Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

	Registrant Details
1. Registration Number	UK API 17661
2. Name or corporate name of registrant	PCCA LIMITED
3. Permanent or legal address of registrant	PCCA LIMITED, UNITS 2 AND 3 REGENTS DRIVE, LOW PRUDHOE INDUSTRIAL ESTATE, PRUDHOE, NE42 6PX, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	PCCA LIMITED, UNITS 2 AND 3 REGENTS DRIVE, LOW PRUDHOE INDUSTRIAL ESTATE, PRUDHOE, NE42 6PX, UNITED KINGDOM
5. National legal basis of registration	Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)
6. Name of responsible officer of the competent authority of the member state validating the registration	Confidential
7. Date	11/06/2026

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site

PCCA LIMITED, UNITS 2 AND 3 REGENTS DRIVE, LOW PRUDHOE INDUSTRIAL ESTATE, PRUDHOE, NE42 6PX, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance
THYROID
1000007072

E	General Finishing Steps
	E.2 Primary Packaging
	E.3 Secondary Packaging

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F	Quality Control Testing
	F.1 Physical / Chemical testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
FLUCONAZOLE (1000002222)	**VIRUPAKSHA ORGANICS LIMITED**, SURVEY NO 10, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, MEDAK DISTRICT, TELANGANA, IN-502 319, INDIA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
THYROID (1000007072)	**BIOIBERICA S.A.U**, CARRER ANTIC CAMI DE TORDERA 109-119, PALAFOLLS, BARCELONA, E-08389, SPAIN	
ALLOPURINOL (1000003843)	**HALEOS LABS LIMITED**, UNIT I, SURVEY NO. 180/2, KAZIPALLY VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, IN-502319, INDIA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
TESTOSTERONE PROPIONATE (2000007380)	**ASG BIOCHEM PRIVATE LIMITED**, GANGANAGAR, 24 PARGANAS NORTH, KOLKATA, WEST BENGAL, IN-700132, INDIA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
HYDROQUINONE (1000008752)	**EASTMAN CHEMICAL COMPANY**, 200 SOUTH WILCOX DRIVE, KINGSPORT, 37660, UNITED STATES	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
ARGININE HYDROCHLORIDE (2000008452)	**AJINOMOTO HEALTH & NUTRITION NORTH AMERICA, INC.**, NORTH CAROLINA PLANT, 4020 AJINOMOTO DRIVE, RALEIGH, 27610-2911, UNITED STATES	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
TACROLIMUS MONOHYDRATE (2000016490)	**BIOCON LIMITED**, 20TH KM HOSUR ROAD, ELECTRONICS CITY, BANGALORE, IN-560 100, INDIA	**BIOCON LIMITED**, 20TH KM HOSUR ROAD, ELECTRONICS CITY, BANGALORE, IN-560 100, INDIA

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METHIMAZOLE (3000012191)	**CHANGZHOU TIANHUA PHARMACEUTICAL CO LIMITED**, NO. 3 HOUYANG CHEMICAL ZONE, GOLD TOWN, JINTAN, JIANGSU, CN-213200, CHINA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
HYDROCORTISONE (1000008762)	**TAIZHOU XIANJU PHARMACEUTICAL COMPANY LIMITED**, NO.3 DONGHAI FOURTH AVENUE, DUQIAO MEDICAL AND CHEMICAL INDUSTRY ZONE, LINHAI, ZHEJIANG PROVINCE, CN-317 016, CHINA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
NIFEDIPINE (1000009680)	**DIPHARMA FRANCIS S.R.L.**, VIA BISSONE, 5, BARANZATE DI BOLLATE (MI), I-20021, ITALY	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
PREGNENOLONE (1000011186)	**JIANGSU JIAERKE PHARMACEUTICALS GROUP CORP**, SANHUANGMIAO, WUJIN, CHANGZHOU, ZHENGLU, JIANGSU, CN-213 111, CHINA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES **MEDISCA INC.**, 6641 NORTH BELT LINE ROAD, UNIT 130, IRVING, 75063-6001, UNITED STATES
TRAMADOL HYDROCHLORIDE (2000008034)	**GVK BIOSCIENCES PRIVATE LIMITED**, PLOT NO. 28A, IDA NACHARAM, HYDERABAD, TELANGANA, IN-500076, INDIA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
HYDROCORTISONE ACETATE (2000007338)	**TIANJIN JINJIN PHARMACEUTICAL COMPANY LIMITED**, 8 JINGFU ROAD, INDUSTRIAL ZONE OF ZHANGJIAWO TOWN, XIQING DISTRICT, TIANJIN, CN-300387, CHINA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES

