The Society of the
Plastics Industry, Inc.

355 Lexington Avenue
New York, New York 10017
(212) 503-0600

AUG 13 1984

TO: SPI Public Affairs Committee
SPI AN Polymers Group
SPI Food, Drug and Cosmetic Packaging Materials Committee
SPI Plastic Bottle Institute
SPI Vinyl Institute

FROM: Fran W. Lichtenberg

DATE: August 8, 1984

RE: Further Correspondence Regarding Regulatory Status of PVC

Attached are (1) a letter from J.H. Heckman to C. Boyden Gray of Vice-President Bush's Office and (2) an explanatory cover letter from J.H. Heckman to interested SPI groups. These letters are a continuation of the correspondence which began this spring as a result of Frank Harris' (Aim Packaging) letters to Sanford Miller of FDA and to selected members of Congress.

Fran W. Lichtenberg

LAW OFFICES

KELLER AND HECKMAN

1150 17TH STREET, N.W.

SUITE 1000

WASHINGTON, D.C. 20036

(202) 457-1100

TELEX
49 95551

TELECOPIER
(202) 296-7682

CABLE ADDRESS "KELMAN"

WRITER'S DIRECT DIAL NUMBER
(202) 457-1110

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESANI JR
MALCOLM D. MACARTHUR
WAYNE V. BLACK
MARTIN W. BERCOVICI
JOHN S. ELORED
CAROLE C. HARRIS
MICHAEL F. MORRONE
LARRY S. SOLOMON
JOHN B. DUBECK
CHRISTINE A. MEADHER
SHIRLEY S. FUJIMOTO

MARK FOX EVENS
PETER L. M.A CRUZ
LAWRENCE P. HALPRIN
DEBORAH SHUR TRINKER
C. DOUGLAS JARRETT
EDWARD L. KORWER
PETER A. SUSSER
SHEILA A. MILLAR
RUSSELL H. FOX
LEE M. WEINER
TIMOTHY BROWN
ILENE RINDEL HELLER
ELLEN F. EPSTEIN

August 6, 1984

SPI Public Affairs Committee
SPI AN Polymers Group
SPI Food, Drug and Cosmetic Packaging Materials Committee
SPI Plastic Bottle Institute
SPI Vinyl Institute

Re: FDA Report on PVC

Ladies and Gentlemen:

In response to an inquiry by Vice President Bush, the Food and Drug Administration (FDA) recently prepared a report on the status of polyvinyl chloride (PVC) and the use of PVC for liquor bottles. Unfortunately, the FDA report contains seriously misleading statements concerning the prior-sanctioned status of PVC together with negative implications on the safety of PVC. We sent a letter to set the record straight after clearing it with SPI President Bill Sessions and the Staff Administrators for the Vinyl Institute (Roy Gottesman), Plastic Bottle Institute (John Malloy), and the Food, Drug and Cosmetic Packaging Materials Committee (Fran Lichtenberg). A copy of the FDA report, the corrective response, and related correspondence are enclosed.

Frank Harris of Aim Packaging, Inc. has been working for many years to clarify the status of PVC liquor bottles. As we reported previously in our April 17, 1984, letter, Mr. Harris generated a number of Congressional inquiries which resulted in commitments from FDA to Congressmen and Vice President Bush that a PVC proposal would be forthcoming later this year. Among the most recent correspondence was a FDA paper titled "Report to the Secretary with Response to Vice President Bush's Inquiries on Behalf of Mr. Frank M. Harris". The FDA report implies that there is no prior-sanction for PVC and that the Bureau of Alcohol, Tobacco and Firearms (BATF) acted without FDA's knowledge and con-

sent when it approved the experimental use of PVC liquor bottles beginning in 1968. Our response details FDA correspondence, speeches, and regulations over the last 28 years underlying the prior-sanction that supports the use of PVC for all food contact applications.

