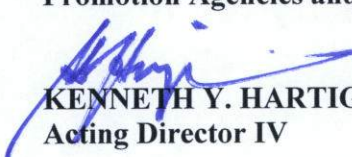


05 July 2013

FDA MEMORANDUM CIRCULAR

No: 2013-028

TO : All Health Products Establishments, Advertising/
Promotion Agencies and other Parties Concerned

FROM : 
KENNETH Y. HARTIGAN-GO, MD
Acting Director IV

SUBJECT : GENERAL GUIDELINES ON THE PROMO
PERMIT APPLICATIONS AND FOR OTHER
PURPOSES

In the interest of service, all concerned parties are hereby enjoined to strictly comply with the subject required timeline as follows:

Activity	Required Timeline
Filing of Application for Sales Promotion Permit	<p>At least thirty (30) days before the actual commencement of the sales promotion <i>(per Article 116 of R.A. 7394 or The Consumer Act of the Philippines)</i></p> <p>Note: The above provision shall be strictly observed starting 05 August 2013.</p> <p>Schedule of Filing; Monday: Food Tuesday: Drug Thursday: Cosmetics 8:00-3:00 PM</p> <p>To be received at the Main Building lobby except for Medical Devices</p>

Processing / Follow-ups	<p>Processing period: Within ten (10) working days upon receipt</p> <p>Follow-up : After ten (10) working days upon receipt</p> <p><i>Release of permits shall be at the respective Centers (except for Medical Devices)</i></p>
Submission of Notice or Invitation for Promo Supervision/Attestation of an Authorized DOH-FDA representative	Seven (7) working days before the actual activity

Thus:

- Application with combined products of different categories will be filed with the designated Centers specified below:

Products Involved	Concerned Center
Drugs, Food, Cosmetics, Device, HHS <i>(or Drug with any product categories)</i>	Center for Drug Regulation and Research (CDRR)
Food, Cosmetics, Device, HHS <i>(or Device with any product categories excluding Drug)</i>	Center for Device Regulation, Radiation Health and Research (CDRRHR)
Food, Cosmetics, HHS	Center for Food Regulation and Research (CFRR)
<i>Cosmetics and HHS</i>	Center for Cosmetic Regulation and Research

- Application for Sales Promotion Permit which falls short of the required timeline for filing **shall no longer be accepted** unless the applicant signifies his intention to comply.

Note: All concerned are reminded that application for Sales Promotion Permit should be accompanied by a duly accomplished Information Sheet which can be downloaded from the FDA website (www.fda.gov.ph).

- The applicant should indicate the O.R number in the assessment slip after payment.

- No follow-up shall be entertained within the processing time. All application shall be processed on a "First In, First Out" policy. Processing time **is within ten (10) working days** after submission, unless the same requires longer period depending on the completeness and/or substance of the accompanying documents. No request to expedite processing shall be entertained.
- Invitation or notice for FDA supervision/attestation of an approved sales promotion activity made or submitted less than seven (7) days before such event, shall automatically be considered for re-scheduling the week after the notice has been made; no short notices shall be entertained.
- For activities requiring the presence of an authorized DOH-FDA representative on a weekly, bi-weekly and monthly basis, a single invitation or notice will suffice, provided that:
 - in case of variation, the specific time and venue shall also be provided at least one (1) week before each activity and;
 - any changes shall be accordingly coordinated with this Office a day before the previously scheduled activity.
- For activities such as printing, seeding and/or drawing of winners be held outside the country, notification to the said event shall be **at least** thirty (30) calendar days to give the DOH-FDA representative ample time to prepare the necessary travel documents.

Note: For queries, follow-ups and notices for promo supervision, please contact the following telephone numbers:

809-55-96	-	CDRR
857-19-91 / 857-19-92	-	CFRR
857-19-40	-	CCRR
711-68-24	-	CDRRHR

This Memorandum shall take effect immediately upon approval and/or after its posting in the FDA website.