Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration
PHILIPPINES

25 AUG 2020

FDA CIRCULAR
No. 2020-027

SUBJECT: **Conduct of Risk-Based Local Inspections in Light of the COVID-19 Pandemic**

I. BACKGROUND

In light of the declaration of the World Health Organization (WHO) of the Coronavirus Disease 2019 (COVID-19) outbreak as pandemic, and the declaration of a State of National Emergency over the entire country by virtue of Republic Act No. 11469 or the "Bayanihan to Heal as One Act", the Office of the President and/or Inter-Agency Task Force (IATF) for the Management of Emerging Infectious Diseases have imposed Community Quarantine upon various areas of the country, limiting the movement and transportation of persons in order to mitigate the spread of the disease.

The Food and Drug Administration, through FDA Circular No. 2020-006 and its amendments, issued a guidance to stakeholders regarding FDA's interim change in work arrangement and acceptance of applications in light of the Community Quarantine declaration due to the COVID-19. The Circular specified that FDA inspectors shall abide by the existing National and Local Government Units (LGUs) ordinances in relation to the Community Quarantine. FDA inspectors may inspect establishments within the vicinity of their municipality or city of residence including nearby and accessible areas to minimize movement of inspectors.

Thus, this Circular is hereby issued as an interim guideline on the risk-based conduct of local inspections of FDA-regulated establishments in light of the Community Quarantine declaration and the New Normal[1] due to COVID-19.

II. OBJECTIVES

This Circular aims to provide guidelines on the conduct of risk-based local inspections to carry out the FDA's regulatory mission while protecting the health, safety, and well-being of the inspectors and the public.

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[1] New Normal – refers to emerging behaviors, situations, and minimum public health standards that will be institutionalized in common or routine practices and remain even after the pandemic while the disease is not totally eradicated through means such as widespread immunization (IATF Omnibus Guidelines).

III. SCOPE

This Circular shall apply to all inspectors of the FDA Field Regulatory Operations Office (FROO) and all FDA-regulated establishments.

IV. GUIDELINES

A. Prioritization

Local inspections shall be conducted in order of the prioritization which shall be classified as follows:

1. For areas under Community Quarantine: Only high priority inspections[2] shall be scheduled; low priority inspections[3] shall be deferred, unless the safety of the inspector(s) can be assured, and the conduct of inspection can be justified. A Letter of Deferral explaining the reasons for postponement of the inspection shall be issued to applicable establishments.

2. For areas where community quarantine is lifted (under the New Normal): Both high priority and low priority inspections will be scheduled.

B. Risk-Assessment

Inspectors shall conduct risk-assessment to determine where and when it is safest to conduct inspection. A risk score will be assigned for each scheduled inspection based on the following criteria (Appendix A):

1. Community quarantine classification of the region/city/province/barangay where the establishment is located

Community Quarantine Level	Risk Score
ECQ/ Localized (barangay level) lockdown	5
MECQ	4
GCQ	3
MGCQ	2
New Normal	1

[2] High Priority Inspections – pre-license inspections for high priority applications as per FDA Circular No. 2020-006 and its subsequent amendments, products with import and export commitment, and referrals from FDA Centers/Offices

[3] Low Priority Inspections – other pre-license inspections, risk assessment/ routine inspections, and post-licensing inspections

2. Number of total active cases in the city/province where establishment is located, using data from the Department of Health (https://www.doh.gov.ph/covid19tracker) and/or the LGU

No. of total active cases	Risk Score
>3,000	5
2,000 – 3,000	4
1,000 – 1,999	3
100 - 999	2
<100	1

3. Expected duration of inspection

Expected duration	Risk Score
1 working day or more	5
Half-day	3
2 hours or less	1

The average risk score (mean) for the three criteria will be obtained. An mean risk score of 3 and above are considered **High Risk**, while a mean risk score below 3 are considered **Low Risk.**

C. Inspection Methods

The results of the risk assessment shall guide the selection of the appropriate inspection method. All inspections covered in this Circular shall be announced and coordinated with the establishment to be inspected.