In addition to setting the record straight on the prior-sanction, our letter notes that the only safety question raised in conjunction with PVC was a concern with residual vinyl chloride monomer (RVCM) levels. Since 1975 the RVCM level has been reduced dramatically. FDA has acknowledged this most recently in a December, 1982 letter from Sanford A. Miller, Director of FDA's Center for Food Safety and Applied Nutrition (then the Bureau of Foods). Our response also included many background documents. We have not enclosed these with this letter because these materials were previously distributed.

We trust that this corrective action will help educate the involved policy-making officials to whom it was distributed. Meanwhile, we look forward to seeing FDA's long-awaited proposal that will disperse the "little black cloud" hanging over PVC. In the interim, if you have any comments or questions, please let us know.

Cordially yours,

Jerome H. Heckman

Enclosures

LAW OFFICES
KELLER AND HECKMAN
1150 17TH STREET, N.W.
SUITE 1000
WASHINGTON, D.C. 20036
(202) 457 1100

TELEX
49 8858
TELECOPIER
(202) 296-7682
CABLE ADDRESS KELMAN
WRITER'S DIRECT DIAL NUMBER
(202) 457-1110

JOSEPH E KELLER
JEROME H HECKMAN
CHARLES H MEEHAN
WILLIAM H BORGHESANI JR
MALCOLM D MACARTHUR
WAYNE V BLACK
MARTIN W BERCOVICI
JOHN B ELDRED
CAROLE C HARRIS
MICHAEL F MORRONE
LARRY B SOLOMON
JOHN B DUBECK
CHRISTINE A MEAGHER
SHIRLEY B FUJIMOTO

MARK FOX EVENS
PETER L M LA CRUZ
LAWRENCE P HALPRIN
DEBORAH SHUR TRIMBLE
C DOUGLAS JARRETT
EDWARD L ROBWER
PETER A BUSBER
SHEILA A MILLAR
RUSSELL H FOX
LEE M WEINER
TIMOTHY BROWN
ILENE RINDEL HELLER
ELLEN F EPSTEIN

August 1, 1984

C. Boyden Gray, Esq.
Counsel to the Vice President
and Deputy Chief of Staff
Office of the Vice President
Washington, D.C. 20510

Re: PVC Liquor Bottles

Dear Mr. Gray:

Mr. Frank M. Harris of Aim Packaging, Inc. has asked that we, as General Counsel for the Society of the Plastics Industry, Inc. and its Vinyl Institute and Plastic Bottle Institute, respond to your letter of June 14, 1984. The letter included materials from the Department of Health and Human Services on the use of polyvinyl chloride (PVC) for packaging distilled spirits. We were particularly disturbed by the enclosure captioned "Report to the Secretary with Response to Vice President Bush's Inquiries on Behalf of Mr. Frank M. Harris" because it contains a number of misleading statements concerning the regulatory status of PVC and its safety as a food packaging material. This letter is intended to set the record straight, so that there is no misunderstanding on this matter in your offices or among the others receiving a copy of this letter.

A. Regulatory Status of PVC

Under the Federal Food, Drug, and Cosmetic Act (Act) substances may be used for food packaging if they fall into one of a number of different categories. The category of concern here governs substances used in accordance with a sanction or approval granted by Food and Drug Administration (FDA) or the United States Department of Agriculture (USDA) prior to the enactment of the Food Additives Amendment of 1958. Incidentally, alcoholic beverages are foods under the Act.

The existence of a prior sanction is a factual question. The simple truth is that the facts are not properly represented in the report provided to you by FDA. By only stating half the case, the memorandum is seriously misleading and gives the impression, for example, that the Bureau of Alcohol, Tobacco and Firearms (BATF) was acting illegally, improperly and without FDA's knowledge and acquiescence when it authorized marketing of liquor in PVC bottles in the late 1960's. Incidentally, again as an example of the factual inaccuracies in the memorandum, it refers to BATF approval on an experimental basis of PVC liquor bottles "in the early 1970's." In fact, BATF authorized the use of PVC liquor bottles in selected sizes on an experimental basis in 1968. See BATF Circular 68-32 (Nov. 21, 1968). We also understand BATF proceeded in this matter only after receiving FDA's concurrence.

