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October 23, 1972

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

RE: Food and Drug Administration "Proposal Regarding Regulation of Prior Sanctioned Food Ingredients;" 37 Fed. Reg. 16407

Gentlemen:

Enclosed herewith, for your information, is a copy of a letter I have just received from John F. Jones of Vistron Corporation. Attached to the letter is a reproduction of a very brief Comment Vistron has made with reference to the Comments we filed on October 10, 1972. For all practical purposes, we think you will find both of these documents self-explanatory. You will note that they relate solely to the request we made in our Comments for the inclusion of SAN resins in what we hope will be ultimate publication by the Food and Drug Administration of a prior sanctioned "ingredients" list which will include all of the basic polymers covered in the so-called Lehman list.

Mr. Jones was good enough to call us after his Comment was filed to let me know that the only purpose of the filing was to amplify the SAN "specification" we gave FDA in our statement. As all of you know, we received the information for the specification we submitted from the companies known to be producing SAN. At the time, we certainly were not thinking of broadening the coverage so that it would include any of the new nitrile-based barrier resins. It is obvious that Vistron was concerned that our filing could have this effect, and therefore moved to protect whatever position it might have as a result of the relatively recent promulgation of Section 121.2614 of the Food Additive Regulations.

It seems to us that the Vistron filing is reasonable although we really have no way of knowing whether it might lead to any untoward consequences, i.e. an inadvertent undermining of the existing SAN prior sanctions, or, worse, the questioning by the Food and Drug Administration of the specifications for all of the other polymers described in the SPI Bulletin entitled "Good Manufacturing Practices Criteria for Plastic Resins Prior Sanctioned Under the Food Additives Amendment of 1958."

It will be interesting to see how this entire matter develops although we suspect it will probably be some time before anything definitive takes place. In any event, you may be assured that we will keep you fully posted on developments.

Cordially yours,

Jerome H. Heckman

Enclosures

VISTRON CORPORATION

MIDLAND BUILDING CLEVELAND OHIO 44115

October 19, 1972

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

Dear Jerry:

Re: Food and Drug Administration
"Proposal Regarding Regulation
of Prior Sanctioned Food
Ingredients"; 37 Fed. Reg. 16407

Enclosed is a copy of the comments we mailed to the Hearing Clerk on October 18, 1972, before I talked to you on the telephone.

Please send me any further comments which you might file in this regard. As I said on the telephone, we had only the one objection to the definition of SAN resins, and we certainly do not wish to be working at cross purposes with other members of the SPI.

Very truly yours,

John F. Jones

John F. Jones
Patent Counsel

JFJ:mr
Enclosure

VISTRON CORPORATION

October 18, 1972

Hearing Clerk
Department of Health, Education, and Welfare
Room 6-88
5600 Fishers Lane
Rockville, Maryland 20852

Dear Sir:

Re: Food and Drug Administration
"Proposal Regarding Regulation
of Prior Sanctioned Food
Ingredients"; 37 Fed. Reg. 16407

We have the following comments regarding the subject proposal and request that they be considered in spite of the fact that this letter is being submitted after the October 10, 1972, deadline.

On or about October 10, 1972, The Society of the Plastics Industry, Inc. (SPI) (of which my company is a member) filed comments on the subject proposal. We agree in general with the SPI comments with one exception--namely, item IV entitled "Proposal to List Poly(styrene-acrylonitrile)". The "SAN" resins which were used in food packaging prior to 1958 included such materials as "Lustran" of Monsanto, "Tyril" and "Styrex" of Dow, "C 11" of Union Carbide, and others. It is well known and documented that these SAN resins are copolymers of styrene and acrylonitrile composed of from 10 to 37% by weight of acrylonitrile and correspondingly 90 to 63% by weight of styrene. The more preferred SAN resins contain from 20 to 35% by weight of acrylonitrile and correspondingly 80 to 65% by weight of styrene (Encyclopedia of Polymer Science and Technology, Volume 1, page 450).

In view of this, we suggest should FDA decide to include SAN resins on the GRAS list (Subpart E, 121.2xxx) that the SAN resins included therein be further defined as containing from 10 to 37% by weight of polymerized acrylonitrile and from 90 to 63% of polymerized styrene.

Respectfully submitted,

John F. Jones
Attorney

JFJ:mr

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