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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...

FDA CIRCULAR NO. 2011-004, November 02, 2011

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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:

- The renewal licensing or registration fee shall be based on the fee charged at the first instance of renewal;

- The percentage (%) shall accordingly increase by 10% for every month until a maximum of four (4) months or one-hundred twenty (120) days;

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- Every fraction (first day and so forth) of a month is considered one whole month for the imposition of the applicable percentage (%);

- 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:

Surcharge/penalty = 2 x Php2,000.00 + 10% (Php2,000.00)

= Php4,000.00 + Php200.00

Surcharge/Penalty = Php4,200.00

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

Surcharge/penalty = 2 x Php2,000.00 + 20% (Php2,000.00)

= Php4,000.00 + Php400.00

Surcharge/Penalty = Php4,400.00

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

2. Certificate of Product Registration:

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If the renewal application is submitted on the first month:

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Using as sample the existing chargeable renewal fee for Food Supplement amounting to Php5,000.00 (AO50 s. 2000)

Surcharge/Penalty = 2 x Php5,000.00 + 10% (Php5,000.00)

= Php10,000.00 + Php500.00

Surcharge/Penalty = Php10,500.00

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

Surcharge/Penalty = 2 x Php5,000.00 + 20% (Php5,000.00)

= Php10,000.00 + Php1,000.00

Surcharge/Penalty = Php11,000.00

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

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Note that the chargeable renewal fees for the first instance of renewal period of five (5) years under Administrative Order No. 50, s. 2000 varies per product line and category.

B. Renewal Applications Received AFTER the 120[th] day from the Expiry Date of License or Registration

(a) Fee = Initial Filing Fee + Total Surcharge/{Penalty

Where:

Total Surcharge/Penalty = 2 x (renewal licensing or registration fee) + 40% (renewal licensing or registration fee)

In addition:

(b)

The previous registration is considered expired and will turn initial. However, the health products manufactured, imported or distributed within the surcharge period (120 days) is deemed valid;

(c)

The application, having turned as new, shall undergo the initial filing and evaluation process, hence, automatically no new transaction/activity is allowed until application is approved. In the case of LTO, all the existing CPRs covered by such license shall be deemed not valid until the license is approved.

Example:

1. License to Operate:

- Using as sample the existing chargeable initial fee for Food Distributor amount- ing to Php4,000.00 and renewal fee of Php8,000.00 (AO50 s. 2000)

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Fee = Php4,000.00 + Total Surcharge/Penalty

Total Surcharge/Penalty = 2 x Php8,000.00 + 40% (Php8,000.00)

= Php16,000.00 + Php3,200.00

= Php19,200.00

Fee = Php4,000.00 + Php19,200.00

Fee = Php23,200.00

2. Certificate of Product Registration:

- Using as sample the existing chargeable initial fee for Food Supplement amounting to Php1,000.00 and renewal fee of Php5,000.00 (AO50 s. 2000)

Fee = Php1,000.00 + Total Surcharge/Penalty

Total Surcharge/Penalty = 2 x Php5,000.00 + 40% (Php5,000.00)

= Php10,000.00 + Php2,000.00

= Php12,000.00

Fee = Php1,000.00 + Php12,000.00

Fee = Php13,000.00

C. Automatic Renewal

There shall be no automatic renewal of an LTO or CPR when the application is filed after the expiration date of the license or registration. In which case, the application shall be treated as ordinary renewal application and the appropriate rules above shall apply.

D. Legal Research Fund (LRF)

Notwithstanding the application of surcharge or penalty, the 1% legal research fund (but in no case be less Php10.00) shall be applied based on the applicable renewal fee alone.

LRF = 1% (Renewal Fee)

But in no case shall the LRF be lower than Ten Pesos (Php10.00).

III. Effectivity

The application of the above computation shall be strictly implemented on November 15, 2011.

Adopted: 02 November 2011

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