Fairly recent FDA correspondence indicates the inconsistency between prior guidance to industry and its report to you. Perhaps the most pertinent correspondence is the enclosed 1980 letter from Manjeet Singh, Assistant to the Director, Division of Regulatory Guidance, Bureau of Foods (now the Center for Food Safety and Applied Nutrition). The letter indicates that PVC bottles are prior-sanctioned and may be used in food contact applications as long as certain volatility and viscosity specifications for the basic resin are satisfied, and good manufacturing practices (GMP) are employed. This, of course, has been general knowledge for many years. Other FDA letters of the same nature are also enclosed.

Singh's 1980 letter is consistent with a 1969 speech at a World Health Organization seminar by William F. Randolph, then with FDA's Petition Control Branch (copy enclosed). In his presentation, Mr. Randolph stated that "FDA recognizes a prior-sanction for all food-packaging applications for polyvinyl chloride basic resins . . ." (emphasis added). At the time, speeches by FDA officials were generally understood by industry to represent statements of Agency policy. Speeches, such as Mr. Randolph's, were not given casually and were reviewed by FDA policy managers at all levels. It is both disappointing and confusing for FDA to seem to be denying a position it has otherwise agreed is correct since at least 1968.

The roots of the Randolph speech can be traced back to work by the Society of the Plastics Industry, Inc. (SPI) after the passage of the Food Additives Amendment of 1958 to catalog and clarify the prior-sanctioned status of plastic resins. The enclosed SPI bulletin from March 1963 lists polyvinyl chloride as a prior-sanctioned resin. That bulletin also contains a 1960 FDA letter and a 1962 USDA letter which directly or by reference confirm the prior-sanctioned status of PVC.

The 1960 FDA letter refers to an October 1956 article by A.J. Lehman of the Food and Drug Administration, which lists "materials for food packaging which we have reason to regard as acceptable." A copy of the Lehman article is also enclosed. You will note that polyvinyl chloride is listed on page 161. Although the listing is under a category for films, a review of the materials on the list indicate that Dr. Lehman could not possibly have intended to restrict their use to films. For example, the same list includes acrylonitrile-butadiene-styrene (ABS) and butadiene-acrylonitrile synthetic rubber which were never used as films.

In any event, all of the foregoing points inexorably to a broad prior-sanction for PVC. The food additive regulations promulgated by FDA also support this conclusion. Several regulations refer to adjuvants for rigid vinyl chloride copolymers. These regulations only make sense if PVC is acceptable for food contact use. See, e.g., 21 C.F.R. §§ 178.3790, 178.2650, and 178.2010 (various entries).

Collectively, all of the materials cited also document the prior-sanction for PVC for all food contact applications. Thus, when BATF approved the experimental use of PVC liquor bottles in 1968 there was a solid foundation showing a prior-sanction. It is sad, but not necessarily unusual that, here, some 15 years after the Randolph speech, FDA is using the infamous "negative-pregnant" fallacy to maintain that no prior-sanction exists because it can not locate a letter explicitly discussing the use of rigid PVC for food contact uses. However, the obvious prior-sanction for rigid PVC is sufficient as a matter of law, common sense, and past FDA practice to support the prior sanction for alcoholic beverages. For example, the previously-mentioned Lehman article discusses various types of approved materials but does not distinguish

between the type of food the package contains. Thus, these materials are considered prior-sanctioned for aqueous, acidic, fatty, or alcoholic foods as those terms are defined by FDA.

B. Safety of PVC Packaging

In addition to providing a misleading picture of the prior-sanctioned status of PVC, the "Report to the Secretary" leaves the impression that rigid PVC may raise a serious safety question. In 1973, FDA proposed to prohibit the use of PVC in contact with alcoholic beverages. 38 Fed. Reg. 14,174 (May 30, 1973). This proposal was withdrawn in 1975 and replaced by another proposal, which has never been made final, to reaffirm the prior sanction for flexible PVC products and can enamels but to prohibit the use of rigid PVC in contact with foods. 40 Fed. Reg. 40,529 (Sept. 3, 1975). The proposals themselves would not have been necessary if rigid PVC had no prior-sanction.

