

AUTOMATIC REVALIDATION OF LICENSE TO OPERATE (LTO)

FDA CIRCULAR NO. 2010-006, March 09, 2010

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In the exigency of service and to expedite the renewal of License to Operate of establishments covered in this Circular, please be informed that this Office shall implement an Automatic Revalidation of those licenses expiring only within the year 2010.

Application for Automatic Renewal shall be accepted not earlier than three (3) months before the date of validity as reflected on the License to Operate (LTO). A renewed LTO shall be issued provided that they should have met the following criteria:

1. Be in operation for a minimum of 1 year
2. Have no violative products relating to food safety
3. Have latest issuance of License to Operate not earlier than 2008
4. Have valid Contract Agreements of the following as required:
 - 4.1 Manufacturing Agreements with toll manufacturer
 - 4.2 Contract of Lease for plant site/office site
 - 4.3 Warehouse (if located separately)
5. Must have been inspected in 2009, have no previous major or critical deficiencies noted for the past year
6. Have existing Quality Manual and/or GMP Manual and/or Food Safety and/or HACCP Manual
7. Have valid Certificates of Product Registration, if applicable
8. Must have no changes in its updated Site Information (SIF), if applicable

All qualified establishments are hereby advised to submit the following documents to Regulation Division II, this Office.

1. Letter of intent and photocopy of Official Receipt for renewal payment.
2. An official declaration attesting that the company has no changes in its manufacturing operations from previous inspections.

For your information and guidance.

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Acting Director IV

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