

SEEPZ SPECIAL ECONOMIC ZONE

ANDHERI (EAST), MUMBAI.

.....

AGENDA FOR

**31st MEETING OF THE APPROVAL COMMITTEE FOR SECTOR
SPECIFIC SPECIAL ECONOMIC ZONE FOR PHARMACEUTICALS
AND BIOTECHNOLOGY AT PUNE OF M/s. SERUM BIO
PHARMA PARK.**

**VENUE : Conference Hall, BFC Building, 2nd Floor, Behind the
Office of Development Commissioner, SEEPZ-SEZ,
Andheri (East), Mumbai – 400 096.**

DATE : 13th January, 2017.

TIME : 11 A.M. Onwards

31st MEETING OF THE APPROVAL COMMITTEE FOR SECTOR SPECIFIC SPECIAL ECONOMIC ZONE FOR PHARMACETICALS AND BIOTECHNOLOGY AT PUNE OF M/s. SERUM BIO PHARMA PARK, UNDER THE CHAIRMANSHIP OF DEVELOPMENT COMMISSIONER, SEEPZ-SEZ ON 13th JANUARY, 2016.

INDEX

Agenda Item No.	Subject
Agenda item No. 01 : -	Confirmation of Minutes of the meeting held on 15.07.2016.
Agenda item No. 02 : -	Application of for broad banding of items with revision of Projection - M/s. Serum Institute of India Limited. (SEZ Unit IV).

Minutes of the 30th Meeting of the Approval Committee held under the Chairmanship of Development Commissioner for Sector Specific Special Economic Zone for Pharmaceuticals and Biotechnology at Pune of M/s. Serum Bio-Pharma Park SEZ, Pune on 15.07.2016.

1. Name of the SEZ : M/s. Serum Bio-Pharma Park.
2. Sector : Pharmaceuticals and Biotechnology
3. Meeting no : 30
4. Date : 15.07.2016

Members Present: -

1. Shri. V. P. Shukla, : Member.
Dy. Development Commissioner
SEEPZ-SEZ,
2. Smt.S. R. Motwani., : Nominee of additional DGFT, Mumbai.
Dy. DGFT
3. Shri. Sanjeev Kamoji, : Nominee of Commissioner of Income Tax,
Income Tax Officer, Pune. Industry 4 (5), Pune.
4. Shri. A.R. Chandorikar, : Nominee of Jt. Director of
Jt. Director, Deptt. Of Industries Industries (MMR) Mumbai.
Government of Maharashtra
5. Shri. R. B. Andhale, : Nominee of MPCB,
Sub Regional Officer, Mumbai.
MPCB
6. Shri. Anil Rupani, : Nominee of Commissioner of
Superintendent Central Excise Pune I Commissionerate.
Central Excise,
7. Shri. Harish Radhakrishnan, : Nominee of Developer.
Asst. Manager,
M/s. Serum Bio Pharma Park.

Agenda Item No. 1: Confirmation of Minutes of the meeting held on 12.02.2016.

The Minutes of the 29th Meeting held on 12.02.2016 were confirmed.

Agenda Item No. 2: Application for inclusion of Product in LOA - M/s. Serum Institute of India Pvt. Ltd. (SEZ Unit II)

The Committee noted that the unit vide their letter dated 15.06.2016 has requested for inclusion of Product i.e. "Pegfilgrastim" in their existing LOA No. SEEPZ/P-SEZ/04(2006)/02/2006-07/5376, dated 28.07.2006.

After deliberation, the Committee approved the proposal of the unit for inclusion of Product in LOA i.e. "Pegfilgrastim".

The meeting ended with the vote of thanks to the Chair.