The basis for the 1975 proposal was a concern with residual vinyl chloride monomer (RVCM) in rigid packaging materials, not with the PVC itself. Since 1975, the RVCM level of rigid PVC plastics has been reduced dramatically. In other words, the basis for the 1975 proposal has been invalidated. FDA has acknowleged this in correspondence with concerned members of industry. The 1980 Singh letter mentioned above substantiates this.

A December 1982 letter from Sanford A. Miller, Director of the Center for Food Safety and Applied Nutrition, is also enclosed. It replies to an inquiry concerning the use of PVC bottles for alcoholic beverages. In this letter, FDA indicated that liquor bottles with low RVCM levels present no safety problem. More specifically, FDA agreed that the estimated daily intake of vinyl chloride from the use of PVC as a liquor container will be well below the "very safe" level derived by FDA's Cancer Assessment Committee.

Although this letter has focused on the prior-sanctioned status of PVC, there is also a substantial body of information to support a claim that PVC packaging is generally recognized as safe (GRAS). The FDA correspondence noted above

points to this. In addition, the widespread use of rigid PVC food contact materials in Europe and the rest of the world, demonstrate the predominant scientific and regulatory position that rigid PVC is safe. See, Fmali Herb, Inc. v. Heckler, 715 F.2d 1385 (9th Cir. 1983). Finally, there have been no reports anywhere of an instance where PVC food packaging has caused injury.

Today, PVC is used in a wide range of food and drug contact applications. The FDA memo you received can only be characterized as a "dark side" of regulation by vague grumblings as opposed to explicit action. We hope that with your help and that of others, FDA will promptly move to reaffirm the propriety of PVC as a container for distilled spirits and all other food applications.

Thank you in advance for any assistance you can afford us.

Cordially yours,

Jerome H. Heckman

Enclosures

cc: The Honorable Howard M. Metzenbaum
The Honorable John Glenn
The Honorable Delbert L. Latta
The Honorable Margaret M. Heckler
Dr. Mark Novitch
Dr. Sanford A. Miller
Robert C. Wetherell, Jr.
Frank M. Harris

FRANK M. HARRIS
chairman and
chief executive officer
June 21, 1984

Mr. Jerome H. Heckman
Keller & Heckman
1150 17th Street, N. W.
Suite 1000
Washington, D. C. 20036

Dear Jerry:

I have attached the response from the Vice President's office, the Secretary of DHHS, and Tom Brown's report ~~to~~ from the FDA.

Also attached is a draft of a letter I was planning to send to Sandy Miller in an effort to try to keep the heat on. I would not send it without first talking with you.

Now, what should we do? This being a folk hero is getting involved.

Sincerely,

Frank M. Harris

Enclosures

gb

AIM PACKAGING, INC. • p.o. box 278 • port clinton, ohio 43452 • (419) 635-2144

OFFICE OF THE VICE PRESIDENT

WASHINGTON

June 14, 1984

Mr. Frank M. Harris
President
AIM Packaging, Inc.
Post Office Box 278
Port Clinton, Ohio 43452

Dear Mr. Harris:

This is in further response to your letter to the Vice President concerning the use of PVC bottles for packaging liquor.

The Department of Health and Human Services has provided the enclosed report on the issues involved in adopting regulations for the use of PVC in contact with food. We understand your concern over the long delay and regret that we cannot forward a more favorable reply.

Once again, Mr. Harris, thank you for bringing this matter to our attention.

Sincerely,

C. Boyden Gray
Counsel to the Vice President
and Deputy Chief of Staff

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Secretary

Washington, D.C. 20201

MEMORANDUM TO THE VICE PRESIDENT

This is in response to your request for information on behalf of Mr. Frank M. Harris concerning packaging of liquor in plastic bottles made from PVC. I am enclosing a report prepared by the Food and Drug Administration on this issue.

