EX-10 13 filename13.htm

**Exhibit 10.7**

**SUPPLY CONTRACT**

dated as of January 3, 2006 by and among

**Eurand S.p.A.**, a company incorporated under the laws of Italy, with offices at Via Martin Luther King, 13, 20060 Pessano con Bornago — Milan, Italy (hereafter called **Customer**)

and

**Nordmark Arzneimittel GmbH & Co.,** a company incorporated under the laws of Germany, with offices at Pinnaualle, 4 25436 Uetersen — Germany (hereafter called **Supplier**)

(each a “**Party**” and Eurand and Nordmark, the “**Parties**”).

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| [\*] | Confidential treatment requested. |

**PREAMBLE**

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| A. | Whereas, *Customer*manufactures drug products containing Pancreatin for sale worldwide (hereafter called the **Drug Product)**; |

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| B. | Whereas, *Customer*is also planning to apply in its own name for *a Marketing Authorization*for the *Drug Product*in the USA, Europe and any other markets and – upon registration – to distribute directly or indirectly the *Drug Product*in the USA, Europe and any other markets; and wishes to be supplied by *Supplier*with Pancreatin of a specified quality, as defined in Article 1 and; |

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| C. | Whereas, *Supplier*manufactures APIs and drug products and is the holder of the manufacturing authorizations issued by the competent authorities. |

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| D. | Whereas, *Supplier*wishes to supply *Customer*with Pancreatin. |

NOW THEREFORE, the Parties agree the following terms and conditions for the supply of Pancreatin.

**DEFINITIONS**

**Affiliate** means a company or other entity or organization or person that owns or controls, is owned or controlled by or is under common ownership or control with another company or other entity or organization or person.

**API** means Active Pharmaceutical Ingredient.

**cGMP** means current Good Manufacturing Practice as defined in the guidelines Part II (Basic Requirements for Active Substances used as Starting Materials) of the “The Rules Governing Medicinal Products in the European Union” (Volume 4, EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use) and the FDA Guidance for Industry Q7A (Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients).

**Contract** is this agreement for the non-exclusive supply by Nordmark to Eurand of the Contracted Product.

**Costs** means any cost or expense, including reasonable attorneys’ fees and costs of investigating and defending against lawsuits, complaints, actions or other pending or threatened litigation.

**Current Supply Agreement** means the agreement signed between the Parties 13th and 21st July 2003.

**Delivery Date** means the date set forth in the Orders with which Customer requests Supplier to deliver Contracted Product to Customer’s warehouse.

**Drug Product**means drug products containing Pancreatin for sale worldwide.

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**Lead Time** means the time mutually agreed upon (as specified in Appendix 3) for each individual Contracted Product, in advance of any requested Delivery Date, by which an Order must be placed by Customer for Supplier to be obligated to deliver by the Delivery Date under this Contract.

**Marketing Authorization** means any approvals, authorizations, licenses or registrations from a relevant health authority for the distribution, promotion, marketing and sale of a drug product.

**Order** means the written purchase orders by fax or by e-mail placed by Customer to Supplier as defined in Article 3.2.

**Quality Agreement** (attached to this *Contract*as Appendix 4) means the agreement between Supplier and Customer defining the roles and responsibilities of the Supplier’s Quality Department when providing services for Customer. This agreement also defines how the Supplier’s and Customer’s Quality Departments will interact with each other.

**Recall** means any action to recover title or possession or halt distribution, prescription, or consumption of Contracted Product or Drug Product sold or shipped to third parties. The term “Recall” also applies to Contracted Product or Drug Product due to non-conformities identified in the Contracted Product that would have been subject to recall if it had been shipped.

