PROCEDURE BULLETIN — TEXAS CITY PLANT P-0907

INSPECTION OF MANUFACTURING FACILITIES BY
THE FOOD AND DRUG ADMINISTRATION

I. PURPOSE

The Food and Drug Administration (FDA) of the United States Department of Health, Education, and Welfare has, among its other duties, the responsibility for inspecting factories, warehouses, etc., where products covered by the Federal Food, Drug, and Cosmetic Act are produced and stored. The purpose of such inspections is to determine the establishment's compliance with the law and to gather evidence for use in enforcement proceedings if violations are found. The purpose of this Manual is to outline the Company's policy and procedures to be followed when a Food and Drug Administration Inspector asks to inspect facilities or products of Monsanto.

II. POLICY

The Company agrees with the spirit and intent of the Food and Drug Administration in desiring to insure that foods, drugs, and cosmetics are safe for use. It obeys the law and willingly cooperates with the FDA in the administration of the Food, Drug, and Cosmetic Act. Thus, it is the policy of the Company to disclose all information within the scope of the FDA's inspection authority and which is requested by an FDA Inspector.

It is further the policy of the Company to treat the Inspectors courteously and in a friendly manner. Nevertheless, with our competitive commercial position also in mind, it is the policy of the Company to decline politely but firmly to permit inspection of products or facilities not covered by the Act and to decline to provide any confidential process or commercial data (even on inspectable products) beyond the requirements of the Act, and to explain our grounds for doing so.

III. SCOPE

FDA inspectors are authorized to inspect facilities for products which are used in foods or may come into contact with foods. At Texas City, this inspection authority is limited to the process units, the warehouses or storage tanks and the shipping containers for polyethylene and lactic acid.

The Inspector will not be permitted to inspect facilities for any product other than those designated, nor will they be given any confidential process or cost information. Laboratory facilities are not inspectable.

IV. RESPONSIBILITIES

A. The Law Department shall be responsible for interpreting and ruling on legal matters where appropriate and shall assist in coordinating compliance with the Act.

B. The Divisional Representative shall be responsible for coordinating that Division's FDA activities. Each division may also designate an Alternate Representative to act in the unavoidable absence of the Division Representative.

The Division Representative will review with the Plant Representative any matters which the Inspector has not been able to resolve at the plant and which have been summarized in writing from the Plant Representative to the Division Representative. If such matters cannot be resolved adequately at this point, the Division Representative will provide appropriate technological and commercial viewpoints and background information to the Company Representative in his review with the FDA.

C. The Medical Department will advise Divisional Representatives on any medical or toxicological question arising in connection with the factory inspection.

D. The Washington Office will keep abreast of existing and new FDA regulations as they bear on factory inspection. It will advise the Law Department, Company and Medical Representatives as relevant matters arise.

E. An FDA Inspection Coordination Committee, consisting of a Law Department Representative, all Division Representatives, a Medical Department Representative, and a Washington Office Representative, shall meet annually or as required to review the conduct and results of inspections and to consider procedures, legislation, and other pertinent matters.

F. A Plant Representative shall be designated at each plant in the Company producing products subject to FDA inspection. Where a plant has activities of more than one business group, this designation will be the responsibility of the host business group. The Plant Representative shall be responsible for carrying out the procedure at his plant, including personal guidance of all FDA Inspectors while they are in the plant.

Several important qualifications are necessary for the Plant Representative: He must be an individual who can explain the Company's position in a courteous and friendly manner and indicate to the Inspector that Monsanto wishes to conform to the full letter and spirit of the law. Second, he must be able, firmly but courteously, to decline to disclose any information that is not authorized by this Manual. Third, he must have a broad knowledge of the products produced at his plant. In particular, he should have a detailed knowledge of inspectable products and know the relation of the products to the end-use applications, conditions of use, "downstream" fabrication or processing, ultimate distribution, etc., especially as they relate to food, drugs, and cosmetics. Finally, his duties should be such as to permit ready availability to an FDA Inspector should he call.

There shall be designated individuals to supplement the information of the Plant Representative - the Manufacturing Superintendent(s), the Chief Chemist, and the Plant Services Superintendent. If the designated Plant Representative is not able to answer a proper question, he will take the Inspector to the appropriate individual of the above group for the answer and will remain with them. The Plant Representative will guide the conversation so that the Inspector's questions are answered clearly and concisely.

To provide coverage for guest Business Groups in the plant, the appropriate Guest Superintendent will normally represent his group.

The plant will designate an Alternate Plant Representative to supervise plant inspections in the absence of the Plant Representative. His qualifications are the same as those of the Plant Representative. He will be selected from one of the individuals designated in the two previous paragraphs.

The Plant Representative has the prime responsibility of dealing with the FDA Inspector. Only in the case of his unavoidable absence can the FDA Inspector be hosted by the Alternate Plant Representative.