Chairperson-cum-
Development Commissioner

**GOVT. OF INDIA,
OFFICE OF THE DEVELOPMENT COMMISSIONER,
MINISTRY OF COMMERCE & INDUSTRY,
SEEPZ (SPECIAL ECONOMIC ZONE)
MUMBAI**

AGENDA NOTE FOR CONSIDERATION OF UNIT APPROVAL COMMITTEE

a) Proposal: -

Application of **M/s. Serum Institute of India Limited. (SEZ Unit IV)** for broad banding of items with revision of Projection.

b) Specific Issue on which decision of UAC is required: -

Approval for addition of following products in the LOA submitted by unit vide letter dated 16.09.2015:-

Sr. No.	Description	Unit	Production Capacity	ITC Code	HS
1	Rabies Human Monoclonal Antibody	Doses/Ltrs/Gms	5 Million Doses	3002 10 13	

c) Relevant provision of SEZ Act, 2005 & Rules, 2006/ Instruction/Notification:

The application of the unit covered in terms of Rule 19 (2) of SEZ Rules, 2006, ***“Provided that the approval committee may also approve proposals for broad-banding, diversification, enhancement of capacity of production, change in the items of manufacture and services activity, if it meets the requirement of the Rule 18”.***

d) Other Information:-

M/s. **Serum Institute of India Limited. (SEZ Unit IV)**. has been granted LOA No. SEEPZ/NEWSEZ/SERUM-PUNE/06/LOA-04/08-09/3274, dated 01.04.2009. for Manufacturing activities i.e. Vaccine for Human medicine (Liquid Vaccines in single or Multi dose or in bulk form) at Bldg. No. SEZ -3, First Floor, SEZ - 4, Second Floor and SEZ-6, Ground Floor, 1st Floor and 2nd Floor, Serum Bio-Pharma Park SEZ, off Soli Poonawala Road, 212/2 Hadapsar, Pune - 411 028 in Serum Bio - Pharma Park SEZ.

The unit has requested for broad banding of items with revision of projection for remaining period of 5 years i.e. 2016-17 to 2020-2021.

.....2/-

The details of the said product, its production capacity, etc., are as under:-

Sr. No.	Description	Unit	Production Capacity	ITC HS Code
1	Rabies Human Monoclonal Antibody	Doses/Ltrs/Gms	5 Million Doses	3002 10 13

Further, the unit has stated that they have completed the first five years of operations in February, 2016 and obtained renewal/revalidation vide letter dated 23.08.2016 of their LOA for the second block of five years, up to 24.02.2021.

The unit seek approval for manufacturing and exporting of Rabies Monoclonal Antibody, in addition to the products approved earlier by UAC.

In this connection they are submitted the following documents for their record:

1. Revised Projection – Foreign Exchange Balance Sheet.
2. List of Capital Goods.
3. List of major raw materials, consumables, chemicals, spares, packing materials etc.
4. Manufacturing flow-chart.
5. Write up on Rabies Monoclonal Antibody.
6. Copy of Manufacturing License issued by FDA, Maharashtra State.

It may be noted that there is minor reduction in the Net Foreign Exchange earnings during five years, because the new product would need slightly higher requirement of imported capital goods, etc., in the initial period of manufacturing. However, the NFE is in the range of 71% which is much higher than prescribed requirement of Positive NFE.

A copy of letter dated **31.12.2016** is enclosed.

In view of the above, the proposal of the unit for broad banding of items with revision of Projection is placed before Approval Committee for Consideration.



SERUM INSTITUTE OF INDIA PVT. LTD.

(FORMERLY KNOWN AS SERUM INSTITUTE OF INDIA LTD.)

Cyrus Poonawalla Group

(SEZ UNIT - IV)

Serum Bio-Pharma Park SEZ

REGD. OFFICE AND LABORATORIES : 212/2, HADAPSAR, PUNE - 411028, INDIA. ■ www.seruminstitute.com
Tel.: +91-20-2660 2281 / 2699 3975 / 76 ■ Fax: +91-20-2699 3974 / 3921 ■ E-mail : exim@seruminstitute.com
CIN - U80903PN1984PTC032945
December 31, 2016.

