

**[ FDA CIRCULAR NO. 2011-004, November 02, 2011 ]**

**COMPUTATION OF SURCHARGE OR PENALTY IMPOSABLE IN  
CASE OF SUBMISSION OF RENEWAL OF APPLICATIONS  
COVERING LICENSE OF ESTABLISHMENTS AND REGISTRATION  
OF HEALTH PRODUCTS AFTER THEIR DATE OF EXPIRATION  
PURSUANT TO SECTION 3, PARAGRAPHS (A)(2) AND (B)(2) OF  
ARTICLE I OF BOOK II OF THE RA 9711 IMPLEMENTING RULES  
AND REGULATIONS, AND OTHER PURPOSES**

**I. RATIONALE**

Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the IRR on Licensing of Establishments and Registration of Health Products, provides that:

An application for renewal of an LTO or a registration received after its date of expiration shall be subject to a surcharge or penalty equivalent to twice the renewal licensing or registration fee and an additional 10% per month or a fraction thereof of continuing non-submission of such application up to a maximum of one hundred twenty (120) days. Any application for renewal of license or registration filed thereafter shall be considered expired and the application shall be subject to a fee equivalent to the total surcharge or penalty plus the initial filing fee and the application shall undergo the initial filing and evaluation procedure.

For applications for renewal filed within one hundred twenty (120) days from its original expiry, the License to Operate (LTO) or Certificate of Product Registration (CPR) shall be considered valid and existing until a decision or resolution by the FDA is rendered on the application for renewal. (Modification inserted)

Thus, consistent with the expressed objective of the FDA Act of 2009 to provide coherence in the FDA's regulatory system for establishments and products under its jurisdiction including implementation of its Implementing Rules and Regulations, the following guidelines is hereby issued relative to the employment of the surcharge or penalty for applications for renewal of licenses to operate of establishments or certificates of registration of health products applied and received after the date of their expiration.

**II. Guidelines**

Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II on Licensing of Establishments and Registration of Health Products of the IRR of RA No.

9711, the surcharge or penalty, which shall be imposed only for applications for renewal of licenses to operate or certificates of product registration received after the date of their expiration, shall be assessed and imposed following the formulas below. This rule applies even in succeeding renewal applications.

**A. Surcharge/Penalty = 2 x (renewal licensing or registration fee) + 10% (renewal licensing or registration fee)**

Where:

- a. The *renewal* licensing or registration fee shall be based on the fee charged at the first instance of renewal;
- b. The percentage (%) shall accordingly increase by 10% for every month until a maximum of four (4) months or one-hundred twenty (120) days;
- c. Every fraction (first day and so forth) of a month is considered one whole month for the imposition of the applicable percentage (%);
- d. The LTO or CPR shall be considered valid and existing until a decision or resolution by the FDA is rendered on the application for renewal.

Example :

**1. License to Operate:**

- If the renewal of application is submitted on the first month:

$$\begin{aligned}\text{Surcharge/penalty} &= 2 \times \text{Php}2,000.00 + \mathbf{10\%} (\text{Php}2,000.00) \\ &= \text{Php}4,000.00 + \text{Php}200.00 \\ \text{Surcharge/Penalty} &= \mathbf{\text{Php}4,200.00}\end{aligned}$$

- If the renewal application is submitted on the first day (and so forth) of the second month:

$$\begin{aligned}\text{Surcharge/penalty} &= 2 \times \text{Php}2,000.00 + \mathbf{20\%} (\text{Php}2,000.00) \\ &= \text{Php}4,000.00 + \text{Php}400.00 \\ \text{Surcharge/Penalty} &= \mathbf{\text{Php}4,400.00}\end{aligned}$$

- The percentage shall increase accordingly until the fourth (4<sup>th</sup>) month or one-hundred twenty (120) days. Any renewal applications filed after the 4<sup>th</sup> month (120<sup>th</sup> day) shall be treated as an initial application and shall follow the guidelines in Item B below.

**2. Certificate of Product Registration:**