The Plant Representative shall accompany the Inspector at all times while he is in the plant.

Foremen, operators, laboratory analysts, etc., will be instructed not to volunteer information or to answer questions of the FDA Inspector. They will refer the Inspector to the Plant Representative for answer.

Each plant will be supplied by the Division Representative with a list of its products judged by the Company to be properly inspectable by the FDA. The Plant Representative will only permit inspection of those products on this list. Should the Inspector differ with the Plant Representative on the decision on any individual product, the Plant Representative will courteously explain the basis of the decision. Should the Inspector still not be satisfied, the Plant Representative will suggest that the Inspector submit his questions in writing for review by the Law Department

If requested by the FDA Inspector, the Plant Representative will enumerate orally the products of his plant which Monsanto considers inspectable.

However, this procedure in its entirety is confidential and is not to be shown to the Inspector; i.e., the procedure itself is not inspectable.

V. PROCEDURE

A. Arrival of Inspector

The Plant Receptionist and the Plant Guard shall have been informed of the identity of the Plant Representative and Alternate. Upon arrival of an FDA Inspector, the Receptionist shall immediately contact the Plant Representative announcing the Inspector. The law provides that the inspection may be carried out at any reasonable time. This is construed to mean any time during regular plant office hours (8:00 A.M. to 4:30 P.M., or whatever other hours are normal for the location, on Monday through Friday, except for official plant holidays).

Should the Inspector call at hours other than the above, the Plant Guard shall invite the Inspector to come back on the next regular work day. The Guard will promptly inform the Plant Representative at his home.

As soon as the Plant Representative learns of the presence of an FDA Inspector in the plant, he will immediately notify the Plant Manager.

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B. Plant Representative's Initial Contact

In the interest of good relations with the Inspector, the Plant Representative will make himself immediately available to the Inspector and proceed to the reception area to meet him. The FDA inspection will take precedence over any other demand on the Plant Representative's attention except serious emergencies. In no event shall the Inspector be kept waiting longer than 15-20 minutes.

C. Plant Manager's Reception of Inspector

The Plant Representative will escort the Inspector to the Plant Manager's office. The Plant Manager, as chief executive officer, shall be the first plant person to interview the Inspector. The FDA is interested in meeting the Plant Manager as the "Responsible Party" for conditions in his plant. In addition to welcoming the Inspector, the Plant Manager will inquire as to the purpose of the inspection (e.g., routine inspection or suspicion of violation in response to complaint). He will also advise the Inspector that the Plant is not engaged in the manufacture of prescription drugs and that the only drugs the company produces are bulk pharmaceuticals. The Plant Manager will confirm to the Inspector the authority of the Plant Representative in guiding him and assisting in the inspection. The Plant Representative will, of course, be present during this interview.

D. Inspection Notice

The Plant Manager or Plant Representative shall request credentials of the Inspector, make note of the Inspector's number and name, and require a properly executed Notice of Inspection (Form FD 482) addressed to the Plant Manager and signed by the Inspector. Under all circumstances these papers must be reviewed and accepted by the Plant Manager or Plant Representative before any inspection is begun.

E. Notification of Division Representative

As soon as possible, the Plant Representative shall notify the Division Representative by telephone or teletype of the arrival of the Inspector, together with any appropriate details.

F. Information Covered by the Act

The inspection authority of the FDA under the Act extends primarily to visual inspection of locations where food, drugs, and cosmetics are made or stored. Legally, Monsanto's obligation during such inspections (except for an inspection of a prescription drug plant) is limited to permitting entry and inspection "at reasonable times within reasonable limits and in a reasonable manner of any factory, warehouse, establishment, or vehicle and all pertinent equipment...' in which food, drugs, devices or cosmetics are manufactured, processed, packed, held or transported in, or for introduction into interstate commerce, as well as inspection of any'...finished and unfinished materials, containers, and labeling therein."

The FDA considers that food additives come within the definition of "food" in the Act since they are deemed to by "components of food". Consequently, plants where these products are manufactured or held are also subject to inspection by the FDA.

It should be noted that the FDA instructs its inspectors to ask permission, during an inspection, to see more information and material than the factory is legally required to show him. For example, the Inspectors are instructed to ask for such items as formulas, complaint files, and other records which the FDA has admitted are not subject to inspection under present law relating to general establishment inspections. However, if such documents and records are given to the Inspector voluntarily by the plant, they may be used by the FDA in proceedings against the Company for violation of the Act. It is important, therefore, that any inspection be restricted to only inspectable items and areas.

Following are categories of items which we are required to disclose during a general establishment inspection by the FDA.

1. Specifications

Only those specifications that are public knowledge shall be released to the Inspector. These are the specifications such as those published in Company Sales Brochures, Technical Data Sheets and Product Profile Sheets, or in any of the official compedia (i.e., the official United States Pharmacopoeia, or the Food Chemicals Codex). No other specifications will be given to the Inspector.

