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GOVERNMENT OF PAKISTAN
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)
*****

Islamabad, the 7th May, 2021.

NOTIFICATION

No. F.7-11/2012-B&A/DRAP.-- In exercise of the powers conferred by sub-section (1) of section 20 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) read with clause (n) and clause (x) of section 7 and clause (d) of section 11 thereof, the Drug Regulatory Authority of Pakistan, with the approval of the Policy Board, is pleased to direct that the fee specified in column (4) of the Table below shall be levied in respect of functions specified in column (2) and (3) thereof, namely:-

TABLE

Sr.	Regulatory functions	Sub-functions	Fee (Rs.)
(1)	(2)	(3)	(4)
Drug Manufacturing License			
1.	**Grant of drug manufacturing license**	By way of basic manufacturing.	45,000
2.		By way of semi-basic manufacturing.	45,000
3.		By way of formulation.	150,000
4.		By way of repacking.	90,000
5.	**Renewal of drug manufacturing license** (If the application for renewal is made before the expiry of the period of validity of license).	By way of basic manufacturing.	22,500
6.		By way of semi-basic manufacturing.	22,500
7.		By way of formulation.	75,000
8.		By way of repacking.	45,000
9.	**Renewal of drug manufacturing license** (If the application for renewal is made after the expiry of the period of validity of license but within sixty days of its expiry).	---	7,500 per day surcharge, in addition to renewal fee
10.	**Site verification and layout**	Site inspection and verification.	7,500
11.		Approval of layout plan.	7,500 per section
12.		Revision or extension of layout plan.	7,500 per section
13.	**Repacking of drugs**	---	7,500 per drug specified in Schedule-D of the Drugs (Licensing, Registering and Advertising) Rules, 1976
Drug Registration			
14.	**Grant of drug registration**	New drug or molecule / drug not manufactured locally.	75,000
15.		Any other drug for import.	150,000
16.		Drug for local manufacture.	30,000

17.	**Renewal of drug registration** (If the application for renewal is made before the expiry of the period of validity of registration)	New drug or molecule / drug not manufactured locally.	30,000
18.		Any other drug for import.	30,000
19.		Drug for local manufacture.	15,000
20.	**Renewal of drug registration** (If the application for renewal is made after the expiry of the period of validity of certificate of registration but within 60 days after the expiry of the period of validity)	New drug or molecule / drug not manufactured locally / any other drug for import.	60,000
21.		Drug for local manufacture.	30,000
22.	**Grant / extension of contract manufacturing permission**	---	75,000 per product
23.	**Pre-registration variation**	Variation in registration application i.e. changes in inactive raw materials, method of manufacture, testing methods or quality specifications, product specification, packing materials including change of labeling specification, etc. except those specified in the following entry (No. 24).	7,500
24.		• Correction in composition as per reference regulatory authority / innovator's product. • Change of source. • Change of manufacturer.	Full fee of registration
25.	**Post-registration variation**	Any variation in registered drug except those specified in the following entry (No. 26).	10,000
26.		• Change of brand name except cases of resemblance. • Change of title / name of manufacturer / marketing authorization holder. • Change / extension in contract manufacturing • Change of source of pellets / bulk drug product / substance. • Approval of additional source of pellets / bulk drug product/substance. • Change of registration status form one manufacturer / marketing authorization holder to another manufacturer / marketing authorization holder.	Full fee of registration

Advertisement			
27.	**Advertisement**	Per advertisement for print media.	15,000
28.		Per advertisement for radio / audio.	22,500
29.		Per advertisement for television / cinema.	37,500
Drug Pricing			
30.	**Grant of additional pack** (price fixation)	Any drug for local manufacture or import (human).	7,500
31.	**Price increase** (hardship cases)		30,000
32.	**Price increase** (linked with consumer price index)		2,000
Import of Therapeutic Goods			
33.	**For clearance of import requests for all therapeutic goods** (active pharmaceutical ingredients, excipients, intermediates, finished products, etc.)	---	2,000 per consignment
Miscellaneous			
34.	**Miscellaneous applications**	Any other application having commercial significance.	7,500

AAMAR LATIF,
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Printing Corporation of Pakistan Press,
Islamabad.

Copy for information and necessary action:-

1. All Director of the Drug Regulatory Authority of Pakistan, Islamabad.
2. Additional Director (MIS), Drug Regulatory Authority of Pakistan, Islamabad.
3. Additional Director (E&M), Drug Regulatory Authority of Pakistan, Islamabad.
4. Additional Director (E&M), Drug Regulatory Authority of Pakistan, Lahore.
5. Additional Director (E&M), Drug Regulatory Authority of Pakistan, Karachi.
6. Additional Director (E&M), Drug Regulatory Authority of Pakistan, Peshawar.
7. Office Incharge, Drug Regulatory Authority of Pakistan, Quetta.
8. PS to Chief Executive Officer, Drug Regulatory Authority of Pakistan, Islamabad.

AAMAR LATIF,
Deputy Director (Legal Affairs).