MARKETING AUTHORIZATION OF VETERINARY PRODUCTS IN THAILAND

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REVIEW ARTICLE

Gupta Rajkumar*

Managing Director, Perfect Pharmaceutical Consultants Pvt. Limited, Pune, India

Corresponding Author's E-mail: guptarmg1952@gmail.com

ABSTRACT

The registration of veterinary drugs in Thailand is much easier than human products. The major requirement is samples and associated technical documents. The documents are checked by FDA under Drug Act BE 2510 (1967). If they are properly provided, the samples are released to Department of Medical Sciences for verifying the quality. Once the samples pass the required tests, the registration no. is allotted and a letter confirming Marketing authorization is issued. The normal time line for registration is about 18 months. The registration fees per product is 250 US dollar.

Keywords: FDA, Drug Act, marketing authorization, Veterinary products.

INTRODUCTION

The veterinary products are in good demand in many ASEAN countries. In general, regulations for the same are less stringent as compared with human products.

In Thailand the marketing authorization for human/ veterinary drugs is controlled under Drug Act BE 2510 (1967) and amendments .The Drug Board meets monthly and may give recommendations or opinions on authorization /registration/deregistration/suspension of the drug products for human/ veterinary use.

The Veterinary Drugs are controlled by Veterinary and Pharmaceutical chemicals Section. (1, 2)

The Marketing Authorization Process:

Drug Act BE 2510 (1967) does not require typical ACTD for registration of veterinary products. The requirements are quite simple and easy to comply (3)

1. Initially, one has to submit following documents through local agent.

Product Labeling or Packaging

(every packaging of products)

Product Leaflet or product information

(every package must have leaflet)

2. If these documents are found compliant, permission to submit a dossier and permission for import of samples is granted. In no case, the samples shall be used for purpose other than registration.

3. The dossier shall contain the following documents:

Thailand FDA is quite stringent about FSC (Free sale certificate) for issuing Marketing Authorizations. FSC is considered valid only when they are issued by the highest health authority. Further, they shall be in original and must contain the manufacturer's name & address and shall indicate that the drug(s) name, dosage form and strength. The certificate must be in English or accompanied by a certified translation. It is valid for five years from the date of issue.