**Regulatory Authorities**means the US FDA, the European authorities (the EMEA and competent authority of each single EU member state), and any other regulatory authority where a request for Marketing Authorization of a drug product containing the Contracted Product has been or will be filed or Marketing Authorization has been or will be obtained,

**Service Level** means the level of service that the Supplier guarantees to the Customer according to Article 3.5.

**Article 1**

**Subject of the Contract**

1.1 This *Contract*is for the non-exclusive purchase by *Customer*from *Supplier*and the non-exclusive sale by *Supplier*to *Customer*of the active pharmaceutical ingredient Pancreatin (hereafter called the **Contracted Product)**as set out in the *Specifications*attached to this *Contract*as Appendix 1 (the **Specifications).**The *Specifications*also include the different *Customer*codes of the *Contracted Product.*

1.2 *Customer*undertakes to purchase from *Supplier*at least [\*]% of *Customer’s*requirements of *the Contracted Product*having *Customer*codes 0001785 (or any future code relating to the code 0001785 N-API quality) and 0001786. *Supplier*undertakes to supply *Customer*with up to 100% of *Customer’s*total requirements of the *Contracted Product,*if requested by *Customer.*Given the strategic importance of the *Drug Product*for *Customer,*it is *Customer’s*intention and strategy not to be dependent on one supply source, but to have alternative suppliers of the *Contracted Product.*

1.3 *Supplier*recognizes the right of the *Customer*to purchase up to 100% of all its requirements of the *Contracted Product*from other suppliers (the *Customer*being thereby released from its obligations under Article 1.2) should *Supplier*be unable to supply *Customer*with the *Contracted Product*both in terms of quantity and quality. However, *Customer*shall use its

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reasonable commercial efforts to reinstate its obligation under Article 1.2 as soon as *Supplier*is once again able to supply the *Contracted Product*to *Customer*in accordance with the quantity and quality requirements of this *Contract.*Subject to Article 8 *Supplier*shall indemnify *Customer*for any amount paid to the alternative supplier exceeding the agreed upon price. Such indemnity will not apply to the first *Order*that *Supplier*has been unable to supply in accordance with this *Contract.*

1.4 *Customer*shall be entitled to modify the *Specifications*at any time in the event that such modification is necessary or expedient based upon post-approval regulatory requirements. In any other circumstances, *Customer*may modify the *Specifications*with the approval of *Supplier,*which approval shall not be unreasonably withheld. In the event that such modifications have a significant impact on the price of the *Contracted Product*or the manufacturing time, the Parties shall negotiate in good faith to amend this *Contract*to reflect the new price and/or manufacturing time.

The *Customer’s*share of costs for modifying the *Specifications*shall be established by the Parties taking into account (a) the possibility for the *Supplier*to also share such costs with its other customers and (b) that *Customer*shall not be responsible for the entire or a disproportionate share of such cost.

The *Supplier*undertakes to timely modify the *Specifications*even if the negotiations between the Parties regarding the new price and manufacturing time are still pending.

If the Parties cannot, in good faith, agree upon a price and/or manufacturing time for the modified products within three months of the date of the *Customer’s*or competent authority’s written request for a modification of the *Specifications,*then the *Contract*will remain in force but *Customer*shall be released from its obligations under Article 1.2.

1.5 Any new agreed upon *Specifications,*or new Pancreatin based products with the agreed upon prices, will automatically be an integral part of the *Contract*and included in Appendix 1 – “Specifications of the Contracted Product” and Appendix 2 – “Determination of the Prices”.

**Article 2**

**Supply**

2.1 *Supplier*undertakes to supply the requirements of *Customer*for the *Contracted Product*in accordance with Articles 1 and 3 for the term of the *Contract*as set out in Article 9. Under no circumstance shall *Supplier*subcontract or otherwise delegate its obligations under this *Contract*to any third party, including any *Affiliate,*without the prior written approval of *Customer.*

2.2 Any (previously authorized) sub-contract executed by *Supplier*in connection herewith shall be fully consistent with the provisions of this *Contract*and any relevant Sale/Purchase Contract, including *Customer’s*right of access to any of the sub-contractors’ facilities.

2.3 *Supplier*shall be and remain in any case fully and solely responsible for any delay or any failure in the performance of this *Contract*or any Sale/Purchase Contract, even when directly or indirectly attributable to the responsibility of any of its sub-contractors.

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**Article 3**

**Forecast and orders**

3.1 Exclusively in order to facilitate *Supplier*in carrying out production planning appropriately, *Customer*will provide *Supplier*with a non-binding estimate of *Customer’s*annual requirements for the *Contracted Product*for each calendar year by September 30th of the previous calendar year. A more detailed non-binding forecast shall be given by *Customer*to *Supplier*by October 31st of each calendar year, setting out the anticipated quantities on a month by month basis. Such forecast shall be updated quarterly by *Customer,*and sent to *Supplier*two months before the end of the calendar quarter prior to the calendar quarter to which such estimate relates. None of such estimates however will constitute a binding order by the *Customer.*The sole document which shall be binding upon the *Customer,*shall be any purchase order issued pursuant to Articles 3.2 and 3.3.

