FEB 7 1969

MERCK & CO., INC.
RAHWAY, N. J. 07065

OFFICE OF COUNSEL
MERCK CHEMICAL DIVISION

February 6, 1969

Mr. Morgan M. Hoover, Secretary
Food, Drug, and Cosmetic Chemicals Committee
Manufacturing Chemists Association
1825 Connecticut Avenue, N. W.
Washington, D. C. 20009

Dear Morgan:

Enclosed is our Ad Hoc Subcommittee's draft of a letter to F&DA commenting on the recent proposed regulations on Good Manufacturing Practices for human foods.

In our opinion, Item 1 is merely an amplification of the point MCA made in its letter commenting on the earlier version of this proposal. The Subcommittee feels that it is necessary this time to cite specific examples which illustrate this point, and this we have done in Item 1.

The point we make in Item 2 is a general legal one, and in my opinion, would be noncontroversial as among members of our committee. I do not think that F&DA's arbitrary and unauthorized expansion of the "good manufacturing practices" concept should go unopposed. If, however, you feel that the inclusion of Item 2 would make necessary obtaining clearance of the members of the committee, for which there is clearly no time, then the Subcommittee has no objection to your deleting Item 2.

One other matter should be noted. The revised proposal not only invites comments in the usual way at the end of the regulations, but also (in the preamble) provides a mechanism for requesting an "exception" to the regulations. In this connection, the preamble also indicates that appendices might be added to the regulations setting forth different criteria specifically directed to particular segments of the food industry. The preamble provides that a "request for an exception" is to be sent to an address on C Street, which, interestingly, is different from the address to which "comments" are to be directed. The Subcommittee carefully considered this matter and decided that MCA should treat its letter as "comments" and not as a "request for an exception". The latter would be inviting a new set of regulations directed specifically at the manufacture of food chemicals. These

might be harsher and more difficult to comply with than the present set.

If you have any questions about this matter, please do not hesitate to call me.

Best regards.

Sincerely,

Frank P. DiPrima
Attorney

FPD:EB
Enclosure

cc: Philip J. Franks
Dr. W. A. Knapp
V. H. Knoop
W. E. McCormick
R. H. Philpitt

DRAFT

Hearing Clerk
Department of Health, Education & Welfare
Room 5440
330 Independence Avenue
Washington, D. C. 20201

Dear Madam:

The FEDERAL REGISTER of December 20, 1968 contains a revised proposal purporting to define "Current Good Manufacturing Practice (Sanitation)" in the "Manufacturing, Processing, Packing, or Holding of Human Foods" (33 F.R. 19023). The revised proposal replaces regulations of similar purpose which appeared in the FEDERAL REGISTER of December 15, 1967 (32 F.R. 17980).

The revised proposal provides that any interested person may submit comments, and the deadline for filing comments was subsequently extended to February 18, 1969.

The Manufacturing Chemists Association is a nonprofit trade association of 184 United States and 14 Canadian company members. Many of these members manufacture chemicals used for components of food, which chemicals are "food" within the meaning of Section 201(f) of the Federal Food, Drug, and Cosmetic Act. Those members who manufacture chemicals used for components of food are "interested persons", and the Manufacturing Chemists Association on their behalf submits the following comments:

1. At the time of the publication of the original proposal, we believed that it was not the intent of the Food and Drug Administration to include chemical manufacturing plants within the scope of the regulations. We believe this also to be true of the revised proposal. This we conclude because many provisions seem entirely inappropriate to chemical manufacture, and were obviously written with food processing plants and not chemical plants in mind. A literal reading of the regulations, however, indicate that they purport to apply to the manufacture of human "food" as the word "food" is defined in the Federal Food, Drug, and Cosmetic Act; as defined, that word would include intentional food additives, some color additives, and other chemicals used for components of food. We pointed this out in our letter to you of February 9, 1968, and we will now set forth this view in more detail.

The following are examples of provisions contained in the

proposal which are inappropriate to the manufacture of chemicals used in foods:

§ 128.3(b). This section provides that plant buildings and structures should be of such size, construction and design to facilitate maintenance and sanitary conditions for food processing purposes. Criteria for the design of food manufacturing plants on the one hand and chemical manufacturing plants on the other, are totally different. For example, in many instances, surface area of equipment in chemical manufacture is kept as small as possible to minimize metallic contamination.

§ 128.3(b)(1). The third sentence provides that fixtures, ducts and pipes should not be suspended over working areas. Drip or condensate generally has no effect, however, on food chemical manufacture, where the chemicals are within a closed system.

§ 128.3(b)(2). Separation by partition is unnecessary in chemical manufacturing operating plants, and certainly is not done in current practice. Where a multiplicity of chemicals are manufactured in a single chemical manufacturing plant, which is often the case, the requirement would be unreasonable and impractical. Food chemicals are usually within sealed vessels during the manufacturing process and are not subject to contamination from the air as are foods in food processing plants. Chemical plants are often deliberately designed without partitions to minimize possible toxic exposure of personnel to the raw materials.

§ 128.3(b)(4). This provision refers to "airborne contaminants", which are not a problem in chemical manufacturing operations.

§ 128.7(a). This requires that raw materials be inspected, cleaned and washed, "to assure that they are clean and wholesome...". This clearly contemplates the handling of agricultural products and is obviously inappropriate to the inspection and receipt of chemical ingredients, which would often be impossible to wash and which are seldom "wholesome".

§ 128.7(b). The requirement that containers or carriers of raw ingredients be inspected on receipt is unnecessary and impossible to comply with when the ingredients are chemicals which are shipped in drums, sealed paper sacks, tank cars, steel cylinders or barges.

These are but a few of the many examples of the inapplicability of requirements set forth in the revised proposal to food chemical operations. Accordingly, we request that an appropriate statement be added to the regulations indicating that they do not apply to the manufacture of chemicals used for components of foods.

2. We believe that the phrase "current good manufacturing

practices" in this context is misleading, and has already led to considerable confusion. The only substantive provision of the Act cited as authority for the revised proposal, and the only substantive provision that the regulations have any relation to, is Section 402(a)(4 which provides that a food is adulterated--

> "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;".

Thus, the revised proposal can only have meaning as interpretive regulations setting forth Food and Drug Administration's view of what constitute "insanitary conditions" under Section 402(a)(4). There is no mention of current good manufacturing practices in any provision of the Act relating to foods. The comparable provision relating to drugs, Section 501(a)(2), includes the same "insanitary conditions" language quoted above, but also provides that a drug is adulterated if it is manufactured, processed, packed or held under methods which do not conform to "current good manufacturing practice". The provisions concerning holding a drug or food under "insanitary conditions" were included in the Act as enacted in 1938. The provision concerning "current good manufacturing practices" was added in 1962. It is therefore obvious that Congress did not intend these two concepts to be synonymous; their co-mingling can only lead to further unnecessary confusion.

Accordingly, we respectfully submit that the words "current good manufacturing practices (sanitation)" and "good manufacturing practices" be deleted from the revised proposal wherever they occur, and the words "sanitary conditions" replace them.

* * *

As requested, these comments are submitted in quintuplicate.

Respectfully submitted,