The Development Commissioner
SEEPZ-Special Economic Zone
Ministry of Commerce & Industry
Andheri (E)
MUMBAI 400 096

Dear Sir,

Re: Application for Broad-banding under Rule 19(2) of SEZ Rules, 2006. —
Request ID No: ~ 421600237144
Ref: Letter of Approval No. SEEPZ/NEWSEZ/SERUM-PUNE/06/LOA-04/08-
09/3274, dated April 1, 2009.

You were kind enough to issue us above Letter of Approval for setting up our Unit in Serum Bio-Pharma Park SEZ at Hadapsar, for manufacture of Vaccines for Human Medicine (Liquid Vaccines in single or multi dose or in bulk form).

We completed the first five years of operations in February, 2016 and obtained renewal / revalidation of our LOA for the second block of five years, up to 24/2/2021.

We have been exploring the possibility of manufacturing new products in our Unit, in addition to the existing liquid vaccines, to meet the requirement in international market. We have identified the following product, which is having great potential in the international market. The details of the said product, its production capacity, etc., are as under :-

Sr. No.	Description	Unit	Production Capacity	ITC HS Code
1	Rabies Human Monoclonal Antibody	Doses/ Ltrs/ Gms.	5 Million Doses	3002 10 13

End use of the product:

Rabies Human Monoclonal Antibody is used to provide a safe therapy for the prevention of rabies. Write-up is enclosed.

28675
28/26/12/15



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CIN - U80903PN1984PTC032945

Manufacturing Facilities:

Serum Institute of India Pvt. Ltd.(SIPL) is recognized in the world as a top class supplier of quality vaccines. SIPL has state of the art manufacturing facility complying with the current Good Manufacturing Practice (cGMP) and are producing and exporting various vaccines and drugs at competitive prices. We are glad to say that our vaccines are being used in the National Immunization Programme of several countries. The in-house expertise and experience give us the skill and advantage to expand and produce new products.

Location/Area for manufacturing this product:

The existing location of our Unit is sufficient for manufacturing this new product.

Marketing Strategy:

Timely supplies of quality vaccines under a dedicated cold chain has enabled the company to gain the confidence of UN Agencies, such as World Health Organisation (WHO), UNICEF, Pan American Health Organisation (PAHO), etc, in reaching out to countries in the remotest place of world.

We are in the business for more than 25 years and currently we export to more than 140 countries in the world, through WHO, UNICEF, PAHO and other Government and semi-government agencies. Marketing of our products becomes easy as our products are already established and accepted in the international market due to it's quality and competitive prices. Further, we have enough technically qualified professionals for marketing our products. We also have marketing agencies of international repute in many countries for marketing our products. We propose to use our existing net-work for the new product.

Manufacturing Licence from FDA:

We have obtained manufacturing license from the Food & Drug Administration, Maharashtra State, for manufacturing this product. Copy enclosed for your reference.

Requirement of Capital goods and inputs:

Capital Goods (List enclosed)	Rs. 7,500 Lakhs
Raw materials, packing materials, consumables, spares, etc. (List enclosed)	Rs. 3,210 Lakhs



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CIN - U80903PN1984PTC032945

In view of the above, we seek your approval for manufacturing and exporting of Rabies Monoclonal Antibody, in addition to the products approved earlier by you.

In this connection, we are submitting herewith the following documents for your record :-

1. Revised Projections – Foreign Exchange Balance sheet.
2. List of Capital goods.
3. List of major raw materials, consumables, chemicals, spares, packing materials, etc.
4. Manufacturing Flow-chart.
5. Write-up on Rabies Monoclonal Antibody.
6. Copy of Manufacturing Licence issued by FDA, Maharashtra State.

Kindly note that there is minor reduction in the Net Foreign Exchange earning during five years, as per the revised Foreign Exchange Balance Sheet furnished now, as compared to the existing NFE earning based on the Foreign Exchange Balance Sheet submitted earlier, due to the reason that the new product would need slightly higher requirement of imported capital goods, etc., in the initial period of manufacturing. However, the **NFE is in the range of 71%** which is much higher than prescribed requirement of **POSITIVE NFE**.

