CIRCULAR BULLETIN

DEPT. Production No. 121

To: All Locations

DATE October 12, 1967

SUBJECT: REGISTRATIONS AND INSPECTIONS BY FOOD AND DRUG ADMINISTRATION (FDA)

Quality Control Procedure - 13

1. The purpose of this Bulletin is to establish a procedure covering:
   a) Location drug registration under the Federal Food, Drug and Cosmetic Act and its 1965 Drug Abuse Control Amendments.

   b) Location inspection by authorized FDA personnel under the Drug, and Cosmetic Act.

   c) Location inspection by authorized FDA personnel under the Federal Hazardous Substances Act.

2. Each location executive is responsible to:
   a) Designate at least one responsible individual to acquaint himself with this procedure and other correspondence on this subject and participate in inspections or to act as the executive's alternate whenever necessary to do so. All inspections are to be scheduled to coincide with the presence of the location executive, his designated alternate, or both individuals.

   b) Cooperate with FDA authorized personnel in order to facilitate inspections and to avoid disruption of work schedules.

   c) Maintain applicable operations at locations in accordance with Good Manufacturing Practices.

3. Location drug registration is required annually if USP, NF or other drug products are made, blended, repackaged or relabeled or if items covered by the Drug Abuse Amendments are wholesaled, jobbed or distributed. Simply, drugs are products used as is or further processed for treatment of disease or which affect body functions in man or animal.

4. If you are aware that any of your products, other than USP or NF are [redacted] for drug purposes, advise this office at once.

5. Locations handling food grade chemicals (food additives) are not required to register but are subject to FDA inspection under the Food, Drug and Cosmetic Act.

6. The procedure for drug registration by the location executive or his designated alternate is:

SUGGESTED RETENTION

☐ Destroy After Noting ☐ Destroy After ☐ Return With Comments

☐ Destroy After Complying ☒ Retain ☐

ASI 00002334

Initial Registration

A. Contact Legal Department to obtain copies of FD 1597 Registration forms and instructions.
B. Complete form and return to FDA.
C. FDA will return validated copy of completed form.
D. Forward copies of validated form to: Legal Department and Director of Production, Chemical Control.

Annual Re-registration

A. FDA will forward annually form FD 1597 - for re-registration.
B. Complete form and return to FDA.
C. FDA will return a validated copy of completed form.
D. Forward copy of validated form to: Legal Department.
E. If form has not been received from FDA by December 15th of any year, contact Legal Department for instructions.

Special Note: Failure to register is a crime subjecting violator to all penalties of the Act, and renders all applicable products misbranded.

7. Registration is not required by the Hazardous Substances Act. The purpose of this act is to assure that all hazardous substances intended or suitable for household use have proper labeling. A hazardous substanc is a substance or mixture of substances which is toxic, corrosive, an irritant, a strong sensitizer, flammable, or which generates pressure through decomposition, heat or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

8. Under both the Food, Drug & Cosmetic Act and the Hazardous Substances Act, the FDA has been given the authority to inspect manufacturing and distribution facilities and equipment.

9. Inspections under the two laws are described in the following tables:

Item	Federal Food, Drug & Cosmetic Act	Federal Hazardous Substances Act
(1) Inspector must:	present appropriate credentials and a written notice of inspection to the location executive or to an authorized Company representative in charge of a facility.	Same

Item	Federal Food, Drug & Cosmetic Act	Federal Hazardous Substances Act
(2) Inspector authorized to:	Inspect such location at reasonable times, within reasonable limits and in a reasonable manner.	a) Inspect such location at reasonable times, within reasonable limits and in a reasonable manner. b) Obtain samples of such materials or packages thereof or of such labeling.
(3) Purpose of Inspection	Determine whether foods, drugs or cosmetics (a) which are misbranded or adulterated, or (b) which are prohibited have been or are being (a) manufactured (b) processed (c) packed (d) transported or (e) held in each location. Determine if drugs which are covered by the Drug Abuse Amendments are being: a) manufactured b) compounded c) processed, or d) distributed by or to unauthorized persons.	Determine whether the labels in use for the various finish d products meet the requirements of the act. Determine the composition of the various materials used in the manufacture of such hazardous substances.
(4) Scope of Inspection	Subject to inspection are all pertinent equipment, finished and unfinished materials, containers and labeling in the factory, warehouse, establishment or vehicle. Specifically, the inspection covers the following items bearing on violations of the Act: a) Records b) Files c) Complaints d) Papers e) Processes f) Controls g) Facilities	Same The inspection covers items bearing on the composition and labeling of hazardous substances.

