

CENTER FOR DEVICE REGULATION, RADIATION HEALTH AND RESEARCH

**CHECKLIST OF REQUIREMENTS FOR
SALES PROMO PERMIT APPLICATION**

INITIAL

1. Accomplished Integrated Application Form
2. Letter of Intent for application of Sales Promo Permit
3. List of Participating Products in Excel format (Sheet 3 of Info Sheet)
4. Copy of the valid Certificate of Product Registration/ Notification/ Exemption
5. Information Sheet and Mechanics of the Sales Promotion
6. Layout of Promo materials (if applicable)
7. Proof of payment
8. Self-Assessment Form for Sales Promo Permit

AMENDMENT

1. Accomplished Integrated Application Form
2. Letter of Intent specifying the type of amendment
3. Copy of previously issued valid promo permit
4. Supporting documents for the requested amendment
5. Proof of payment
6. Self-Assessment Form for Sales Promo Permit

Note:

- Applicant company to coordinate with the Central Releasing Unit for the procedure of releasing of promo permit via Courier Service (as per FDA Circular No. 2014-012, Requiring Proof of Courier Service Payment for Promotouon Advertisment Permit)