We shall be grateful if you will kindly add the new products in our LOA as early as possible and oblige.

Thanking you,

Yours faithfully,

For **SERUM INSTITUTE OF INDIA PVT. LTD. (SEZ UNIT-IV)**


P.C. NAMBIAR
DIRECTOR (GROUP EXIM)

Encl: As above

/ravi

FOREIGN EXCHANGE BALANCE SHEET (REVISED)

Rs. In Lakhs

20/6-2024

Sl. No.	Particulars	1st Year 2016-17		2nd Year 2017-18		3rd Year 2018-19		4th Year 2019-20		5th Year 2020-21		Total		USD '000 1 USD= Rs. 65.00		USD '000 1 USD= Rs. 67.00	
		Existing	Revised	Existing	Revised	Existing	Revised	Existing	Revised	Existing	Revised	Existing	Revised	Existing	Revised	Existing	Revised
1	FOB Value of Exports in first five years	75,000	75,000	75,000	76,000	75,000	77,500	75,000	80,000	75,000	82,500	375,000	391,000	576,923	583,582		
2	Foreign Exchange outgo for the first five years	12,410	12,410	21,225	24,330	21,275	24,788	21,325	25,175	21,325	26,013	97,560	112,715	150,092	168,231		
3	Net Foreign Exchange earning for the first five years. (1) - (2)	62,590	62,590	53,775	51,670	53,725	52,713	53,675	54,825	53,675	56,488	277,440	278,285	426,831	415,351		

For SERUM INSTITUTE OF INDIA PRIVATE LIMITED
(SEX UNIT-IV)

P. C. NAGESHAR
DIRECTOR (GROUP-EXM)

DETAILED FOREIGN EXCHANGE BALANCE SHEET (REVISED)														
Sl. No./Particulars	2016 - 17		2017 - 18		2018 - 19		2019 - 20		2020 - 21		TOTAL 5Yrs		Revised TOTAL 5Yrs in USD '000	
	Existing	Revised	Existing	Revised	Existing	Revised	Existing	Revised	Existing	Revised	Existing	Revised		Existing
	Rs. Lakhs	Rs. Lakhs	Rs. Lakhs	Rs. Lakhs	Rs. Lakhs	Rs. Lakhs	Rs. Lakhs	Rs. Lakhs	Rs. Lakhs	Rs. Lakhs	Rs. Lakhs	Rs. Lakhs	1USD=Rs.65/-	1USD=Rs.67/-
1	75,000	75,000	75,000	76,000	75,000	77,500	80,000	75,000	82,500	375,000	391,000	576,923	583,582	
2														
first five years :-														
i	2,500	2,500	2,500	4,500	2,500	4,500	4,000	2,500	4,000	12,500	19,500	19,231	29,104	
ii	200	200	7,500	7,700	7,500	7,750	8,000	7,500	8,250	30,200	31,900	46,462	47,612	
iii	10	10	11,500	1,510	1,550	1,550	1,500	1,500	1,650	6,010	6,320	9,246	9,433	
iv	-	-	-	-	-	-	-	-	-	-	-	-	-	
v	-	-	-	75	187.50	187.50	375	-	562.50	-	1,200	-	1,791	
vi	-	-	-	-	-	-	-	-	-	-	-	-	-	
vii	-	-	-	-	-	-	-	-	-	-	-	-	-	
viii	250	250	250	500	250	500	300	300	600	1,350	2,400	2,077	3,582	
ix	50	50	75	125	75	150	150	75	150	350	625	538	933	
x	9,000	9,000	9,000	9,120	9,000	9,300	9,600	9,000	9,900	45,000	46,920	69,231	70,030	
xi	250	250	250	500	300	550	600	300	600	1,400	2,500	2,154	3,731	
xii	-	-	-	-	-	-	-	-	-	-	-	-	-	
xiii	-	-	-	-	-	-	-	-	-	-	-	-	-	
Registration Expenses	100	100	100	200	100	200	200	100	200	500	900	769	1,343	
Books & Periodicals	50	50	50	100	50	100	100	50	100	250	450	385	672	
TOTAL (i) to (xiii)	12,410	12,410	21,225	24,330	21,275	24,788	25,175	21,325	26,013	97,560	112,715	150,092	168,231	
Net Foreign Exchange Earning for the first Five Years (1) - (2)	62,590	62,590	53,775	51,670	53,725	52,713	54,825	53,675	56,488	277,440	278,285	426,831	415,351	

