ARTA
ANTI-RED TAPE AUTHORITY
OFFICE OF THE PRESIDENT

POLICY RECOMMENDATIONS

RECOMMENDATIONS

Under Section 7, Rule III of Joint Memorandum Circular No. 2019-001 otherwise known as Implementing Rules and Regulations of RA 11032 or the "Ease of Doing Business and Efficient Government Service Delivery Act of 2018", the Anti-Red Tape Authority ("Authority'), motu propio or upon complaint that a regulation is outdated, redundant, or adds undue regulatory burden to the transacting public, may exercise its power of review in accordance with the Act and recommend the repeal of the reviewed law, executive issuance and/or local ordinance, if warranted.

Likewise, under Section 4, Rule VIII of the IRR, the Authority has the power to issue a declaration of completeness and order the concerned office or agency to issue the approval, extension, and/or renewal of the license, clearance, permit, certification, or authorization which is deemed automatically approved as provided by Section 10 of the Act.

By virtue of the powers granted to this office, this Authority hereby issues herein policy recommendations to the Food and Drug Administration (FDA) pursuant to its policy of eliminating red tape and by virtue of its mandate under **Section 17 of R.A. 11032**.

A. ISSUANCE OF ORDER OF AUTOMATIC RENEWAL

During the various meetings conducted with the Food and Drug Administration (FDA), it was manifested and admitted that by representative of various centers of FDA that many of the applications for the renewal of licenses or permits are purely ministerial.

However, FDA further represented that the volume of the applications received by its office and the alleged lack of manpower resulted in the backlog complained of against the administration. Many of the pending applications refer to automatic renewal of existing Certificate of Product Registration and License to Operate.

Under Sections 3 (A) (2) and 3 (B) (2) of Book II, Article I of the Implementing Rules and Regulations of R.A. 9711 or the *Food and Drug Administration (FDA) Act of 2009* the automatic approval of applications for License to Operate and Authorization/Certificate of Product Registration is mandatory provided it complied with the three (3) essential documents, to wit:

BOOK II

ARTICLE I
Licensing of Establishments and Registration of Health Products

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Sec. 3. Approval of License of Establishments and Registration of Health Products.

A. ***License to Operate.***

xxx xxx xxx

2. Renewal of License. No application for renewal shall be accepted unless the prescribed renewal fee is paid.

There shall be automatic renewal of the LTO when the following conditions are satisfied:

i. *The application is filed before the expiration date of the license;*
ii. *The prescribed renewal fee is paid upon filing of the application; and*

iii. *A sworn statement indicating no change or variation whatsoever in the establishment is attached to the application.*

xxx xxx xxx

For applications for renewal filed within one hundred twenty (120) days from its original expiry, the LTO shall be considered valid and existing until a decision or resolution by the FDA is rendered on the application for renewal.

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B. ***Authorization/Certificate of Product Registration.***

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(2) Renewal of Registration. No application for renewal shall be accepted unless the prescribed renewal fee is paid.

There shall be automatic renewal of the CPR when the following conditions are satisfied:

i. *The application is filed before the expiration date of the registration;*
ii. *The prescribed renewal fee is paid upon filing of the application; and*
iii. *A sworn statement indicating no change or variation whatsoever in the product is attached to the application.*

xxx xxx xxx

For applications for renewal filed from within one hundred twenty (120) days from its original expiry the CPR shall be considered valid and existing until a decision or resolution by the FDA is rendered on the application for renewal.

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The use of the word "shall" in its own implementing rules direct its mandatory implementation. For this reason, the Authority hereby exercises its power under Section 4, Rule VIII of the IRR to issue a declaration of completeness and order FDA to issue the automatic approval of all pending automatic renewal applications for License to Operate and Certificate of Product Registration which have complied with the three (3) documents mentioned in the IRR of FDA. . The Authority finds no compelling reason why the aforesaid applications should remain pending considering all the foregoing provisions with regard to their processing have been complied with.

