HOFFMANN-LA ROCHE INC.

NUTLEY • NEW JERSEY • 07110

September 25, 1967

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

Dear Dr. Knapp:

This letter contains our comments with respect to the Proposed Revised FDA Food Additives Procedural Regulations which were requested by Mr. Hoover on behalf of the Manufacturing Chemists' Association in his letter of September 18, 1967. Hopefully these comments will be of some assistance to you in preparing comments to be filed by the Association if it is decided that comments will be filed.

(1) We believe that §121.7(a)(3) should be revised to delete the word "chemical" prior to the word "assay". It is strongly urged that to limit the assay methods acceptable to chemical methods is an unneeded and illogical restriction as there may be practical biological, physical or other methods which cannot be technically defined as "a chemical" assay. The imposition of such a restriction would unduly limit the constant search by quality control personnel for better and more practical methods of assay, some of which may be other than chemical methods.

Furthermore, neither §505 nor §409 of the Food, Drug and Cosmetic Act (the latter indicating that the methods for determining the quantity of additives in or on foods should be practicable) require ~~or even imply~~ that such methods should be limited to chemical methods.

(2) Section 121.7(b) as now proposed could be construed to mean that petitions for non-drug food additives for use in animal feeds or drinking water will no longer be processed by the Bureau of Veterinary Medicine. We believe that these petitions should continue to be administratively processed by the Bureau of Veterinary Medicine; and, therefore, we suggest that this section be modified as follows:

Section 121.7(b) "Petitions for food additives that are non-drug substances for use in the drinking water or feed of animals shall be submitted in the form described in §121.50 and shall be submitted to the Bureau of Veterinary Medicine for evaluation."

(3) We strongly urge that §121.9(c) be deleted as it is our belief that analytical methods and toxicology should be entitled to protection as trade secrets and therefore should be considered as confidential by FDA. In this connection §301(j) of the Food, Drug and Cosmetic Act makes it an offense for any person to use to his own advantage or reveal to other than the secretary or officers or employees of the department or to courts under certain circumstances any information acquired under §§404, 409, 505, 506, 507, 704 or 706 concerning any method or process which as a trade secret is entitled to protection. We believe that the arbitrary designation of analytical methods and toxicology as nonconfidential and not entitled to protection as trade secrets, is in fact an attempt to usurp the function of the courts to determine, by applying traditional concepts of law, what may or may not be a trade secret.

As a practical matter, since the development of methodology may be a major expense involved in the development of a marketable food additive, the originator should be entitled to some degree of protection. Arguments that disclosure of methodology is necessary to permit other experts to evaluate such methods are rebuttable as there are other means available to the FDA of substantiating the analytical methods set forth in the Food Additive Petition.

(4) Section 121.50(b) permits reference to information previously submitted by the petitioner to the agency provided that the previous submission is in a current food additive Master File, or it is in some other form of submission not over ten years old. We believe that precluding the petitioner from making reference to a previous submission not in the food additive Master File and more than ten years old is unduly restrictive and would serve no useful purpose if the particular material has been kept current. We therefore suggest that this regulation be amended to permit reference to any previous submissions by the petitioner (even though not in the food additive Master File) no matter how long ago the original submission was made so long as the petitioner has kept it current over the years. The present regulation would automatically exclude reference to information previously filed which is in an NDA, Pesticide Petition, or other file originally submitted to FDA more than ten years ago. The exclusion of such a reference may require duplication of effort and would serve no useful purpose.

(5) Section 121.51(b) should be revised so as to delete the words "or as appropriate".

Section 409(b)(5) of the Food, Drug and Cosmetic Act clearly states that "notice of the regulation proposed by the petitioner shall be published in general terms by the secretary within thirty days after filing." Congress has clearly not required the agency to specify in detail in a food additive proposal the specific claims made for the food additive. In the past, the agency has noticed human food additive proposals in the Federal Register on a broad general basis in accordance with the statutory authority. On the other hand, with respect to animal food additive petitions, the agency has set forth the proposal in great detail. It is suggested that human food additive proposals and animal food additive proposals should be treated equally, and both should be published in the Federal Register in general terms.

Publication of the details of a proposal (prior to approval) is an invitation for purchasers to use the food additive (particularly in animal feeds) for a use which has been proposed but not yet approved. The publishing of the proposal

in general terms without reference to specific claims, would eliminate this possibility.

Very truly yours,

Philip J. Franks
General Attorney

PJF:kc

cc: Mr. Morgan M. Hoover
Manufacturing Chemists Assoc. Inc.

Mr. James Hulse
Chas. Pfizer & Co., Inc.

Dr. George P. Vincent
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