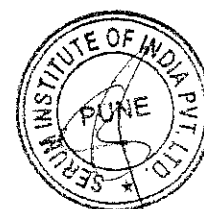
For SERUM INSTITUTE OF INDIA PRIVATE LIMITED
(SEZ UNIT-IV)

P. C. NAMBIAR
DIRECTOR (GROUP-EXIM)

Rabies Human Monoclonal Antibody

1. List of Capital Goods :

Sr. No.	Equipment Description
1	Garment Storage Cabinets
2	Fermenters
3	Non-jacketed Mixing Vessels
4	Jacketed Mixing Vessels
5	SIP Docking Skids
6	Bio-safety Cabinets
7	Tabletop Centrifuges
8	Water Baths
9	Portable pH Meters
10	Bio-analyzers
11	Particle Counters
12	Peristaltic Pumps
13	Garment Storage Cabinets
14	Weighing Balances
15	Conductivity Meters
16	Magnetic Stirrers
17	Laminar Air Flow Units
18	Osmometers
19	Filter integrity Machines
20	Sealing Machines
21	Portable pH Meters
22	Portable Conductivity Meters
23	Air Samplers
24	SS Pressure Vessels
25	CIP Systems
26	CIP Systems with SCADA
27	Autoclaves
28	Jacketed Harvest Collection Vessels
29	Jacketed Load Preparation Vessels



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Sr. No.	Equipment Description
30	Jacketed Elution Collection Vessels
31	CIP Re-circulation Skids
32	SIP Docking Skids
33	Chromatography Systems
34	Chromatography Columns
35	Chromaflow Columns
36	Spectrophotometer
37	Peristaltic Pumps
38	Chromaflow Packing Stations
39	HPLC Systems
40	Jacketed Buffer Preparation Vessels
41	Cell Bank Storage Systems





