

COMMITTEE CORRESPONDENCE
Manufacturing Chemists' Association, Inc.

Committee: Food, Drug, and Cosmetic Chemicals

Address Writer Care Of:
The B.F. Goodrich Co.
500 S. Main St.
Akron, Ohio 44318

Subject:

Date: September 21, 1967

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

Dear Dr. Knapp:

Following are the comments that The B.F. Goodrich Company wishes to make with respect to the proposed procedural regulations of FDA as published in the August 8, 1967 Federal Register:

- (1) In paragraph 121.50(b), reference is made to the use of master files not over ten years old. To us, the paragraph is not entirely clear as to whether master files are to be discarded at the end of ten years, or merely that the information which is more than ten years old is not applicable. We will take strong issue with the discarding of master files after a ten year period.
- (2) Paragraph 121.50(f) states, that analytical methods and a summary of the toxicological data are not considered confidential. We believe the paragraph should be modified so that all of this information would be kept confidential and not be revealed, under any circumstances, except in an enforcement action. If it is deemed necessary to publish this information in a regulation, then the petitioner should be given the opportunity, prior to publication, to decide whether he wishes to have it published or whether he wishes to withdraw the petition.
- (3) Paragraph 121.51(a) (1) states, that one copy of the petition will be retained by FDA. We do not believe this should be done, but rather all copies should be returned to the petitioner.

Very truly yours,

W. E. McCormick
W.E. McCormick,

mj

cc: James Hulse
George Vincent
Morgan Hoover

ASI 00001850