The Plant Representative should have on hand the specifications that can be disclosed for each inspectable product. However, the law does not require that the Inspector be permitted to examine analytical data on properties included in specifications, nor does it require disclosure of test methods relating to specifications. Only those test methods published in the official compendia may be given to the Inspector.

2. Samples

If the Inspector requests a sample of any finished or unfinished goods given on the plant list of FDA inspectables, it will be provided him.

In all cases, the Plant Representative will take a sample identical to the one provided to the Inspector and will label his sample in full detail. The representative will offer to furnish sample bottles, both for the Inspector and for the plant files, unless the Inspector prefers to use his own sample containers. The Inspector must furnish a Receipt for Sample (Form FD-484) fully describing each sample that he takes -- date, place, method of sampling, person sampling.

The Plant Representative will arrange for prompt and careful analysis of his own sample. The FDA is required to inform the Company of the results of the analysis of its sample. Upon receipt of this information, the Plant Representative will compare it with the results obtained by his own laboratory on his sample and submit the data as a supplement to his Inspection Report (Section V-J of this Manual). Resolutions of differences, if any, will be taken up with the Division Representative.

3. Visual Inspection of Plant Production Facilities

The Inspector is legally permitted to inspect visually all relevant areas of the manufacturing and warehousing facilities for inspectable products that are relevant to purposes of Act plus "all pertinent equipment, finished materials, containers, and labelling" pertaining to such inspectable products.

Note that the Inspector's responsibility is principally to inspect for possible product contamination with a manufacturing process, and is not to examine the technology of the process itself. Naturally, it is not proper to reveal confidential process information. It is in order, however, for him visually to inspect housekeeping, cleanliness, and sanitation as they may affect the end-product.

4. Warehouse and Shipment Records

(a) The permissible area for FDA inspection includes warehousing facilities within the plant area which are utilized for the storage or handling of inspectable products shipped or to be shipped in interstate commerce. The Inspector's attention will likely be directed particularly to housekeeping, cleanliness, orderliness or arrangement, and the storage of food, drugs, and cosmetics at a safe distance from toxic materials.

(b) It should be noted that the Inspector is entitled to have access to and to copy certain records kept by carriers transporting inspectable products in interstate commerce and warehouses and others receiving such products from interstate commerce, showing the following:

(1) The movement of such products in interstate commerce;

(2) The holding of such products during or after interstate movement;

(3) The quantity of such products shipped or held after shipment;

(4) Shipper's name; and

(5) Consignee's name.

Those parts of the company which may be subject to such inspections should permit the Inspector to look at and copy such records ONLY after obtaining from the Inspector a written statement describing the nature or kind of food, drug, device or cosmetic covered by his request for inspection. A

failure to obtain such a statement from the Inspector may mean that any evidence of violation of the Act contained in such records can be used in a criminal prosecution of the person from whom the records were obtained.

5. Package Labels

The Inspector shall be permitted to inspect labels for FDA-inspectable products and will be given samples of such labels on request.

6. General Technical Literature

Technical bulletins designed for customer use, trade literature, and reprints of papers that have appeared in the technical journals often answer many of the questions of the Inspector. These should be freely given to him. Additionally, the Inspector should be referred to appropriate literature published in the technical journals.

7. Information and Items Relative to Prescription Drugs

The FDA's inspection authority relating to establishments manufacturing, processing, packing or holding prescription drugs is far more comprehensive than that relating to other establishment inspections. It covers all things bearing upon any adulteration or misbranding of prescription drugs except:

(a) Financial data;
(b) Sales data other than shipment data;
(c) Pricing data;
(d) Personnel data other than that relating to qualifications of technical and professional personnel performing functions subject to the Act;
(e) Research data other than data otherwise subject to reporting to the FDA.

Prior to showing any such information to the Inspector, the Plant Representative must confirm with the appropriate Division Representative and the Law Department that the product at issue is in fact a prescription drug product under the Act.

8. Marginal Information Not Covered by the Act

In the normal course of events, the Plant Representative will politely decline to disclose information not specifically described in this Manual. However, should questions arise concerning the Inspector's authority to examine any such information, the Plant Representative will request the Inspector to put his request in writing for review by the Law Department.

G. Information Not Covered by General Establishment Inspection of the Act

Following are categories of items that the general establishment inspection provisions of the Act do not require us to disclose and that the Plant Representative will not reveal to the Inspector except as permitted in Section V, Part F.

1. Files, Books and Other Records

In the event of a general establishment inspection, the Act does not require the Company to provide access to any files, books, or other records.* For example, complaint files, personnel files, processing records, production rates, and manufacturing processes ordinarily will not be shown to the Inspector. In special cases, however, the Plant Representative may seek clearance from the Divisional Representative and the Law and Patent Departments to permit the Inspector to examine such documents.