3.2 *Customer*will place firm written purchase orders by fax or by e-mail (hereafter “**Order**”) with *Supplier*for the *Contracted Product,*specifying the quantity and the Customer Code of the ordered *Contracted Product,*no later than the designated *Lead Time*(as foreseen in Appendix 3) before the required *Delivery Date.*The *Delivery Date*set out in the *Order*is the date upon which delivery is to be made to the *Customer’s*warehouse. *Supplier*shall deliver the *Contracted Product*so ordered on the *Delivery Date,*or not earlier or not later than five (5) working days with respect to the *Delivery Date*designated on the applicable *Order*unless otherwise provided below. *Supplier*will acknowledge receipt of the *Order*by sending an *Order*confirmation to *Customer*by fax or e-mail within one (1) week of receipt of the *Order.*However, such confirmation to *Customer*shall be required for information purposes only since the receipt by *Supplier*of an *Order*(provided that it is in accordance with the provisions of this *Contract)*shall entail the immediate and automatic execution of a sale/purchase contract for the relevant ordered *Contracted Product*(each, **a Sale/Purchase Contract**) which shall be governed by this *Contract*and the specific provisions of the *Order.*

3.3 *Customer*will be entitled to place *Orders*for amounts exceeding the quarterly estimated quantities as set out in Article 3.1 above. In such case, the *Supplier*shall be obligated to fulfill such *Orders*up to a maximum of [\*] above such quarterly estimate in accordance with the terms of this *Contract,*as set out in Article 3.2. For any quantities ordered in excess of [\*]% of the quarterly estimate, *Supplier*will use its reasonable commercial efforts to supply these additional requirements as close to the specified *Delivery Date*as possible and will inform *Customer*within one (1) week of receiving the *Order*on which date such additional quantities of *Contracted Product*(i.e. in excess of [\*]) will be delivered. Notwithstanding the above, *Supplier*shall supply the excess quantity no later than the beginning of the immediately following calendar quarter provided that there is not less than eight (8) weeks until that date. *Customer*however has the right to cancel the *Order*and order the relevant *Contracted Product*from another supplier if such a delay is not acceptable and must inform the *Supplier*of such cancellation immediately.

3.4 Independently of that which is provided for in Art. 3.3, *Supplier*shall continuously keep a security stock free of charge for each *Customer*code of the *Contracted Product,*of a total quantity that corresponds to the average consumption foreseen for a period of 3 months as determined in the *Customer’s*forecast applicable from time to time, in order to satisfy both unforeseen and urgent requests from *Customer*and to be able to supply ordered *Contractual Product*should *Supplier*have any production problems for whatever reason.

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Should the *Drug Product*only be allowed by the FDA to be manufactured with *Contracted Product*only originating from US and / or Canadian glands, the *Supplier*undertakes to execute long tern supply contracts with suppliers of porcine glands of American and / or Canadian origin in order to ensure the availability of such glands to manufacture the *Contracted Product.*

3.5 With the exception of ‘Force Majeure’ events pursuant to Article *8, Supplier*guarantees the following service level (hereinafter called the **Service Level):**

(a) Subject to the specified *Lead Time,*85% of any *Contracted Products*subject of *Orders*received from *Customer*in any calendar year shall be delivered no later than the required *Delivery Date.*In the event that any *Order*contains requirements for more than one code of the *Contracted Product, Supplier*shall be obliged to supply by the required *Delivery Date*a minimum of 85% (eighty-five percent) of each ordered code.

