Translation

REGULATION OF THE FOOD AND DRUG ADMINISTRATION RE: COLLECTION OF FEES FOR INFORMATION SERVICES ON ADVERSE REACTIONS RESULTING FROM THE USE OF HEALTH PRODUCTS, B.E. 2548 (2005)*

Whereas it is expedient to prescribe fees for information services on adverse reactions resulting from the use of health products in accordance with the nature and preparation of the information, and persons having the duty to provide services and collect revenue;

By virtue of the provisions of clause 5 of the Rule of the Ministry of Finance Re: Revenue from the Provision of Information Services of the Food and Drug Administration, B.E. 2548 (2005), in conjunction with the Letter of the Ministry of Finance No. 0409.3/16503, dated 5th September B.E. 2548 (2005), the Secretary-General of the Food and Drug Administration hereby issues the Regulation as follows.

Clause 1. This Regulation is called "Regulation of the Food and Drug Administration Re: Collection of Fees for Information Services on Adverse Reactions Resulting from the Use of Health Products, B.E. 2548 (2005)".

Clause 2. This Regulation shall come into force as from the day following the date of its publication.

Clause 3. In this Regulation:

"information" means information relating to adverse reactions resulting from the use of health products;

"revenue" means money received by the Food and Drug Administration from marketing authorization holders who request information services for commercial benefits;

"handling expenses" means revenue spent for the expenses of personnel recruitment, procurement of materials and durable articles for the purpose of providing information services as may be spent according to the budgetary appropriations.

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* Published in the Government Gazette, Vol. 123, Special Issue, Part 79d, pages 12 - 13, dated 21st July B.E. 2549 (2006)

Clause 4. Any person who wishes to request information shall submit a request to the Health Product Vigilance and Chemical Safety Center in accordance with the form annexed to this Regulation.

Clause 5. The Head of the Health Product Vigilance and Chemical Safety Center or a person entrusted by the Head shall prepare information in accordance with the request and collect fee in accordance with the amount prescribed in the Annex of this Regulation. An invoice shall be issued to the information requester to make payment at the Finance Subdivision. The information requester shall present the receipt of fee payment to receive the requested information.

Clause 6. The Finance Subdivision shall deposit the revenue to the Ministry of Finance in accordance with the Rule of the Ministry of Finance Re: Revenue from the Provision of Information Services of the Food and Drug Administration, B.E. 2548 (2005).

Clause 7. The Health Product Vigilance and Chemical Safety Center shall have the duty to prepare a report of performance outcome in accordance with the Rule of the Ministry of Finance Re: Revenue from the Provision of Information Services of the Food and Drug Administration, B.E. 2548 (2005).

Clause 8. Revenue received from the provision of information services may be used by the Health Product Vigilance and Chemicals Safety Center to pay for handling expenses, in accordance with the orders, regulations and rules of the official service.

Clause 9. The Secretary-General of the Food and Drug Administration shall have charge and control of the execution of this Regulation.

Announced on the 26th day of December B.E. 2548 (2005)
Pakdee Pothisiri
Secretary-General of the Food and Drug Administration

Information Request Form

Day .... Month ..... Year .....

To: Secretary-General of the Food and Drug Administration

I ..... wish to request information regarding adverse reactions resulting from the use of health products, as follows:

1) Product name: ..... Information from: ..... (year) to ..... (year) Information format: ❒ By year ❒ Summary ❒ Detailed reports

2) Product name: ..... Information from: ..... (year) to ..... (year) Information format: ❒ By year ❒ Summary ❒ Detailed reports

3) Product name: ..... Information from: ..... (year) to ..... (year) Information format: ❒ By year ❒ Summary ❒ Detailed reports

4) Product name: ..... Information from: ..... (year) to ..... (year) Information format: ❒ By year ❒ Summary ❒ Detailed reports

5) Product name: ..... Information from: ..... (year) to ..... (year) Information format: ❒ By year ❒ Summary ❒ Detailed reports

I agree to pay information service fees in accordance with the Regulation of the Food and Drug Administration Re: Collection of Fees for Information Services on Adverse Reactions Resulting from the Use of Health Products, B.E. 2548 (2005).

Please be informed and proceed accordingly

Signature .....

(.....)

Information Requester

Information Service Fees

Annexed to the Regulation of the Food and Drug Administration Re: Collection of Fees for Information Services on Adverse Reactions Resulting from the Use of Health Products, B.E. 2548 (2005)

Drug Level	1-3 Drugs	4-10 Drugs	More than 10 drugs
By Year: Number of reports/drug in a year, grouped according to the organ systems	1,000 Thai Baht/Drug	1,000 Thai Baht/Drug	1,000 Thai Baht/Drug
Summary: Number of reports/adverse reactions in alphabetical order	1,000 Thai Baht/Drug	1,000 Thai Baht/Drug	1,000 Thai Baht/Drug
Detailed Reports	**1-3 Reports**	**4-10 Reports**	**More than 10 reports**
Individual patient (Case Report)	500 Thai Baht/Report	300 Thai Baht/Report	200 Thai Baht/Report