

MCA

MANUFACTURING CHEMISTS ASSOCIATION

1825 CONNECTICUT AVENUE, N. W. • WASHINGTON, D. C. 20009 • (202) 483-6126

August 10, 1971

Mr. T. W. Hanavan
E. I. du Pont de Nemours & Company
1007 Market Street
Wilmington, Del. 19898

Dear Taylor:

Thanks for your letter of August 9 regarding
FDA's Guidelines on Chemistry and Technology.

I shall await Bill Knapp's thoughts on the
suggestion that MCA offer technical comment,
particularly with respect to paper additives, before
making any contact with FDA.

In the meantime, I am informing Bob Miller
by attaching to his copy of this letter a copy of
your letter.

Sincerely yours,

M. M. Hoover
M. M. Hoover, Secretary
Food, Drug, and Cosmetic
Chemicals Committee

*Knapp
Miller*

*Called M. M. to tell him that
my committee work on food and
regulations and was not concerned
with methods by which extraction
data was obtained. M. M. will
find some to take over*

*Called R. M. M. - Gupel at Papan and meeting
Suppliers to handling since API held up 121.5126 regulation
for long time. Email accepting & joining the casting of API should be
interim position. All on MCA who are interested are also on
on SPI. MCA may send SPI summary. R. M. M. will contact
Hanavan when he (TW) returns from vacation*

ASI 00002812



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
WILMINGTON, DELAWARE 19898

LEGAL DEPARTMENT

August 9, 1971

Mr. Morgan M. Hoover
Manufacturing Chemists Association
1825 Connecticut Avenue, N. W.
Washington, D. C. 20009

Dear Morgan:

The attached copy of a letter from Jerry Heckman to members of SPI's FD&CP Materials Committee is generally self-explanatory.

Of significance is the first full paragraph on page 2 in which Holtz of FDA suggested possible MCA interest in offering technical comment on the approach to food packaging guidelines, particularly with respect to paper additives. Unfortunately, I was not in a position to be able to attend the June 18 seminar in which Holtz's working draft was discussed and possibly distributed; though I suspect Bill Knapp, whom I am copying on this letter, was. In any case, we can obtain a copy.

I don't think we should miss this opportunity to provide comment and since Bill Knapp, as I recall, chaired the subcommittee on this question when FDA's proposed guidelines were initially published several years ago, I think it would be appropriate for him to reactivate his group and set up a meeting with Holtz. By this letter, I am also asking Bill to comment on my suggestion.

Sincerely,


Taylor W. Hanavan

TWH:ema
Attachment

cc: William A. Knapp

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESE, JR.
ROBERT R. TIERNAN
WAYNE V. BLACK
THOMAS J. HUGHES, JR.
DAVID L. HILL
MARTIN W. BERCOVICI
MARC K. SHAYNE

LAW OFFICES
KELLER AND HECKMAN
1712 N STREET, N.W.
WASHINGTON, D.C. 20036

TELEPHONE
202 296-2700
CABLE ADDRESS "KELMAN"

August 4, 1971

TO: SPI Food, Drug, and Cosmetics
Packaging Materials

Re: Proposed Revision of FDA's
Guidelines

Dear Committee Members:

As you may recall from my recent memorandum to you on the subject, Mr. Geary of the Food and Drug Administration invited Dan Dixler to sit in with various members of the FDA Staff on August 2 at a "working session" directed towards a proposed revision of the FDA's Guidelines on Chemistry and Technology. The remainder of this letter constitutes Dan's report to me on this meeting.

Present at the session for the FDA were Al Holtz, who served as the informal chairman; Mr. Garnett Higginbotham; Henry Young (he is now in Petitions Control), Dr. Joseph MacLaughlin and Dr. John Howard. The attention of the group was directed towards the revision of a working draft that Al Holtz had prepared in preparation for the June 18 Seminar.