Furthermore, the Authority recommends that the FDA strengthen its Post Audit Compliance against the grantees of the licenses and permits to monitor and ensure their truthful representation and statements made in their application and sworn statement/undertaking for renewal of license and permit. For erring licensees and permittees who made false entries and misrepresentations in their application and sworn statement for automatic renewal, it is recommended that the severe penalty of revocation and cancellation of an existing license or certificate be imposed by the FDA by virtue its power under Section 4, Article I, Book II of the IRR of RA 9711.This is without prejudice to the filing of criminal case including a perjury case against the licensee and permittee or any of its duly authorized representative who made the misrepresentation or false entry in the Sworn Statement / Undertaking for automatic renewal of its license or certificate.

B. CONDUCT OF FURTHER CONSULTATIONS WITH ITS STAKEHOLDERS IN RELATION TO A.O. NO. 19-2019

Another concern raised by the complainants against the FDA is the lack of consultations with the stakeholders in coming up with the definition or classification of Household and Urban Hazardous Substances (HUHS) under Administrative Order No. 19-2019. Notably, this order effectively reinstates the regulation of HUHS, which was already deregulated since 2013. An argument raised by FDA's stakeholders is that through this new order, an additional requirement is being imposed upon them resulting in an additional regulatory requirement.

The Authority recognizes the power of the Department of Health to issue administrative orders to ensure the health and safety of the public, the soundness of which is beyond the former's jurisdiction. Nevertheless, it is strongly recommended to the FDA, the agency concerned in drafting of the corresponding circular implementing such order, to conduct further consultations with the affected stakeholders in determining the products to be considered HUHS.

C. RE-FOCUSING OF STAFFING ASSIGNMENT

Anent the challenges of FDA insofar as manpower or staffing is concerned, the Authority takes notice of the fact that some of the agency's pharmacists are assigned to tasks that are merely ministerial. As such, the Authority strongly recommends that FDA review and re-focus its staffing assignment whereby its pharmacists will be designated to functions or positions requiring their technical knowledge and skill. The positions that will require ministerial duties should be left to non-pharmacist employees, which need not be in *plantilla* positions.

D. RECOGNITION OF ACCREDITATION OF FDA'S LOCAL COUNTERPART

The Authority also notes that a Certificate of Good Manufacturing Practice (CGMP) require plant inspections locally and abroad. For a foreign CGMP, each importer or distributor here in the Philippines should cause for the inspection of the manufacturer's plant abroad for every product applied for. This process inevitably results in prolonged processing time for an application since such inspection has to be scheduled and shall greatly depend on the availability of inspectors.

In order to expedite such process and save inspection costs from the applicant which expense will be passed on to the public, the Authority recommends that the inspection and subsequent accreditation of a plant with the regulatory agency concerned, or FDA's foreign counterpart, should be sufficient. The Authority seeks to eliminate redundancy in the process of securing accreditation wherein FDA inspects a plant which has already been inspected and accredited by the food and drug authority of a foreign country.

E. REORGANIZATION OF PROCESS; EVALUATION PRIOR TO PAYMENT OF FEES

It is likewise important to take note of the forfeiture of the payments made by applicants in case of disapproval of applications. As it stands, FDA's process requires the payment of fees prior to the evaluation of applications and the subsequent consequent inspection. As a result, the applicants are made vulnerable to loss of funds since disapproved applications entails forfeiture of the payment made.

Thus, the Authority strongly suggests that the payment of fees should be made only after the evaluation of each application.

Corollary to such recommendation is the evaluation of applications immediately upon the submission of all the required documents. The evaluators should be transferred to the frontline service, making them visible to the applicants. This necessarily avoids the old practice in most government agencies where evaluators are at the back-office, which becomes an avenue or opportunity for corruption. This will display transparency and will inevitably expedite the

process since applicants are immediately informed if their respective applications are in order.

Makati City, 09 September 2019.

Recommended by:

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