Marketing Authorization Process

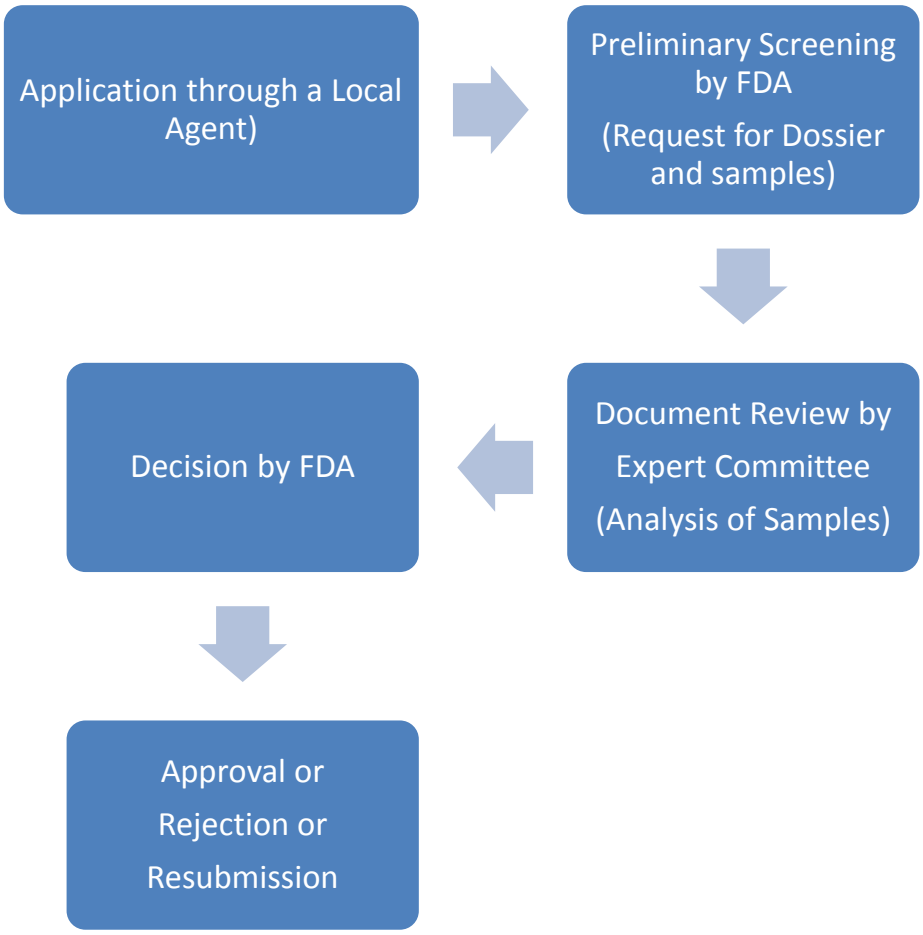

Figure 1: Marketing Authorization Process

Table 1: Documents required for Dossier application

Sr.no	Documents	Description
1.	Finished Product Specification	In tabular Format
2.	Certificate of Free Sale Issued by official of Government (FDA)	This certificate shall contain following information: Manufacturer name and address Name of products, Active ingredient, and quantity of ingredient A wording "can sell in your country" Further the certificate shall be legalized by the Royal Thai Embassy in India
3.	Certificate of GMP	Local GMP, WHO GMP
4.	Products label	Actual label
5.	Products leaflet	Actual product leaflet which will accompany the product
6.	Safety Data Sheet	MSDS
7.	Batch Formula	Unit Formula and batch Formula
8.	Method of Manufacture	Description and Flowchart
9.	Data of Active Ingredients	In case of official drug, provide the Monograph
10.	Data of Inert ingredients	Monograph or other control method Certificate of analysis

11.	Document of In-process control	Test process, detail of test and standard
12.	Document of finished product control	Conclusive table of finished product specification In case of official drug, used monograph
13.	Data of analysis	HPLC Chromatogram, UV-IR Spectrum In case of analysis of active ingredients by chromatography (HPLC or GC) must be have standard of system suitability example : % RSD of Acceptance limit, Tailing factor, Resolution factor Detail of analysis others
14.	Document on Packaging	Size Packaging details Type of package
15.	Document of Labeling	Specimen label
16.	Document of Storage	Room temperature for storage
17.	Document of Stability	Accelerate Study (more than 4 months) + Long term study (more than 6 months) = 2 lots **or** Long term study (12 months) = 2 lots **or** Long term study (until finished of shelf life) Conclude of period of validity with environment storage condition

CONCLUSION

It is quite easier to register veterinary Drugs in Thailand. Currently the documents and submission format required are quite simple. Till now eCTD has not become compulsory. However, the proposed label, sample and free sale certificate is mandatory for registration.

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CONFLICTS OF INTEREST

The author declares that there are no conflicts of interest.

REFERENCES

1. Food and Drug Administration, Thailand [Internet]. Thailand: FDA; [cited 2016 Feb 12]. Available from: www.fda.moph.go.th/eng/drug/laws.stm
2. Code of Practice For Control Of The Use Of Veterinary Drugs in Thailand. [Internet]. Bangkok: Royal Gazette Vol.126 Special Section 187D; 2009 Dec 28 [cited 2016 Feb 11]. Available from: www.acfs.go.th/standard/download/eng/veterinary_drugs.pdf
3. The drug Act B.E. 2510 (1967) [Internet]. Thailand: Thailaws.com; 1967 [cited 2016 Feb 13]. Available from: www.thailaws.com/law/t_laws/tlaw0071_1.pdf

