that's all right,--"it has been our policy in regulating coatings for varied substrates e.g., cellophane, polyolefins, polycarbonate, nylon, etc. to require petitioning and separate extraction data for each type of regulated substrate. It is our opinion that coatings which have been found acceptable for one regulated substrate on the basis of proper extraction and toxicological data could have coverage for other regulated substrates within the same limitations of composition, conditions of film, preparation and exposure of time, temperature, food types, etc. as were evaluated for the initial regulated substrate.

"This opinion is based on the fact that the composition of regulated polymer-substrate does not seem to affect the extractability of the super-imposed coating. However, it would seem that only FDA would be aware of all of the conditions which were considered before any particular regulation was promulgated. The Society should consider, for example, incorporation of §2514 into §2526 as a package rather than piecemeal. Likewise, future petitions should consider the most extreme conditions for coatings and substrates to maximize the utility of the regulation and broadened coverage."

Now, I think the problem as I understand it is [at this point the tape ran out and we lost some of the exchange.] -- or to all other substrates, rather, then there would be a problem. But if it did contain enough information, then it could be broadened. The difficulty is, as Dick points out in this note to me, that you may not know whether that original petition contained enough data. Now we're solving that problem by releasing all that data under the Freedom of Information Act.

In the future you should be able to get the underlying safety and functionality data and to determine whether that would be sufficient to broaden all of these coatings coverages, etc. to all substrates. Now, I am ready to be corrected by either of my colleagues. Is that an accurate statement? They are nodding their heads in wonderment. Excellent. I survived that test. Does that answer the question?

(INQUIRER FROM AUDIENCE) If a particular coating is suitable and approved for use on one substrate, for example, cellophane,

is it or should it be permissible to use that coating on another substrate where its use is not specifically permitted?

(HUTT) I honestly don't know. That's a technical question. I would suggest that any of you who want to pursue this collar my friends in the back and try to determine from them what would and would not be feasible. That is obviously a technical issue that I am just not qualified to answer.

[Question from audience paraphrased by Mr. Hutt]-- Well, perhaps I just don't understand the question. You're asking if the coating is all right for use on the substrate, is it all right by itself? What would you use it on? By itself as a free form? Well, I'm afraid I just can't answer that. There's nothing legally improper about it, if, again, you've satisfied all the extraction and toxicological requirements. There is no legal impediment to doing it. It would require a petition, obviously.

Well, I have gone through the ten questions. They were not intended to be the only questions this morning, and I still have at least thirty seconds.

(INQUIRER FROM AUDIENCE) My question concerns the environmental impact statements. Let's take the material polypropylene, for example. There are at least eight varieties of polypropylene, a number of producers of polypropylene and a number of companies that form polypropylene into bottles for food and industrial uses. Now, at what layer or level do you foresee the Environmental Impact Analysis Reports being prepared to satisfy your requirements?

(HUTT) That's why you have a trade association--to make that kind of determination. The trade association can get all those different levels together on the entire issue and say "now you take this part of it, and we'll put together this part of it, and then we'll all get together and file the final thing together." I would think if everybody filed his own, there could be chaos--at least it would be lots of fun.

(INQUIRER FROM AUDIENCE) I don't see where this would have any meaning unless the reports were filed on an individual basis.

(HUTT) Well, it could be, in a sense, filed on both. Obviously, the issue of whether the manufacture of an ingredient has an environmental impact in and of itself, simply the plant manufacture, is somewhat different from whether the massive use of this type of bottle floating around in the rivers and streams and in trashcans or when burned in an incinerator, have an environmental impact. Now, the latter is an industry-wide problem, the

former may be an individual company problem. This is the kind of thing that I would think the industry would have to sort out through its association, work together on, and decide how it would handle it.

(INQUIRER FROM AUDIENCE) If such a statement were filed on, for example, polypropylene would it be acceptable for all polypropylene?

(HUTT) In what aspect? I still don't understand the question. If it covered all polypropylene it would cover all polypropylene. If it didn't, it wouldn't. I don't know how to handle that question.

(INQUIRER FROM AUDIENCE) In this sort of statement, wouldn't it be necessary to include manufacturing data? After all, one company may make it our way and another company could make it differently.

(HUTT) It would make a difference if there were a substantial difference between the two types of manufacture. If there is no significant difference, then you could handle all types of manufacture as a combined submission. But if there were major differences, if the one company used a whole series of components that raised completely different environmental questions, and another one used quite a different series, and, therefore, had different type of pollution potential, then they would have to be handled separately. I would suggest that what I am trying to say is that this is largely a matter of common sense. You group things together that can be grouped together, and you don't if they can't be.

(HECKMAN) We had some experience with that in connection with the PVC liquor bottle.

(INQUIRER FROM AUDIENCE) Yes, but we have a plastic material that has a wide range of potential uses including plastic bottles. We went to so much trouble to get that approved that we don't want to fool with it. Can we ask for a regulation that says for all food contact uses except beverage bottles?

(HUTT) Surely. There is no problem in that. In fact, you could sell it, if you wanted to, for cosmetic use and not use it for any foods. As long as it wasn't used for foods or beverage use, or whatever, you can place whatever limitation on it you want.

I'm afraid the witching hour has come, and as much as I would rather stay here than go see Congressman Fountain, he has a little more authority over me than you do. It's been very nice being with you. I've enjoyed it.

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