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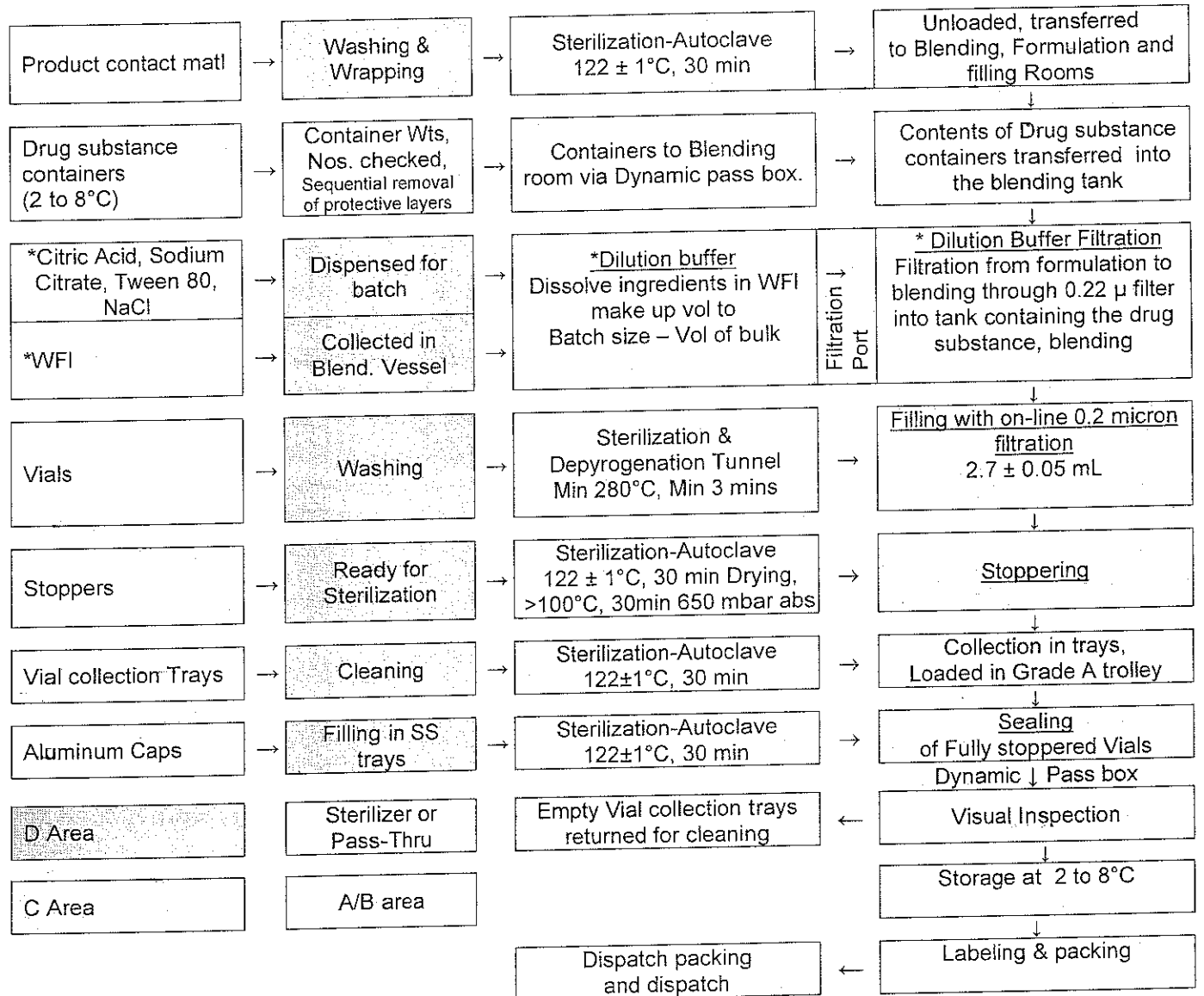
Cyrus Poonawalla Group

(SEZ UNIT - IV)
Serum Bio-Pharma Park SEZ

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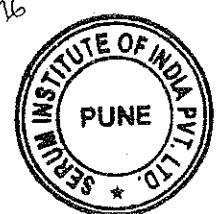
RABIES MONOCLONAL ANTIBODY

OVERALL PROCESS FLOW CHART



*The step involving the formulation of buffer and its use to dilute the incoming Drug substance is only applicable for 100 IU product.

Kolhu
24/12/16
Rajiv S Lochan
DIRECTOR



Government Recognised Four Star Export House

Tel. No. : 020 - 2447 0276
Fax. No. : 020 - 2447 7555

No. Drugs/Mfg./ 417 /2016/Z-III
Office of Joint Commissioner (Pune Divn.)
Food & Drug Administration (M.S.)
791/93, Lucky Bldg., New Guruwar Peth,
PUNE - 411 042

Date: 27 OCT 2016

To,
M/s. Serum Institute of India Pvt. Ltd.,
212/2, Hadapsar,
PUNE - 411 028

SUB. : Drugs and Cosmetics Act 1940 and Rules thereunder - -
Grant of permission to manufacture additional products -
Rabies Human Monoclonal Antibody (rDNA)

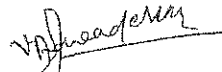
REF. : 1) Your application Ref. YCD/202/570/2016 dt. 23/08/2016
2) A letter from Drugs Controller General (I) New Delhi bearing
File No. 28D/Hum.Vac/62/Serum/16-BD dt. 26/10/2016

