



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



01 September 2014

**FDA CIRCULAR**  
No. 2014-020

**SUBJECT: Submission of Compliances to Notice of Deficiencies (NODs) Relative to Registration Applications and Corrective Action/ Preventive Action (CAPA) Plan based on Inspection Findings.**

As part of the Food and Drug Administration's regulatory reforms to help industry stakeholders comply with the requirements in the licensing of establishments and registration of products, the Public Assistance, Information and Receiving (PAIR) Unit will now accommodate **daily and over the counter submission** of compliances to the Notice of Deficiencies (NODs) issued by the Center for Drug Regulation and Research (CDRR) as well as submitting Corrective Action/Preventive Action (CAPA) Plan for licensing applications for drug establishments. **The need to send an e-mail request following the PAIR procedure to secure an appointment schedule will be waived provided the following conditions are met:**

1. All documentary requirements should be scanned as PDF file and saved in a USB device. For compliances to NODs issued by the CDRR, **all documents initially submitted for an application whether initial or renewal**, should also be scanned as PDF file and included in the electronic submission aside from the additional (compliance) documents required to be submitted.
2. The Integrated Application Form should be properly filled-up with all the required information including the initial/original Routing Slip Number (RSN) or the 14-digit Document Tracking Number (DTN). The electronic copy of the Integrated Application Form as excel file should also be included in the USB device.

3. Printed copies of the Integrated Application Form and clear photocopies of the issued NODs or Inspection Report should be submitted together with the USB during the submission of the compliance/CAPA Plan. This facilitates the processing of the request. Hard copies of the Integrated Application Form and the issued NODs/Inspection Report should be placed in an expandable plastic envelope properly labelled .
4. Additional payment, whenever applicable, as reflected in the issued NODs/Inspection Report should be made prior to submission of the compliance documents/CAPA Plan to the PAIR receiving staff. The applicant company is responsible in accomplishing the Assessment Slip which should be presented to the FDA Cashier or any Landbank office for payment purposes.
5. Compliance to NODs and inspection findings including the CAPA Plan should be submitted within the prescribed period and will be endorsed accordingly to the appropriate Offices.

This issuance takes effect immediately.



**KENNETH Y. HARTIGAN-GO, MD**  
Acting Director General