Item	Federal Food, Drug & Cosmetic Act	Federal Hazardous Substances Act
(2) Inspector authorized to:	Inspect such location at reasonable times, within reasonable limits and in a reasonable manner.	a) Inspect such location at reasonable times, within reasonable limits and in a reasonable manner. b) Obtain samples of such materials or packages thereof or of such labeling.
(3) Purpose of Inspection	Determine whether foods, drugs or cosmetics (a) which are misbranded or adulterated, or (b) which are prohibited have been or are being (a) manufactured (b) processed (c) packed (d) transported or (e) held in each location. Determine if drugs which are covered by the Drug Abuse Amendments are being: a) manufactured b) compounded c) processed, or d) distributed by or to unauthorized persons.	Determine whether the labels in use for the various finished products meet the requirements of the act. Determine the composition of the various materials used in th manufacture of such hazardous substances.
(4) Scope of Inspection	Subject to inspection are all pertinent equipment, finished and unfinished materials, containers and labeling in the factory, warehouse, establishment or vehicle. Specifically, the inspection covers the following items bearing on violations of the Act: a) Records b) Files c) Complaints d) Papers e) Processes f) Controls g) Facilities	Same The inspection covers items bearing on the composition and labeling of hazardous substances.

Item	Federal Food, Drug & Cosmetic Act	Federal Hazardous Substances Act
(4) Continued	The inspection does not cover: a) Financial Data b) Sales data (other than shipment data) c) Pricing data d) Personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to regulation)	The inspection does not cover: a) Files or formulae b) Research data c) Complaints d) Personnel Records e) Patent Information f) Production Figures g) Sales figures h) Products which are not hazardous substances
(5) Frequency	Registered establishment must be inspected by FDA personnel at least once every two years and may be inspected more frequently. Nonregistered establishments have no prescribed frequency.	No prescribed frequency.

10. When definite requests are made by FDA personnel for information which is not required to be disclosed under the Acts, ask for a letter detailing the information desired and send it to the Legal Department for further handling. Other responsibilities of the location executive or designated alternate are:
    a) Cooperate with authorized FDA personnel.
    b) Always accompany FDA representative while on premises of plant facility.
    c) Obtain a receipt for each sample of materials taken by FDA.
    d) [redacted] results of all analyses of samples taken. [redacted] that the FDA furnish results of all analyses [redacted] of samples taken of food additives and hazardous sub-[redacted]
    e) [redacted] report on each FDA inspection or visit and [redacted] to Director of Chemical Control, to Legal Department, and to Packaging Coordinator, Allied Advertising.

11. All questions concerning this procedure, the Acts it concerns and our actions to ensure compliance with the Acts should be referred to the Legal Department and to the Manager of Quality Control.

C. M. Murphy
Manager of Quality Control

CMM:gsw
Carbon copies - see next page

cc: Vice President, Mfg., Mr. W. C. Ruch
Directors and Managers of Production
Directors and Managers of Sales
Director of Technical Service, Mr. J. F. Adams
General Managers
Manager of Warehouse Operations, Mr. M. B. Eisen
Legal Department, Associate Counsel, Mr. R. E. Mumford
Allied Advertising, Packaging Coordinator, Mr. E. J. Hogan
Production Supervisors
Jacksonville Works, Supt.-Southern Plant, Mr. H. J. Freeman
Menasha Works, Supt.-Northern Plants, Mr. C. E. Ploudre

N Koch