Please let me know if I can be of further assistance.

Margaret M. Heckler

Margaret M. Heckler
Secretary

Attachment

REPORT TO THE SECRETARY WITH RESPONSE TO VICE PRESIDENT BUSH'S INQUIRIES ON BEHALF OF MR. FRANK M. HARRIS

This report has been prepared in response to concerns raised by Mr. Frank M. Harris, President of Aim Packaging Inc., Port Clinton, Ohio, concerning the use of polyvinyl chloride (PVC) bottles for packaging liquor.

The Food and Drug Aministration (FDA) has reviewed the status of its pending actions on PVC and, specifically, action being proposed on PVC liquor bottles. The background section reflects the numerous scientific, policy, and legal issues which FDA must continually assess and update in approving a food additive. The approval process of PVC has been further complicated by the non-existence of a prior-sanctioned general use, the carcinogenic and migratory properties of vinyl chloride monomer (of which PVC is made), and the legal history of the constituents policy. Each of these considerations will be discussed below.

Background

The PVC bottle was cleared on an experimental basis by the Bureau of Alcohol, Tobacco and Firearms (BATF) for packaging liquor in the early 1970's. This clearance was given on the premise that PVC bottles were prior-sanctioned (cleared for use before the enactment of the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act in 1958) for general use.

However, after the 1975 proposal (discussed below), a thorough check of all FDA regulations and records of companies producing PVC prior to 1958 revealed that there were no "prior-sanctions" or regulations that would cover this use. Moreover, in the 1975 proposal FDA requested persons aware of prior-sanctioned uses to submit proof of the sanctions. No proof was submitted, and to date, there is no legal authority to use PVC bottles.

Reports in 1973 that PVC bottles were the cause of off flavors in liquor led to the discovery that vinyl chloride monomer (VCM), the basic starting material used to produce PVC, was migrating from the PVC bottle walls into the liquor.

Because of this problem, FDA proposed to restrict the use of PVC to non-alcoholic food in 1973. Upon receipt of additional scientific data, FDA withdrew the original proposal and in 1975 proposed to ban all rigid and semi-rigid PVC, including the bottle.

This proposal generated additional scientific studies on contamination of food from PVC and numerous toxicological studies on VCM. The results of chemistry studies indicate that there will always be some residual VCM in PVC polymers, but do not indicate a level below which there would be no migration of VCM to food or liquor. The results of toxicology studies confirm that VCM is a carcinogen to both test animals and humans.

Since publication of the 1975 proposal, industry has improved production procedures of PVC, particularly bottles, to lower VCM levels from the 1,000 parts per million level (common in 1973) to the currently achievable levels of 10 parts per billion or less. At the same time, FDA has been developing a policy for the approval of food additives containing carcinogenic constituents.

This new policy provides a means to permit the safe use of materials that contain very small amounts of unavoidable carcinogenic components when the "additive as a whole" has not been found to be carcinogenic. The course of action prior to establishment of this policy would have been to ban PVC under the "Delaney clause" of the Federal Food, Drug, and Cosmetic Act, as had been previously proposed.

FDA fully explained the scientific, legal and policy bases under which it would approve food and color additives that contain carcinogenic constituents in an advance notice of proposed rulemaking published in the Federal Register on April 2, 1982. On June 4, 1982, FDA utilized the new policy to permanently list D&C Green No. 5.

Following the listing of D&C Green No. 5, FDA was challenged on the policy in the court of appeals (Scott v. FDA, 6th Circuit). On February 23, 1984, the court afirmed FDA's interpretation of the Delaney clause and rejected the challenge to FDA's action. Since April 1982, FDA has followed this policy in other cases involving food and color additives with minute amounts of carcinogenic constituents.