The entire discussion was directed toward indirect additives connected with plastics packaging. Mr. Holtz reiterated that paper additives presented different testing problems in that "equilibrium" extractions are often meaningless. He stated that he had been in touch with a representative of the American Paper Institute (API) to obtain their assistance and guidance in preparing a set of guidelines suitable for paper additives. He further stated that the API representative informed him that the paper industry,

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as such, considered that the testing and FDA status of paper additives should be in the province of the additive suppliers, not the problem of the paper-makers.

Since Al felt that many of the leading paper additive suppliers were also active on this committee, he requested that I forward to the SPI-FDCPMC members his continuing request for industry cooperation in connection with paper additives. He suggested that those members who are also active in, for example, the Manufacturing Chemists Association, may want to respond to his request through that organization.

The first part of the session was devoted to efforts on my part to change the basic premise under which Holtz had worked from the point of view of eliminating the need to file unnecessary petitions. Not unexpectedly, this proved to be an exercise in futility since delimiting the coverage of the law is as much a legal question as a technical one and, therefore, Mr. Holtz could not effectively negotiate in this sphere.

We then began a point-by-point consideration of Holtz's draft. The attempt was made to present as forcefully as possible industry's needs for: (a) eliminating demands for information not directly related to FDA's evaluation of the safety of an indirect additive, (b) clear and precise enunciation of the information the FDA does require and, (c) clearly indicating as optional that information which even FDA agrees is optional in certain cases.

More specifically, for example, the draft required that data be presented regarding molecular weight and molecular weight distribution for every polymeric

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additive other than thermosets. This was objected to as being an unnecessary burden unneeded to assure the safety of an additive. In a similar vein, we urged that the Guidelines eliminate the mandatory request for an abrasion test; and raised the question as to whether this test is meaningful in any food packaging application.

A good deal of attention was directed towards improving the clarity of the presentation so that a competent chemist who was a novice in petition-related chemistry could follow the Guidelines and obtain all the data that the FDA is likely to require. In this general area, it was urged that the format be organized so as to be both logical and internally consistent.

The important question of the sensitivity and validation of analytical methods was discussed and the revised Guidelines should explicitly and clearly point out that all analytical methods must be properly validated. This will require the presentation in the petition of a complete discussion of the methods used (by reference to the literature where appropriate) and evidence proving that the method is effective for its use in the petition. Related to this is the question of the sensitivity of the analytical method used, particularly where "none" of a sought-for substance is found; and it was urged that the sensitivity required be explicitly related to toxicological considerations. In this connection, the FDA personnel voiced the hope that the "soon-to-be-issued" Guidelines on Toxicology would offer some clarification.

Al Holtz hoped that a new draft would be ready in about one month and indicated that he would then be in touch with us to further consider this new revision.

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It is our intention, of course, to continue working with the FDA as closely as we can. We will keep you fully informed.

While writing to inform you about this activity in which we are engaging, and on the likely possibility that many of you may be wondering what has happened to the Minutes of the last Committee meeting, and the Transcript of the FDA Seminar, I thought I would take this opportunity to let you know that neither of these important matters has in any way been forgotten.

As regards the Minutes, they are fully typed except for one small section. Due to a misunderstanding, one of the reports given at the Meeting was not supplied to us although we previously thought that it had been. We have been in touch with the party whose report we have been awaiting and have been assured that it will be in our hands this week. Thus, we should be able to send the Minutes to Charlie Condit for reproduction next week.

Relative to the Transcript, here we remain at the mercy of the Food and Drug Administration Staff which is still "editing" its portion of some of the presentations. My secretary has been contacting Mr. Kedzior almost daily in this connection and has been receiving promises that the FDA edited transcript will be returned to us momentarily. I am hopeful that it will be in our hands soon but you should understand that even after we receive the document, it will probably require two or three weeks for retyping, reproduction, and distribution. We are sorry that you are being inconvenienced in this way but we are doing the best we can and will try to minimize your waiting time.

Cordially yours,