2. Operating Data

The law does not require us to submit operating manuals, process descriptions, and similar records and procedures to the Inspector. Furthermore, we are not required to show operating log sheets (blank or filled out), strip charts, or other recorded data. Obviously the Inspector, during his visual inspection, will have an opportunity to look at guages, recorders, etc. This is proper. Thus, only operating data that he can directly observe is inspectable.

* But note exceptions in Section V, Part F, Subparts 4 (b), relating to certain warehouse and shipment records, and 7, relating to prescription drugs.

If the Inspector requests a description of any manufacturing or technical process, he should be referred to public technical literature containing general process descriptions.

3. Photographs and Sketches; Tape Recorders

The FDA instructs its Inspectors to bring a camera with them on their inspections and to take pictures which may be of use as evidence in proceedings for violations of the Act. They are also instructed not to ask management's permission to take photographs. The Inspector is to be treated like all outside personnel with respect to taking photographs and paragraph V.J of Plant Procedure P-0700 should be followed. Should the Inspector take a hidden camera into the plant on the inspection, the Plant Representative should ask the Inspector to turn over the camera to the plant during the remainder of the inspection and should also request copies of any pictures taken inside the plant.

The Inspector is not permitted to make detailed sketches of processes and equipment since this may reveal trade secrets and confidential process information, nor is he permitted to use tape recorders or similar devices during an inspection. Should an Inspector question such refusal, the Plant Representative should ask the Inspector to submit a written request, to be reviewed by the Law Department, for permission to use such a device.

4. Customer Lists and Shipping Data

The Plant Representative may disclose to the Inspector the names of only those customers who have granted permission to be identified as customers of Monsanto. Lacking specific information to that effect (which will be supplied to the plants by the Division Representative), the Plant Representative shall decline to identify our customers or give invoices of outgoing material. This is commercial information which some customers do not wish us to disclose. (But see Section V, Part F, 4 (b).)

5. Cost Data

Since cost data and volume data (dollars and pounds) are extremely confidential, they shall not be disclosed to the Inspector.

6. Specifications

The Plant Representative shall also decline to give specification tolerances regarding functional properties that could be unique to our product or unique to special applications. For drugs, only those limits given in the official United States Pharmacopoeia, National Formulary, or the Homeopathic Pharmacopoeia should be disclosed. Similarly, for food additives, only those limits given in the Food Chemicals Codex are subject to disclosure.

7. Non-Inspectable Areas

The Inspector shall not be taken to any part of the plant that does not involve products listed as inspectable on the plant product list. Multipurpose equipment used for inspectable products, but not currently in production of the inspectable product, is not inspectable.

It may be necessary for the Plant Representative to politely decline to give certain items of information or to show the Inspector certain parts of the plant. Should this be necessary, the Plant Representative shall explain the basis for his action in a casual and friendly manner, attempting to satisfy the Inspector that the information or areas in question are not relevant to the product under inspection or to the enforcement of the Act.

Should the Inspector be dissatisfied with the polite refusal to disclose information not covered by the Act, the Plant Representative should suggest that the Inspector submit a written request covering the information or areas at issue.

H. Safety

The Inspector will be required to follow all standard plant safety regulations during the course of his inspection.

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I. Completion of Inspection

At the completion of the factory inspection, the Plant Representative will take the Inspector back to the Plant Manager for a brief review of the inspection.

If the Inspector has any adverse comments regarding filth, improper sanitation, or other conditions or practices relating to a possible violation, he is required by the Act to submit them in writing (FD Form 483, LIST OF OBSERVATIONS, for food, cosmetics and devices, and FD Form 2275, DRUG INSPECTIONAL OBSERVATIONS, for drug products) to the responsible officer (the Plant Manager) before leaving the premises. However, if the Inspector does not submit such a written report, he should not be asked for it since the absence of a report indicates that the inspector has not found violations.

Should any subsequent report concerning the inspection be received from FDA, the Plant Representative or Plant Manager will immediately contact the Division Representative and the Law Department to develop an appropriate action plan.

J. Plant Representative's Inspection Report

Within three working days following an inspection, the Plant Representative shall submit copies of a complete written report to the Division Representative, the MICC Representative, the MICC Law Department, the Corporate Medical Department, the Plant Manager, and other appropriate members of plant management.

Should any situations or Inspector's comments warrant it, the Plant Representative shall telephone the Division Representative at the first opportunity on the day of the inspection.

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APPENDIX A
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PERSONS RESPONSIBLE FOR FDA CONTACTS

DIVISIONAL REPRESENTATIVES:

Plastics & Petrochemicals	L. P. Paradis
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PLANT REPRESENTATIVES:

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