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PROGESTERONE (1000009777)	**PHARMACIA & UPJOHN COMPANY LLC**, 7000 PORTAGE ROAD, KALAMAZOO, 49001, UNITED STATES **JIANGSU JIAERKE PHARMACEUTICALS GROUP CORP**, SANHUANGMIAO, WUJIN, CHANGZHOU, ZHENGLU, JIANGSU, CN-213 111, CHINA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
MELATONIN (1000000731)	**SWATI SPENTOSE PRIVATE LIMITED**, UNIT-I, PLOT NUMBER A-1/2102, 2103 AND A-2/2120, PHASE III, G.I.D.C., DISTRICT VALSAD, VAPI, GUJARAT, IN-396195, INDIA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
HYDROCHLOROTHIAZIDE (1000008764)	**CHANGZHOU PHARMACEUTICAL FACTORY**, 518 LAODONG EAST ROAD, CHANGZHOU, JIANGSU PROVINCE, CN-213018, CHINA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
LOPERAMIDE HYDROCHLORIDE (2000008494)	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
TRETINOIN (1000009303)	**OLON SPA**, VIA MILANO 186, GARBAGNATE MILANESE (MI), I-20024, ITALY	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
ENALAPRIL MALEATE (2000007672)	**NEULAND LABORATORIES LIMITED**, UNIT 1, SURVEY NO. 347, 473, 474, 490/2, VEERABHADRASWAMY TEMPLE ROAD, BONTHAPALLI VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT, TELANGANA, IN 502313, INDIA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
SODIUM VALPROATE (2000007475)	**KATWIJK CHEMIE B.V.**, SNIJDERSTRAAT 6, KATWIJK ZH, NL-2222 BA, NETHERLANDS **PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES

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KETOPROFEN (1000008346)	**SAURAV CHEMICALS LIMITED**, VILLAGE BHAGWANPURA, DERABASSI BARWALA ROAD, SAHIBZADA AJIT SINGH NAGAR, DERABASSI, IN-140507, INDIA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
LIOTHYRONINE SODIUM (2000008504)	**AZICO BIOPHORE INDIA PRIVATE LIMITED**, PLOT NO. 40/A, JN PHARMACITY, PARAWADA MANDAL, ANAKAPALLI, ANDHRA PRADESH, IN-531021, INDIA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
CLIOQUINOL (1000004182)	**ESKAY SPECIALITY CHEMICALS**, PLOT NO. 207B & 208, SURAT SPECIAL ECONOMIC ZONE, ROAD NO. 4, G.I.D.C., SACHIN, GUJARAT, IN-394230, INDIA **PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
DRONABINOL (1000003105)	**PURISYS LLC**, 1550 OLYMPIC DRIVE, ATHENS, 30601, UNITED STATES	**PURISYS LLC**, 1550 OLYMPIC DRIVE, ATHENS, 30601, UNITED STATES
METHYLPHENIDATE HYDROCHLORIDE (2000008305)	**NORAMCO, LLC**, 500 SWEDES LANDING ROAD, WILMINGTON, 19801, UNITED STATES	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
SPIRONOLACTONE (1000009436)	**ZHEJIANG LANGHUA PHARMACEUTICAL CO. LIMITED**, ZHEJIANG PROVINCIAL CHEMICAL & MEDICAL MATERIALS BASE, LINHAI ZONE, LINHAI, ZHEJIANG PROVINCE, CN-317016, CHINA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
METHENAMINE HIPPURATE (2000012262)	**NURAY CHEMICALS PRIVATE LIMITED**, GROUND FLOOR, PLOT NUMBER 111, SIDCO INDUSTRIAL ESTATE, KAKKALUR, THIRUVALLUR, TAMIL NADU, IN-602003, INDIA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES

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SILDENAFIL CITRATE (2000006954)	**AMOLI ORGANICS PRIVATE LIMITED**, BLOCK NUMBER 422, ECP CANAL ROAD, VILLAGE LUNA, TALUKA PADRA, VADODARA, GUJARAT, IN-391440, INDIA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
TESTOSTERONE (1000009354)	**JIANGSU JIAERKE PHARMACEUTICALS GROUP CORP**, SANHUANGMIAO, WUJIN, CHANGZHOU, ZHENGLU, JIANGSU, CN-213 111, CHINA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
LEVOTHYROXINE SODIUM (2000013292)	**EXCELLA GMBH & CO. KG**, NUERNBERGER STRASSE 12, FEUCHT, D-90537, GERMANY **AZICO BIOPHORE INDIA PRIVATE LIMITED**, PLOT NO. 40/A, JN PHARMACITY, PARAWADA MANDAL, ANAKAPALLI, ANDHRA PRADESH, IN-531021, INDIA	**MEDISCA INC.**, 6641 NORTH BELT LINE ROAD, UNIT 130, IRVING, 75063-6001, UNITED STATES **PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
GABAPENTIN (1000007380)	**SOLARA ACTIVE PHARMA SCIENCES LIMITED**, A1/B SIPCOT INDUSTRIAL COMPLEX, KUDIKADU, CUDDALORE, TAMIL NADU, IN-607005, INDIA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
MIRTAZAPINE ANHYDROUS (2000014212)	**MEDISCA PHARMACEUTIQUE INCORPORATION**, 6090 HENRI BOURASSA BOULEVARD W, SAINT-LAURENT QC, H4R 3A6, CANADA	**MEDISCA PHARMACEUTIQUE INCORPORATION**, 6090 HENRI BOURASSA BOULEVARD W, SAINT-LAURENT QC, H4R 3A6, CANADA
CHLORAL HYDRATE (1000005193)	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
NALTREXONE HYDROCHLORIDE (2000007614)	**MALLINCKRODT CHEMICAL INCORPORATED**, 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES