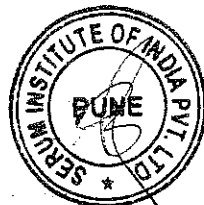
Sir,

With reference to your application under Ref. (1) above, you are hereby granted permission to manufacture the additional product Rabies Human Monoclonal Antibody (rDNA) 100 IU/2.5 mL & 250 IU/2.5 mL, for domestic & export purposes, under your Drug Mfg. Lic. No. 10 (in Form 28-D), as per the list of additional products approved by CLAA/DCG(I) vide letter under Ref.(2) above. One copy of the approved list of products, duly endorsed by the CLAA/DCG(I), is enclosed herewith.

You are advised to ensure that the carton label, product label and package insert are in compliance with the Drugs and Cosmetics Act. You are also directed to submit a copy set of carton label, product label and package insert to this office & to the office of DCG(I) for information and record.

Yours,

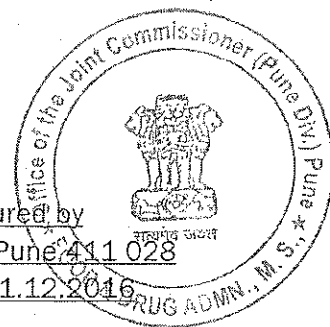

(V. A. JAWDEKAR)
Joint Commissioner (Pune Divn.)
Food & Drug Administration,
Maharashtra State, Pune



Copy to:

- 1) The Drugs Controller General (I), FDA Bhawan, Kotla Road, New Delhi 110 002
- 2) The Dy. Drugs Controller (I), CDSCO (West Zone), Mumbai 400 008
- 3) The Head, Central Drugs Laboratory, Kasauli, Himachal Pradesh 173 204

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List of Additional products permitted to be manufactured by
 M/s. Serum Institute of India Pvt. Ltd., at 212/2, Hadapsar, Pune-411 028
 in Form 28-D bearing No. 10 dt. 30.06.1988, valid upto 31.12.2016

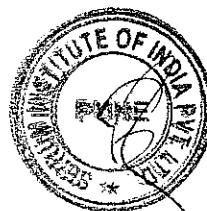
Sr.	Name of the Product	Composition	Pack Size	Purpose
1.	Rabies Human Monoclonal Antibody (rDNA)	Each ml contains: Rabies Human Monoclonal Antibody 40 IU	100 IU/2.5mL	Domestic
2.	Rabies Human Monoclonal Antibody (rDNA)	Each ml contains: Rabies Human Monoclonal Antibody 100 IU	250 IU/2.5mL	Domestic
3.	Rabies Human Monoclonal Antibody (rDNA)	Each ml contains: Rabies Human Monoclonal Antibody 40 IU	100 IU/2.5mL	Export
4.	Rabies Human Monoclonal Antibody (rDNA)	Each ml contains: Rabies Human Monoclonal Antibody 100 IU	250 IU/2.5mL	Export
5.	Rabies Human Monoclonal Antibody (rDNA) Rabishield - 100	Each ml contains: Rabies Human Monoclonal Antibody 40 IU	100 IU/2.5mL	Export
6.	Rabies Human Monoclonal Antibody (rDNA) Rabishield - 250	Each ml contains: Rabies Human Monoclonal Antibody 100 IU	250 IU/2.5mL	Export

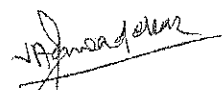
[DCG(I) Permission in Form 46 bearing No. MF-79/2016 dt. 07.06.2016]


 Central Licence Approving Authority

Dr. G. N. SINGH
 Drugs Controller General (India)
 Dte. General of Health Services
 Ministry of Health & Family Welfare
 FDA Bhawan, Kaila Road, I.T.O.
 New Delhi-110002

26 OCT 2016




 (V. A. JAWDEKAR)
 Joint Commissioner (Pune Divn.)
 Food & Drug Administration,
 Maharashtra State, Pune