In order to implement the use of the "carginogenic constituents policy" it is necessary for FDA to perform a risk assessment on the intended uses of an additive. One important factor in this assessment involves review of data from available bioassays of the constituent. Although Dr. Cesare Maltoni (Italy) performed the earliest work that found VCM to be a concinogen, he would not permit review of his experimental data, even by visiting FDA toxicologists. FDA evenutally was able to obtain the needed data from a similar study by Dr. V.J. Feron, published in 1981, permitting FDA to calculate the risk associated with certain uses of PVC containing residual VCM. The calculations indicate that all present and anticipated amounts of PVC would be safe, if appropriate limits were established on levels of residual VCM in the various classes of PVC food-contact packaging materials.

While the main scientific issues were settled by late 1982, there has remained the task of reviewing, summarizing the responding to several thousand pages of comments received in response to the 1975 proposal: the review of the economic impact of the new action to be proposed, as required by the Regulatory Flexibility Act and Executive Order 12291; and the review of the environmental aspects of the situation. Of these

issues, the comments have been reviewed and responses prepared for inclusion in a new FDA proposal, which would withdraw the 1975 proposal and would at the same time address the use of PVC in contact with foods including liquor bottles.

The economic and environmental issues are the only outstanding items that must be considered in the development of a new proposal. In the case of the economic assessment, there is a possibility that permitting the PVC bottle for liquor would be competition unwelcomed by the glass industry. BATF has been involved in a suit on poleythylene terephthalate liquor bottles following BATF approval of their use to package liquor in late 1982.

The environmental impact issue is complicated by the fact that BATF issued an Environmental Impact Statement on PVC bottles in the early 1970's. Under current Council on Environmental Quality Regulations, FDA, as the lead agency in this action, must determine if a Supplemental Environmental Impact Statement is necessary.

Summary

In summary, the FDA has been working to resolve each of the many issues that have prevented earlier action to address the use of PVC in contact with food. A proposed regulation is being drafted for publication in the Federal Register later this year. Although we expect to complete the matter shortly, there is a likelihood of a lawsuit challenging our decisions, so that the effective date of our order might be stayed pending the outcome of litigation.

Copies of the cited Federal Register publications and other materials are attached for your information.

Attachments

Tab A - May 17, 1973 Proposal
Tab B - September 3, 1975 Proposal
Tab C - April 2, 1982 ANPR - Carcinogenic Constituents
Tab D - February 23, 1984 Decision Scott v. FDA

Prepared by:DHHS/FDA/CFSAN:TBrown:472-5690

United States Senate

COMMITTEE ON
ENERGY AND NATURAL RESOURCES
WASHINGTON, D.C. 20510

June 8, 1984

Mr. Frank M. Harris
AIM Packaging, Inc.
P. O. Box 278
Port Clinton, Ohio 43452

Dear Mr. Harris:

Enclosed is a report from the Food and Drug Administration concerning my inquiry about the use of PVC bottles.

I hope that my expression of concern will be of some help and note, of course, that the agency plans to publish regulations relating to PVC bottles later in the year.

Very sincerely yours,

Howard M. Metzenbaum
United States Senator

HMM:DS

Food and Drug Administration
Rockville MD 20857

JUN 04 1984

The Honorable Howard M. Metzenbaum
United States Senate
Washington, D.C. 20510

Dear Senator Metzenbaum

Thank you for your letter of May 1, 1984, on behalf of Mr. Frank M. Harris, President of Aim Packaging, Inc., Port Clinton, Ohio, concerning the use of polyvinyl chloride (PVC) bottles for packaging liquor.

The Food and Drug Administration (FDA) has reviewed the status of its pending actions on PVC and particularly any action that is being proposed on PVC liquor bottles. The problem pointed out by Mr. Harris in his letter exists, but because it concerns a number of legal, scientific and policy issues, it has been very difficult and time consuming to resolve.

FDA has been working to resolve each of the many issues that have prevented earlier action to address the use of PVC in contact with food. A proposed regulation is being drafted for publication in the Federal Register later this year.

If we can be of further assistance, please let us know.

Sincerely yours,

Robert C. Wetherell, Jr.

Robert C. Wetherell, Jr.
Associate Commissioner
for Legislation and Information

Enclosure
Constituent's letter