The inspection can either be remote, on-site under agreed controlled conditions, or a combination of the two:

	Inspection Method
High Risk	Remote inspection OR Combination of remote + on-site inspection under agreed controlled conditions
Low Risk	Combination of remote + On-site inspection under agreed controlled conditions OR On-site inspection under agreed controlled conditions

1. Remote Inspection
   a. The general inspection process shall follow the existing process of the FDA, but remote inspection shall be used in lieu of on-site visit.
   b. Communication with the establishment shall be done online through e-mail and/or phone call.

c. Virtual meeting conferencing platforms (e.g., Google Meet) shall be used if possible. Virtual meetings shall be documented and/or recorded with permission from the establishment.
d. Documents for inspection shall be transmitted via a file-sharing platform (e.g., Google Drive) and shall be subject to desktop review.
e. Photos or videos shall be used to tour the facility and/or obtain proof of compliance.
f. Collection of samples, if necessary, shall be coordinated with the establishment.

2. On-site Inspection under Agreed Controlled Conditions
   a. The existing inspection process of the FDA shall be followed with additional measures taken to protect both parties from infection.
   b. Focal person(s) from the establishment who will interact with the inspector(s) shall be limited to 1-2.
   c. The duration of the inspection shall be minimized as much as possible without compromising the inspection agenda.
   d. FDA inspectors shall inspect establishments within the vicinity of their municipality or city of residence including nearby and accessible areas, as determined by the Management.

D. Inspection Report and Certificate of Compliance

1. In cases where remote inspection/ combination approach was done, the method of inspection shall be indicated in the inspection report.
2. For inspection with positive certification, the method of inspection shall be indicated in the Certificate of Compliance issued to the establishment and the following statement shall be included as a footnote:

   "This Certificate has been granted on the basis of a [remote inspection and/or combination of remote and on-site inspection] as per FDA Circular No. [FDA Circular Number]"
3. An on-site follow-up inspection shall be conducted when circumstances permit.
4. If the outcome of the remote inspection does not permit the granting of the Certificate, a clock-stop will be triggered until an on-site inspection is possible.

V. REPEALING CLAUSE/SEPARABILITY CLAUSE

Provisions of previous FDA circulars and memoranda that are inconsistent with this issuance are hereby withdrawn, repealed, and/or revoked accordingly. In case any part, term or provision of this Circular is declared contrary to law or unconstitutional, other provisions which are not affected remain in force and effect.

VI. EFFECTIVITY

This Circular is an interim guideline during the COVID-19 outbreak in the Philippines and shall be effective immediately.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

Appendix A
Risk Assessment Form

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

COVID-19 INSPECTION RISK ASSESSMENT FORM

RFO: _____

Name of Establishment:	
Business/ Office Address:	
Warehouse Address:	
Type of Establishment:	
LTO Number:	
Date/s of Inspection:	
Purpose of Inspection:	

Risk Assessment:

Criteria	Risk Score
Community Quarantine Level *ECQ/ Localized (barangay-level) lockdown – 5 | MECQ – 4 | GCQ – 3 | MGCQ – 2 | CQ lifted/ New Normal - 1*	
No. of Total Active Cases *More than 3,000 – 5 | 2,000 to 3000 – 4 | 1,000 to 1,999 – 3 |100 to 999 – 2 | Less than 100 – 1*	
Expected Duration of Inspection *1 working day or more – 5 | Half-day – 3 | 2 hours or less – 1*	

Mean Risk Score: _____

Inspection Method to be Used: ☐ Remote Inspection | ☐ On-site Inspection | ☐ Combination

Accomplished By:	
_____ (Print Name & Signature) Designation	_____ (Print Name & Signature) Designation
Approved By:	
_____ (Print Name & Signature) [Supervisor]	