(b) Subject to Articles 3.1 and 3.2, the delivery of all other *Contracted Product*subject of *Orders*(i.e. the remaining 15%) which are not delivered by the required *Delivery Date,*shall be delivered by no more than two (2) weeks from the required *Delivery Date.*In such a case, *Customer*will be notified as soon as possible in writing by *Supplier*of the actual date of delivery of such delayed *Contracted Product.*

(c) In the event that any portion of any lot of delivered *Contracted Product*is incomplete or does not meet the *Specifications,*the entire lot will be considered defective and not to have been delivered by the *Delivery Date,*provided that the defect in the lot is due to the fault of *Supplier.*

Should the *Service Level*not be met in relation to any twelve month period (from January 1st to 31st December of each year), *Customer*shall be released from its purchase obligations under Article 1.2 in the following contractual year. If the *Service Level*is achieved in such following contractual year, the original purchase obligation as foreseen in Article 1.2 shall be reinstated starting from the subsequent year (e.g. *Service Level*not met during 2008, then *Customer*is released from its purchase obligations under Article 1.2 in 2009. If during 2009 the *Service Level*is met, the original purchase obligation as foreseen in Article 1.2 shall be reinstated starting from 2010).

**Article 4**

**Conditions of supply**

4.1 Deliveries of the *Contracted Product*shall be at *Customer’s*warehouse as indicated in the relevant *Order*(CIP, all costs included).

4.2 Without prejudice to Article 5, *Supplier*shall enclose in each lot of delivered *Contracted Product (Supplier*will use reasonable commercial efforts in good faith to use the minimum number of lots to fulfill *Orders*where the minimum lot shall be not less than [\*]) a certificate of compliance stating that the *Contracted Product*meets the *Specifications.*The minimum quantity of *Contracted Product*per *Order*shall be [\*]. The *Contracted Product*delivered by *Supplier*shall have at least [\*] of residual shelf life or retest period, as set out in the certificate of analysis referred to in Article 4.3 (for example, if the retest period is 6 months, *Customer*will not accept batches of *Contracted Product*that are due to be retested earlier than 4.8 months from their delivery).

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4.3 *Supplier*shall perform all the in-process and final release quality control tests and quality assurance reviews on the *Contracted Product*as are required by the *Supplier’s*last DMF (Drug Master File) for the in-process control tests and the *Specifications*for the final release tests, and shall certify in writing to *Customer*that each batch of the *Contracted Product*delivered to *Customer*was manufactured in conformity therewith and that the *Contracted Product*contained in each shipment complies with the *Specifications,*and the other terms and conditions of this *Contract.*All deliveries of *Contracted Product*by *Supplier*shall be accompanied by all appropriate documentation required under applicable laws in order for *Customer*to offer the *Contracted Product*for sale, including (i) a certificate of analysis as provided for by the cGMP and (ii) a quality assurance or quality control certification that the *Contracted Product*supplied hereunder has been manufactured in conformity with cGMPs and other applicable regulations, which will be added to the certificate of analysis form by *Supplier.*

4.4 *Customer*undertakes that it shall inspect each lot of the delivered *Contracted Product*promptly upon receipt at *Customer’s*plant, to verify that the lot is complete and was not damaged in shipment and will promptly inform *Supplier*of any non-compliance. *Customer*will subsequently test the *Contracted Product*in accordance with the *Specifications. Supplier*shall keep “reserve/retention” samples of *Contracted Product*under proper storage conditions as specified in cGMPs (Eudralex, volume 4, part II, chapter 11.7) and will be responsible for all stability testing of the *Contracted Product,*as required to meet ICH (International Conference of Harmonization) requirements (as they may be amended from time to time).

4.5 In the event of deviations from the *Specifications*or shortages being found during the *Customer’s*tests as provided for in Article 4.4, *Customer*shall send a report to *Supplier*as soon as possible and in any event within four (4) weeks of receipt of the *Contracted Product*at *Customer’s*warehouse. Should *Supplier*and *Customer*agree that the claim is valid, *Supplier*undertakes to supply *Customer*free of charge and as soon as possible (but in any event not later than two (2) weeks at *Customer’s*warehouse from the date of the notice of claim) with a replacement quantity of the *Contracted Product. Supplier*shall also reimburse to *Customer*all shipping costs and expenses incurred by it arising out of or in connection with the claimed non-compliance of the *Contracted Product*delivered by *Supplier.*

Any dispute arising between *Customer*and *Supplier*concerning the conformity of any delivery of *Contracted Product*with the *Specifications*which cannot be settled between the two Parties, shall be submitted to an independent expert appointed by both Parties and the relevant cost will be borne by the Party in default.

