Manufacturing License Cardinal Health

Department of Health
MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
Market Towers, 1 Nine Elms Lane, London, SW8 5NQ
Telephone 020-7273 [illegible] *Facsimile* 020-7273-0676

Date 22/10/2003

Cardinal Health UK 417 Limited (formerly Unipack Ltd/PCI Services)
Attn: Mr P J Clapp
Sedge Close, Headway
Great Oakley, Corby
Northamptonshire
NN18 8HS

COMMERCIAL IN CONFIDENCE

Dear Mr Clapp

MEDICINES ACT 1968:
MANUFACTURER'S LICENCE **LICENCE NO. ML/1380/1**

1. A manufacturer's licence for the purpose of section 8(2) of the Medicines Act 1968 is renewed in accordance with the application dated 16 September 2003. The formal documents are enclosed.

2. This licence authorises manufacture and assembly by the licence holder named; if the business should change hands, the company or person taking over the business will have to obtain a new licence before commencing the manufacture or assembly of products.

3. This licence is subject to the limitations specified in the licence and to the statutory provisions contained in the Regulations listed in Part III of the enclosed documents.

4. Manufacture and assembly may only be carried out in accordance with the terms of the relevant product licence, unless a specified exemption applies which allows manufacture and assembly to take place otherwise than in accordance with a product licence.

5. This licence relates to the manufacture and assembly of products on the premises and under the supervision of the persons specified. If any change of premises or of those persons take place, prior approval must be sought from the Licensing Authority. Any proposal to make structural alterations to the premises must also be notified to the Licensing Authority.

6. The Licensing Authority has power to suspend licences if fees are unpaid.

Yours sincerely

Licence Office Supervisor

MEDICINES ACTS 1968 AND 1971

MANUFACTURING AND ASSEMBLY

MANUFACTURER'S LICENCE NO. ML/1380/1 has been granted under and subject to the provisions of the Medicines Acts 1968 and 1971 to

Cardinal Health UK 417 Limited (formerly Unipack Ltd/PCI Services)
Sedge Close, Headway
Great Oakley, Corby
Northamptonshire
NN18 8HS

to authorise the holder of the licence to carry out the processes of manufacture and/or assembly of medicinal products of the description or general classification specified in Part I, at the premises therein specified, and in accordance with the particulars set out in Part II. The licence is subject to the further provisions specified in Part III.

The licence, unless previously suspended, revoked or varied as to the period of its validity, will continue in force until 21 October 2008.

Date granted 22 October 2003.

A person authorised to sign on behalf of the Secretary of State for Health

Medicines and Healthcare products Regulatory Agency
(On behalf of the Department of Health)
Market Towers
1 Nine Elms Lane
Vauxhall
London SW8 5NQ

MEDICINES ACTS 1968 AND 1971

MANUFACTURING AND ASSEMBLY

MANUFACTURER'S LICENCE NO. ML/1380/1

PART I - Particulars of the premises, the Manufacturing and Assembly operations, and the personnel to which the licence relates.

1. The premises at which operations are carried out including those premises where any testing associated with the operations takes place.

Cardinal Health UK 417 Limited (formerly Unipack Ltd/PCI Services)
Sedge Close, Headway
Great Oakley, Corby
Northamptonshire
NN18 8HS

1.1 Use of products manufactured and/or assembled on the premises.

Products for human use only

1.2 General classification of products manufactured and assembled on the premises.

1.2.1 Sterile products

None

1.2.2 Non-sterile products

Solid non-sterile unit-dose forms - capsules, hard gelatine

1.2.3 Active Ingredients (Biological) produced or handled and appearing in the finished product

None

1.2.4 Other Active Ingredients produced or handled and appearing in the finished product

None

MEDICINES ACTS 1968 AND 1971

MANUFACTURING AND ASSEMBLY

MANUFACTURER'S LICENCE NO. ML/1380/1

PART I (Continued)

1.3 Assembly (only) activities

Filling of primary containers

Labelling of primary containers

Dosage forms assembled

Liquid dosage forms

Semi-solid dosage forms (including creams and ointments)

Solid dosage forms (including tablets and powders)

Strip and/or Blister Packing manufacture for Export.

1.4 Other specific processes/activities

Strip and/or blister packing

Manufacture for export

Except in so far as may be expressly indicated the categories of manufacture or assembly above do not include the manufacture or assembly of biological products (ie the products the purity and potency of which cannot be adequately tested by chemical or physical means) or of antibiotics, sterile products or products for administration by parenteral injection.