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RASAGILINE MESYLATE (2000005590)	**GLENMARK PHARMACEUTICALS LIMITED**, PLOT NO. 3109, G.I.D.C. INDUSTRIAL ESTATE, ANKLESHWAR, BHARUCH DISTRICT, GUJARAT, IN 393002, INDIA	**GLENMARK PHARMACEUTICALS LIMITED**, PLOT NO. 3109, G.I.D.C. INDUSTRIAL ESTATE, ANKLESHWAR, BHARUCH DISTRICT, GUJARAT, IN 393002, INDIA
CLONIDINE HYDROCHLORIDE (2000008010)	**YUNG ZIP CHEMICAL INDUSTRY COMPANY LIMITED**, 59 YOUSHI ROAD, YOUTH INDUSTRIAL DISTRICT, DAJIA, TAICHUNG, TW-437101, TAIWAN	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
BACLOFEN (1000009324)	**PHARMACEUTICAL WORKS POLPHARMA S.A.**, 19 PELPLINSKA STREET, STAROGARD GDANSKI, PL-83-200, POLAND **PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
TRIAMCINOLONE 21-ACETATE (2000003684)	**NEWCHEM S.P.A.**, VIA ROVEGGIA 47, VERONA, I-37136, ITALY	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
ESTRIOL (3000004591)	**ZHEJIANG XIANJU PHARMACEUTICAL CO., LTD**, NO. 15 WEST FENGXI ROAD, MODERN INDUSTRIAL PARK, XIANJU, TAIZHOU, ZHEJIANG, CN-317300, CHINA **QINHUANGDAO ZIZHU PHARMACEUTICAL COMPANY LIMITED**, NO. 10 LONGHAI ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, QINHUANGDAO, HEBEI PROVINCE, CN-066 004, CHINA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
KETAMINE HYDROCHLORIDE (2000008609)	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES

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ESTRADIOL (1000017043)	**YICHENG GOTO PHARMACEUTICALS**, GROUP 1 GAOKENG, XIAOHE, YICHENG, HUBEI PROVINCE, CN 441400, CHINA **QINHUANGDAO ZIZHU PHARMACEUTICAL COMPANY LIMITED**, NO. 10 LONGHAI ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, QINHUANGDAO, HEBEI PROVINCE, CN-066 004, CHINA **ZHEJIANG XIANJU PHARMA**, NO. 1 XIANYAO ROAD, XIANJU, ZHEJIANG PROVINCE, CN-317300, CHINA	**MEDISCA PHARMACEUTIQUE INCORPORATION**, 6090 HENRI BOURASSA BOULEVARD W, SAINT-LAURENT QC, H4R 3A6, CANADA **PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
CANNABIDIOL (1000000540)	**PURISYS LLC**, 1550 OLYMPIC DRIVE, ATHENS, 30601, UNITED STATES	**PURISYS LLC**, 1550 OLYMPIC DRIVE, ATHENS, 30601, UNITED STATES
LIDOCAINE (1000015338)	**SWATI SPENTOSE PRIVATE LIMITED**, UNIT-I, PLOT NUMBER A-1/2102, 2103 AND A-2/2120, PHASE III, G.I.D.C., DISTRICT VALSAD, VAPI, GUJARAT, IN-396195, INDIA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
PRASTERONE (1000006301)	**JIANGSU JIAERKE PHARMACEUTICALS GROUP CORP**, SANHUANGMIAO, WUJIN, CHANGZHOU, ZHENGLU, JIANGSU, CN-213 111, CHINA	**PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED**, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
CANNABIS FLOWER (4000016460)	**CASTLE ROCK FARMS INC (BC GREEN)**, 253 DAVID BROWN WAY, PRINCETON BC, V0X 1W0, CANADA	**CASTLE ROCK FARMS INC (BC GREEN)**, 253 DAVID BROWN WAY, PRINCETON BC, V0X 1W0, CANADA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

THYROID (1000007072)

ALLOPURINOL (1000003843)

TESTOSTERONE PROPIONATE (2000007380)

ARGININE HYDROCHLORIDE (2000008452)

HYDROCORTISONE (1000008762)

NIFEDIPINE (1000009680)

PREGNENOLONE (1000011186)

PROGESTERONE (1000009777)

MELATONIN (1000000731)

KETOPROFEN (1000008346)

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CLIOQUINOL (1000004182)

DRONABINOL (1000003105)

METHYLPHENIDATE HYDROCHLORIDE (2000008305)

METHENAMINE HIPPURATE (2000012262)

SILDENAFIL CITRATE (2000006954)

TESTOSTERONE (1000009354)

GABAPENTIN (1000007380)

CLONIDINE HYDROCHLORIDE (2000008010)

BACLOFEN (1000009324)

ESTRIOL (3000004591)

ESTRADIOL (1000017043)

LIDOCAINE (1000015338)

PRASTERONE (1000006301)

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