The decision of said expert shall be binding on *Supplier*and *Customer.*However, in the event of dispute and whilst awaiting the decision of the expert, *Supplier*undertakes to supply *Customer*as soon as possible, but in any event not later than two (2) weeks at *Customer’s*warehouse from the date of the notice of claim, with a replacement quantity of the *Contracted Product.*

The charges, including the fees and expenses of the expert, relating to any dispute described in this paragraph shall be paid by *Supplier*if the expert declares the delivery not to be in conformity with the *Specifications*and/or the relevant *Order*and by *Customer*if the expert declares the delivery to be in conformity with the *Specifications*and/or the relevant *Order.*The sole remedy for shortages of the *Contracted Product*or the rejection of *Contracted Product*that does not meet the *Specifications*shall be *Supplier’s*supply of replacement *Contracted Product*as soon as possible and reimbursement of costs in accordance with this Article 4.5.

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4.6 Upon request of *Customer, Supplier* agrees to provide *Customer* with the documentation described in the *Quality Agreement.*

4.7 The execution by *Customer*of any inspection or test, as well as of any other document released upon any inspections and tests made at any time on the *Contracted Product*shall not discharge *Supplier*from any of its obligations and liabilities under Article 5 “Warranties”, or from any liability or responsibility deriving from the existence or the subsequent arising out or discovery of any defect, damage, discrepancy, lack of quality or irregularity affecting the *Contracted Product.*

**Article 5**

**Warranties**

5.1 Without prejudice to its obligations to supply *Customer*with up to 100% of *Customer’s*total requirements of the *Contracted Product,*if requested by *Customer. Supplier*warrants a production capacity of up to [\*] metric tons p.a. Should *Customer*require quantities exceeding the [\*]mt p.a., the Parties will make specific agreements in good faith to meet *Customer’s*requirements.

5.2 *Supplier*warrants to have all the authorizations, licenses and permits necessary to carry out the activities contemplated by this *Contract*and, generally, to perform all its obligations provided for hereunder and that it shall operate in full compliance with the laws and regulations applicable from time to time, also in the future, in relation to this *Contract.*Without prejudice to the generality of the foregoing, *Supplier*undertakes to seek to obtain approved supplier status from the FDA, EMEA and every local competent authority as an API manufacturer for the USA, Europe and other markets, to pass any regulatory inspection and undertakes to continuously satisfy all the relevant necessary regulatory requirements and maintain a “state of conformity” to the cGMP regulations (FDA, EU and other markets) for the purposes of maintaining such regulatory approval.

5.3 *Supplier* warrants that the *Contracted Product* shall, when delivered to *Customer,* be free from defects of any kind (including materials, workmanship and manufacturing process) and comply with the *Specifications*.

5.4 *Supplier*warrants that the *Contracted Product*shall be produced in a facility and in a manner compliant with current EU and US cGMP and all other applicable laws and in accordance with the *Quality Agreement.*Furthermore, *Supplier*warrants that its personnel that will carry out the activities contemplated by this *Contract*shall have the necessary qualifications, skills and organization to correctly perform such activities and will not need to sub-contract any of them. *Supplier*also warrants the availability of the necessary number of its personnel to duly carry out such activities. *Supplier*also represents and warrants that it complies and shall comply with all laws and regulations applicable from time to time, also in the future.

5.5 *Supplier*further warrants that upon delivery to *Customer’s*warehouse the *Contracted Product*will not have been adulterated or misbranded in any way.

5.6 *Supplier*warrants that the *Contracted Product*worldwide will not infringe or violate any patent or other industrial or intellectual property right of any third party.

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5.7 *Supplier’s*warranty obligations under this Article 5 shall continue as to each delivered *Contracted Product*for a period of [\*] years from its delivery to *Customer.*

5.8 Each Party represents that it has maintained and shall maintain during the term of this *Contract,*as well as four years after termination of this *Contract,*sufficient product liability insurance, with appropriate policy limits, to cover the risks associated with the performance of its obligations under this *Contract,*but in any event each Party shall maintain pharmaceutical product liability insurance with limits not less than [\*] per claim / per year and [\*] per year in the aggregate for bodily injury (including death) and consequential damage. Each Party agrees to provide the other Party with copies of certificates of insurance, when applicable, upon request as written evidence of such coverage.

5.9 *Supplier* will maintain appropriate records to enable the immediate identification of *any* batches of the *Contracted Product*delivered to *Customer*.

