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| **DEFICIENCY:** | **BASIS:** |
| Non-submission of complete/clear/readable (if applicable, with corresponding English translation of all information in foreign language(s)) loose label/artwork/picture of the product for proper evaluation and to determine compliance to the regulations of FDA Philippines (AO 2014-0030). | The submitted label must be COMPLETE/CLEAR/READABLE, ifapplicable, with corresponding English translation of all information written in foreign language(s) and compliant to Administrative Order2014-0030/with additional labelling guidelines (e.g. products covered by CODEX). |
| Inconsistent declaration of supplier/manufacturer/country of origin on thelabel/e-Registration data entry/other submitteddocuments (e.g. ProformaInvoice/HACCP/CFS/GMP/etc) | The declaration of establishments/companyinformation/country of origin must be consistent with the declaration in the e-Registration data entry/on the label/on other submitted documents. |
| No valid LTO or Non-renewal of expired LTO uponapplication of CPR. | The applicant company must have a valid LTO upon application of CPR. |
| Non-inclusion of the product line being applied in the FDA approved list of products produced by the manufacturer. | The product being registered must be included in the FDA approved list (LTO) of products produced by the manufacturer. |
| Inconsistent declaration of the applicant company’s activity and LTO number. | The applicant company must declare the correct LTO number consistent with their activity in relation to the product being registered. (e.g. if the product is imported, the applicant company must have an LTO as Importer, and thecorresponding LTO No. of such must be declared in the e-Registration data entry. |
| Use of food additives which are not included in Updated List of Food Additives. | The food additive(s) used in the product being registeredmust be listed in AO 88-A s. 1984/BC 2006-016/CodexGeneral Standards for Food Additives |
| Use of drug ingredient (e.g. MONACOLIN K from Red yeast rice extract, Sennosides or Sennaglycoside from Senna leaves) on the product. | Republic Act 9711 |

**COMMON CAUSES OF DENIAL/DISAPPROVAL IN E-REGISTRATION**

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| The salt used is not iodized. | If the product contains salt and is locally manufactured, for local distribution, it must comply to RA 8172.\*Upon application of CPR, submit COA to determinecompliance to RA 8172. |
| Non-declaration on the label and in the data entry of the components of a multicomponent ingredient. | The complete list of ingredients must be declared in accordance to AO 2014-0030 (on the label) and FDA Circular 2016-014 (in the e-Registration data entry). |
| Non-submission of Certificate of Analysis signed/verified by competent technical staff to determine compliance with mandatory fortification of flour/cooking oil/sugar/rice. | If the product is covered by RA 8976, certificate of analysis signed/verified by competent technical staff must be submitted todetermine compliance of the product being registered to RA 8976. For reiteration, the result(s) reflected on the submittedCOA must show conformance to the acceptable level(s) as indicated on RA 8976. |
| Non-submission of safety data (e.g. Acute Toxicity Test or LD-50 Test) of the finished product (if applicable)Non-submission of shelf life study/ stability data containing relevant information on the critical parameters of the finished product, periodconducted, conclusion, and signed/verified by competent technical staff to support shelf life declaration.Non-submission of Certificate of Analysis on thephysical/chemical/microbiological analysis signed/verified by competent technical staff. | For Food Supplement, submit the above-mentioned additional documents. |
| For products covered by FDA Circular 2013-010:Non-submission of Certificate of Analysis for microbiological parameters signed/verified by competent technical staff to determine compliance with FDA regulations. | Submit Certificate of Analysis reflecting actual test results (of the concerned parameter(s)), signed/verified by a competent technical staff, to determine compliance to FDA Circular 2013-010 |
| Non-submission of data capture documents, forAmendment/Reapplication/Renewal Data Capture applications ONLY. |  |
| Filing of dual/multiple applications for the same product without cancelling the first application. |  |
| Non-submission of Certificate of Analysis signed/verified by a competent technical staff, reflecting specific/required parameters, for products with standards of identity/covered withspecific Codex Standards/covered with specificissuance/regulations. | Submit Certificate of Analysis reflecting actual test results (of the concerned parameter(s)), signed/verified by a competent technical staff, to determine compliance to thespecific technical regulation/issuance. |
| Submission of UNCLEAR/NOT READABLE files anddocuments | All documents attached in the e-Registration System must be CLEAR and READABLE for proper evaluation. |