MEDICINES ACTS 1968 AND 1971

MANUFACTURING AND ASSEMBLY

MANUFACTURER'S LICENCE NO. ML/1380/1

PART I (Continued)

Personnel responsible for operations on the premises on behalf of the licence holder		Name, qualifications and membership of professional body
1.5	Responsible for supervising the production operations	Mr D Hopper MBA - Master of Business Administration DMS - Post Graduate Diploma in Management Studies CMS - Postgraduate Certificate in Management Studies.
1.6	Responsible for quality control	Mrs E Hepburn B.Sc (Hons) Pharmacy., M.R.Pharm.S, QP
1.7	Available as "qualified person(s)"	Mrs E Hepburn B.Sc (Hons) Pharmacy., M.R.Pharm.S, QP Mr M F Constantine C.Chem., FRSC., MIQA, QP Mr R Sizeland B.Sc Chemistry; Diploma in Management Studies; Qualified Person

MEDICINES ACTS 1968 AND 1971

MANUFACTURING AND ASSEMBLY

MANUFACTURER'S LICENCE NO. ML/1380/1

PART I (Continued)

2. The premises at which operations are carried out including those premises where any testing associated with the operations takes place.

Cardinal Health UK 417 Limited (formerly Unipack Ltd/PCI Services)
Lancaster Way, Wingates Industrial Park
Westhoughton, Bolton
Lancashire
BL5 3XX

2.1 Use of products manufactured and/or assembled on the premises.

Products for human and veterinary use

2.2 General classification of products manufactured and assembled on the premises.

2.2.1 Sterile products

None

2.2.2 Non-sterile products

None

2.2.3 Active Ingredients (Biological) produced or handled and appearing in the finished product

None

2.2.4 Other Active Ingredients produced or handled and appearing in the finished product

None

2.2.5 Other dosage forms manufactured and/or assembled

Licensable medical devices (e.g. intra-uterine device)

A) Hormones
B) Antibiotics (eg. Erythromycin) but not

MEDICINES ACTS 1968 AND 1971

MANUFACTURING AND ASSEMBLY

MANUFACTURER'S LICENCE NO. ML/1380/1

PART I (Continued)

Penicillins or Cephalosporins.

2.3 Assembly (only) activities

Filling of primary containers

Labelling of primary containers

Dosage forms assembled

Liquid dosage forms

Semi-solid dosage forms (including creams and ointments)

Solid dosage forms (including tablets and powders)

2.4 Other specific processes/activities

Form/fill/seal

Strip and/or blister packing

Manufacture for export

Assembly for export

Except in so far as may be expressly indicated the categories of manufacture or assembly above do not include the manufacture or assembly of biological products (ie the products the purity and potency of which cannot be adequately tested by chemical or physical means) or of antibiotics, sterile products or products for administration by parenteral injection.

MEDICINES ACTS 1968 AND 1971

MANUFACTURING AND ASSEMBLY

MANUFACTURER'S LICENCE NO. ML/1380/1

PART I (Continued)

Personnel responsible for operations on the premises on behalf of the licence holder		Name, qualifications and membership of professional body
2.5	Responsible for supervising the production operations	Mr M Page B.Sc (Hons) Biochemistry
2.6	Responsible for quality control	Mr K Griffiths
2.7	Available as "qualified person(s)"	Mr S W Vass BSc. Joint Honours Chemistry and Biology, MSc. Pharmaceutical Analysis
		Mr I Sulley HNC (Chem), CNAA
		Mr D Benoliel
		Dr J A Farooqi B.Sc (Chemistry, Physics & English) M.Sc (Analytical & Organic Chemistry) M.Phil (Physical Organic Chemistry) PhD (Physical Organic Chemistry).
		Mr A D Ruffle GRSC., C.Chem., FBIM., FRSC.

MEDICINES ACTS 1968 AND 1971

MANUFACTURING AND ASSEMBLY

MANUFACTURER'S LICENCE NO. ML/1380/1

PART III - Further provisions (Continued)

4. The holder of the licence shall conduct all manufacturing operations in respect of those products for which a product licence is not required, so as to ensure that the products shall conform to the standards of strength, quality and purity applicable to them in accordance with the specification made by the person to whose order they are manufactured or the specification under which the products are sold or supplied.

In relation to such products the holder of the licence shall either:-

(a) provide and maintain such staff, premises and plant as are necessary for carrying out in accordance with such specification any tests of the strength, quality or purity as required by that specification or,

(b) make arrangements with a person approved by the Licensing Authority for such tests to be carried out on his behalf by that person, and

(c) make arrangements for a qualified person to be at all times available for the purpose of checking that each batch of medicinal products has been manufactured and assembled in accordance with the appropriate provisions and to certify accordingly in a register.

5. The manufacture or assembly of any proprietary medicinal product pursuant to this licence shall not commence until the approval of the Licensing Authority has been given on the appropriate product licence to use of the site(s) named on this licence for the manufacture of that product.

* By virtue of section 47 of the Medicines Act 1968 when new standard provisions are made by regulation, such provisions shall be deemed to be incorporated in existing licences as from the end of the three months from the date on which the regulations come into operation, but it is provided that at any time before the end of that period the holder may apply to the Licensing Authority to direct that the new provisions should not be incorporated.