

## Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



23 August 2013

## FDA MEMORANDUM CIRCULAR No. 2013-031

TO

: FDA Inspectors, Field Regulatory Operations Officers, Industry

Regulatory Affairs Officers And Company Representatives, and

**Other Concerned Parties** 

SUBJECT :

SPECIFIC POLICIES ON SCHEDULE OF INSPECTIONS, INCLUDING

POLICIES ON MEANS OF TRANSPORTATION AND MEALS

The Office of the Director General has recently received reports that runs counter to the current reforms being implemented by the Food and Drug Administration (FDA) among the officers and employees to ensure the highest standards of personal conduct and ethical standards in the delivery of service and discharge of duties without fear or favor. According to the report, some industry regulatory officers or company representatives have been placed in embarrassing and compromising situations when, allegedly, FDA inspectors request or demand that vehicles should be provided going to establishment or suggest that their transportation be paid. The reports received also include expectations from inspectors for meals to be provided or paid for by the companies.

In the past, similar misunderstanding has also reached the FDA management, but upon investigation the offer to bring FDA inspectors to the establishments were actually offered by the industry regulatory affairs officers or company representatives themselves, who are in a hurry to be inspected and receive the License to Operate (LTO) in time for the opening of their branches or comply with government bidding requirements, among other hosts of reason. Offer to partake meals is usually part of Filipino customs and traditions, which the inspectors consider and are sensitive to.

Reports of alleged unethical conduct, as well as dishonesty and corruption, on the part of the FDA inspector will not be tolerated by the FDA. This Memorandum Circular (MC) is being issued so that both parties will have a common understanding on the schedule of inspection and provision of transportation and meals during inspections, among other guidelines.

1. The FDA provides transportation allowance to all inspectors, or upon request, provide FDA vehicle to bring inspectors to the establishments.









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- 2. The FDA Inspectorate shall schedule all inspections of establishments on a "first come, first serve basis", and shall be transparent to the company applicants.
- 3. The FDA inspector shall be in the establishment on time. The establishment are enjoined to report tardiness and absence of the inspectors to FDA via <a href="mailto:report@fda.gov.ph">report@fda.gov.ph</a>.
- 4. Rescheduling of inspections shall be done by the company through a written request, stating the reason for the request for rescheduling. If the company report on the tardiness or absence of inspectors have been verified/validated, rescheduling of inspections shall be scheduled by the FDA Inspectorate at the earliest time possible.
- 5. Under no circumstances should the FDA Inspector accept offers from the company to provide transportation in order to conduct inspection. Companies are prohibited, if not requested to refrain, from making such offer either to prevent embarrassment and misunderstanding.
- 6. Forms of benefits, favor and gratuity, such as free meals and transportation or gifts, shall be politely declined by the inspectors. The FDA Inspectors shall not take offense of the rude offer, but explain the provisions of this MC and to act promptly and expeditiously at all times.
- 7. FDA inspectors shall be required to write or email their supervisors if there were technical and administrative incidence, experience or problem encountered with the regulatory affairs officers or company representatives in the discharge of their duties and responsibilities, including forms of harassment. In case of heavy traffic, the FDA inspector shall report the same to their supervisors.
- 8. If for any reason the FDA inspectors would not like to write or email their supervisors, the FDA inspectors may directly report to the FDA Director General or the FDA Deputy Director General for Administration and Finance.
- 9. Establishments may report all complaints via report@fda.gov.ph.

For more information or clarification, kindly email info@fda.gov.ph.

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Acting Director General



ISO 9001:2008 Management System

