



PHILLIPS PETROLEUM COMPANY

BARTLESVILLE, OKLAHOMA 74003

918 336-6600

RESEARCH AND DEVELOPMENT DEPARTMENT

October 6, 1967

FDA Procedural
Regulations for Petitions
Schn-99-67R

Dr. William A. Knapp
Allied Chemical Corporation
P. O. Box 405
Morristown, New Jersey - 07960

Dear Dr. Knapp:

Morgan Hoover has asked that comments on the proposed Procedural Regulations for Food Additives Petitions be sent to you and other members of the Manufacturing Chemists' Association's task group. On the assumption that the initial deadline of October 7 will be extended by the Food and Drug Administration, I am sending our comments as an attachment to this letter.

It is my understanding that the MCA committee is working with the corresponding committee of the Society of Plastics Industries on this matter. I am submitting these comments to Mr. Jerome Heckman, SPI Counsel, however, in the event that separate submissions will be made by the two committees to the Food and Drug Administration.

Very truly yours,

A. Merrill Schnitzer
Food, Drug and Toxicant
Coordinator

AMS:map

Attachment

cc: Mr. James Hulse
Chas. Pfizer and Co.
Dr. George P. Vincent
Olin Mathieson Chemical Corp.
Mr. M. M. Hoover
Manufacturing Chemists' Association

ASI 00001833

Comments on Procedural Regulations for Food Additives
Petitions as Proposed by the Food and Drug Administration
(32 FR 11443)

Section 121.50, subpart (e) IIA2a, requires for indirect additives that the names, empirical formulas, and molecular weights shall be provided for each substance or its reaction product(s) incidentally present in the food "unless adequate reasons for omission are advanced for particular components." There are instances, as in the case with many rubber formulations, where the final reaction products are not known. Will the FDA consider this to be "adequate reasons"? Is it really necessary in view of the fact that data must be submitted showing the material is safe for its intended use?

Section 121.50, subpart (e) IIA2biii, requires that the manufacturing process and catalyst be revealed. An additive might be made by a number of different processes and using different catalysts; its final composition and the safety thereof is the crucial consideration. The regulations that are issued do not specify catalysts nor methods of manufacture that must be used, but only that "good manufacturing practice" is required. Further, catalysts and methods are usually proprietary information. Part (f) of Section 121.50 states that trade secrets will not be revealed unless necessary in a regulation or in an administrative hearing. FDA officials are asking for the responsibility for making a decision that they need not be called on to make; they can insure the safety of an additive even if they do not know the details of how it was made.

Part (c) of Section 121.50 requires that petitions be submitted on 8 x 10 1/2-inch pages. This vexatious requirement is either red tape for red tape's sake or a bargaining point. The usual size of commercial typing paper is 8 1/2 x 11 inches and this should be acceptable; most firms would have to special order the smaller paper. This requirement is not found in Section 130.4 which covers new drug applications, nor in Section 8.4 which covers color additives petitions, nor in 120.7 which covers petitions for pesticides residues.

Subpart (e) IA5 states ".... If safety depends upon virtual lack of migration, the rationale shall be explained briefly." If there is no migration, or virtually none, why should it be necessary to file a petition at all? It should be possible to set a safe and reasonable migration limit below which migration may be ignored. A safe level should be safe irrespective of whether analytical techniques are sensitive to parts per million or parts per billion.

Subpart (e) IIB1 requires for a direct additive, if converted to another substance by oxidation or some other process, that data be submitted to show the degree of conversion. This may be speculative since it could depend to a large extent on how the food is handled by the final customer after the container was opened.