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TELEPHONE HUDSON 3-6126

Manufacturing Chemists' Association, Inc.

(FOUNDED 1872)

1825 CONNECTICUT AVENUE, N. W.
WASHINGTON, D. C. 20009

May 23, 1967

TO: Members of the Food, Drug, and Cosmetic Chemicals Committee

SUBJECT: Plant Inspections Questionnaire

Gentlemen:

I am enclosing a copy of the questionnaire prepared by the Subcommittee on Plant Inspections (Messrs. Bell and Knoop) for your review prior to the June 13 meeting.

This will serve as a basis for discussion at the meeting. The ultimate purpose is to develop a set of guidelines for use by MCA member companies.

Sincerely yours,



Morgan M. Hoover

MMH:sjg

Enclosure

ASI 00002339

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This questionnaire has been prepared to assist in the development of guidelines for use by member companies in matters pertaining to plant inspection by regulatory personnel. We would appreciate your cooperation in completing and returning it to the Plant Inspection Subcommittee, Manufacturing Chemists Association, 1825 Connecticut Avenue N. W., Washington, D.C. 20009. Company identification would be helpful, but is not required.

1. Does your company operate facilities which are registered under the Federal Food, Drug and Cosmetic Act?_____.
2. Have these facilities been inspected by F.D.A. personnel?_____. If so, how often have you been inspected during the most recent 12 month period?_____.

If the answer to either of the above questions is negative, the following do not apply. We would, however, appreciate your returning the questionnaire completed as far as is applicable to your situation.

3. Since inspections may be conducted under more than one authorization, please indicate which one (or more) of the following types of inspections were involved.
 - a. Factory Inspection, Sec. 704_____.
 - b. Drug Abuse Control Amendments (1965), Sec. 511(d)._____.
 - c. Federal Hazardous Substances Labelling Act, Sec. 11(b)._____.
 - d. Other (please specify)_____.
4. Have you been asked by F.D.A. inspectors for information on general or specific matters not in the course of a factory inspection?_____. If so, please explain_____.
5. Does your company manufacture or handle prescription drugs?_____.
6. During plant inspections, were any questions asked or requests made to examine facilities or records which you considered to be not within the scope of the various laws?_____. If so, explain.
7. If the answer to No. 6 was yes, how was the situation finally resolved?

8. Please indicate whether your company has adopted a policy of complete cooperation with the F.D.A. even though the request may be unauthorized, or whether you insist that the inspectors keep within the letter of the law.
9. Has any action been taken against your company by F.D.A. as a result of these inspections?_____. If so, explain.
10. Have your operating personnel been furnished with written instructions to govern their participation in the inspections?_____. If so, please attach a copy.
11. Please include any other comments or suggestions you feel would be helpful to other member companies.