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

TELEPHONE
202 296-2700
CABLE ADDRESS "KELMAN"

JOSEPH E. KELLER
JEROME H HECKMAN
CHARLES M MEEHAN
WILLIAM H BORGHESANI, JR
ROBERT R. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W BERCOVICI
MARC K. SHAYE

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

Gentlemen:

For the benefit of those of you who may not receive Food Chemical News regularly, we are herewith enclosing reproductions of pages seven and eight from this week's edition since these pages set forth a report on the current status of FDA's activity relating to the anticipated Food Additive Regulation clearing certain colorants for plastic articles, and also the status of the FDA "Toxicological Guidelines" project which will probably have an important bearing on the incidental additives field.

I might mention in passing that we have now received the direct, though informal, impression from Dr. Wodicka, the Director of the Bureau of Foods, that the so-called "Ramsey Proposal" as such is truly dead but that FDA is attempting to come up with some other way to eliminate the need for the filing of comprehensive Food Additive Petitions in cases where the filing and processing of such petitions constitute an apparently unnecessary burden for both industry and government. We are unable to give you any more definitive information in this connection because Dr. Wodicka was rather vague about the matter with us. What seems apparent, however, is that progress will depend to a considerable extent on the anticipated "Toxicological Guidelines."

We do plan to follow-up with Dr. Wodicka to try to get a better fix on what FDA may have in mind, and to see if there might be some way to provide constructive input in due course. As the matter develops, we will of course keep you posted.

If any of you have comments, questions, or suggestions pending such developments, please do not hesitate to let us know.

Cordially yours,

Jerome H. Stetson

Note: For those of you who are undoubtedly wondering still, we have nearly completed our retyping of the June 18 Seminar transcript now so that it will probably be sent to the SPI office for reproduction and distribution this week or next. As for the Minutes of the June 3 meeting, I spoke with the party whose report has still not been received today and was promised that we would have it in the next day or two. This is the only thing that has been holding up our sending the Minutes to Charlie Condit so, here again, the material should be completed very soon now.

J. H. H.

Mercer concluded that "problems that have been encountered due to the use of drugs in animals raised for food" would be minimized by "uniformity of requirements and restrictions between countries. . ."

Summarizing FDA's requirements for safety and efficacy data to clear New Animal Drugs, the FDA-er said, "We will be willing to review with other countries the requirements they have for similar products and uses."

Discussing the Swann Committee Report in Great Britain, which recommended banning feed use of antibiotics which are used for therapeutic purposes in humans, Mercer said: "These restrictions have, of course, raised questions in the mind of producers as to the likelihood of similar restrictions being adopted in other countries and what effect such restrictions might have on the international movement of food from animals which have been fed antibiotics."

He said, "It is our understanding that this matter has been given consideration by the appropriate committee of the so-called Common Market countries of Europe."

Noting that a 15-man scientific task force has been studying the question of antibiotic use in feed and will report to FDA soon (See FOOD CHEMICAL NEWS, June 21, Page 27), Mercer said, "If the report leads to some restrictions in the use of antibiotics in animal feed, but the restrictions adopted in the U. S. are different from those adopted in Great Britain, the lack of uniformity could present problems in the international trade of food of animal origin."

Discussing pesticide residues in meat, the FDA-er said such imports have sometimes been found "to have residues of chemicals in excess of allowable limits for similar food produced in the U. S." Noting that such imports are detained at the port of entry, Mercer said, "This may be due to the differences in the regulations of the countries in regard to permissible uses of such chemicals and/or the permitted level of residues which are granted as tolerances for the chemical." He then referred to the Codex efforts on pesticide tolerances (See FOOD CHEMICAL NEWS, Aug. 9, Page 15).

FDA PREPARING BLANKET ORDER ON PLASTICS COLORANTS

The Food and Drug Administration is believed readying for publication a Food Additive Order to clear colorants for plastic articles.

The agency in 1967 proposed a Food Additive Order for synthetic organic colorants in food packaging paper and paperboard (See FOOD CHEMICAL NEWS, Aug. 7, 1967, Page 11), but this proposal has run into a number of snags. In addition to difficulties regarding extraction testing, the colorants proposal became involved in FDA considerations of "toxicological insignificance."

The principle of toxicological insignificance, as such, is dead at FDA, but the agency's planned "toxicological guidelines" may have a similar effect by placing few requirements on substances which get into foods in small amounts (See FOOD CHEMICAL NEWS June 28, Page 10).

At any rate, the blanket clearance for plastics colorants is now expected to precede finalization of the Order for paper colorants.

New Order Will Be Based on Petitions

The paper colorants Order is not expected to be an FDA proposal. Instead, it will be a final Order based on a number of Food Additive Petitions which have been filed for colorants. Morton International filed a Petition to clear phthalocyanine blue, phthalocyanine green, titanium dioxide-barium sulfate, and carbon black in polyethylene containers for dry food (See FOOD CHEMICAL NEWS, May 11, 1970, Page 32). Pennwalt filed a Petition to clear iron oxide, carbon black, and phthalocyanine blue as colorants for polyvinylidene fluoride resins (See FOOD CHEMICAL NEWS, June 8, 1970, Page 35). Eastman Chemical Products filed a Petition to clear use in polyolefin articles of phthalocyanine blue, phthalocyanine green, chromium oxide green, barium sulfate, and quinacridone red (See FOOD CHEMICAL NEWS, March 22, Page 38). Dr. Carl A. Nau filed a Petition to clear use of carbon black in polyethylene and ethylene alkene-1 copolymers (See FOOD CHEMICAL NEWS, Oct. 2, 1967, Page 16).

FDA-ers expect that issuance of the Order will inspire firms to Petition for its amendment to add more colorants for plastic articles. The agency has been encouraging such submissions, and has solicited data on use of indirect additive colorants.

It is expected that the Order for colorants for plastics also will clear the colorants and pigments now approved under §121.2514 for resinous and polymeric coatings. Industry spokesmen have requested that these be included in the new Order.

Questions regarding use of colorants which are not listed in the new Order may well lead to the filing of Petitions for their clearances, although it is understood that some of them do not migrate into food.

DDT CANCELLATION HEARING IS LAUNCHED

A long, landmark hearing on DDT was launched Tuesday, August 17, with requests that use of the chlorinated hydrocarbon be allowed for four or five or more years.

The Environmental Protection Agency is seeking to cancel DDT pesticide registrations for cotton and food crops (See FOOD CHEMICAL NEWS, Aug. 9, Page 10).

The hearing is expected to run three days a week (Tuesday through Thursday) for about three months. It is being held before Hearing Examiner Edmund M. Sweeney in Hearing Room C, 10th floor, Ballston Towers, 4015 Wilson Blvd., Arlington, Va. Approximately 125 witnesses are scheduled.

The roster of parties in the action show the Department of Agriculture alligned with 31 companies which are petitioning to retain the insecticide's registration. Washington attorney Robert L. Akerly represents this industry group. EPA is alligned with a member of environmental groups, including Environmental Defense Fund, National Audubon Society, Sierra Club and the West Michigan Environmental Defense Council.