**Article 6**

**Delivery price**

6.1 The price of the *Contracted Product* and the rules that discipline the price are specified in Appendix 2 of this *Contract*.

**Article 7**

**Payment conditions**

7.1 The price for the *Contracted Product*shall be paid within 60 days from the date of the *Supplier’s*invoice, which shall be issued by the *Supplier*not earlier than the date of shipment of the relevant *Contracted Product.*

7.2 *Customer*shall be entitled to set-off (if it is the case also on a provisional basis) any amount due to *Supplier*hereunder (and at any rate suspend the relevant payment pursuant to Article 1460 of the Italian Civil Code) against any amount which is or may become due by *Supplier*to *Customer*under this *Contract.*

**Article 8**

**Force Majeure**

8.1 Each of the Parties shall be excused from the performance or delay in performance of its obligations under this *Contract*in the event such performance is prevented by Force Majeure (as defined in the next sentence) and such performance shall be excused as long as the condition constituting such Force Majeure continues plus an additional thirty (30) days after termination of such condition; provided, that the non-performing Party shall provide prompt notice to the other Party of the particulars of the occurrence constituting Force Majeure and of its cessation and the non-performing Party uses commercially reasonable efforts to remove the hindrance and to fulfill its obligations. Force Majeure shall mean any cause or causes which wholly or partially prevent or delay the performance of obligations arising under this *Contract*and which are not reasonably within the control of the non-performing Party, including Acts of God, government regulations, labor disputes (only at national level), floods, fires, civil commotion, embargoes, shortage of labor or materials due to disease or pestilence, or any delays in transportation or detention by customs, health or other government authorities.

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**Article 9**

**Duration of contract - Termination**

9.1 This *Contract*shall come into force (the **Effective Date)**from the date of the *Marketing Authorization*grant of the *Drug Product*in the USA and will expire on the fifth (5th) anniversary of such date, unless earlier terminated as set forth in Article 9.2. It is hereby agreed that one year before the expiration date the Parties shall meet to discuss and negotiate the possible extension or renewal of this *Contract.*The Parties recognize that the date of registration and the subsequent *Drug Product*launch very much depend on the collaboration between the Parties and the preparation by both Parties of the data to be provided to the FDA. The *Customer*foresees the date of registration as taking place by 28th April 2008.

9.2 An event of default under this *Contract*shall be deemed to exist upon the occurrence of any one or more of the following events:

(a) failure by *Supplier*to correctly and fully perform any of its obligations under Articles 1.1, 1.2,3,4.2, 10, 12.3 and 12.5.

(b) failure by *Customer* to correctly and fully perform any of its obligations under Articles 1.2, and 10.4.

(c) failure by either Party hereto to perform fully any material provision of this *Contract*and such breach continues (i) for a period of sixty (60) days after notice of such non-performance or (ii) if the non-performing Party shall commence within such sixty (60) days and shall thereafter proceed with all due diligence to cure such failure and such failure is not cured within such longer period (not to exceed sixty (60) days) as shall be reasonably necessary for such Party to cure the same with all due diligence;

(d) either Party liquidates its business; there is a request to appoint a receiver, administrator or similar officer over any of such Party’s assets or business; a Party makes an arrangement for the benefit of its creditors; or a Party goes into liquidation or is submitted to any other insolvency procedure.

9.3 Upon the occurrence and during the continuation of any event of default hereunder, the Party not in default shall have the right, at its option, to terminate this *Contract*in whole or terminate only the Sale/Purchase Contract affected by the event of default and to pursue any other remedies provided under this *Contract*or now or hereafter existing under the applicable law.

**Article 10**

**Recall**

10.1 In the event of an actual or threatened *Recall*of the *Drug Product*required or recommended by a governmental agency or authority of competent jurisdiction, or if a *Recall*is reasonably deemed advisable by either Party, or jointly deemed advisable by both Parties, such *Recall*shall be promptly implemented and administered by *Customer*in a manner which is appropriate and reasonable under the circumstances and in conformity with accepted trade practices. The *Costs*of any such *Recall*shall be borne by the Party or Parties whose actions or omissions caused the *Recall*to be necessary. *Supplier*shall have no obligation to pay *Costs*of a *Recall*to the extent such *Recall*is (a) caused

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| [\*] | Confidential treatment requested. |

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by actions of third parties occurring after such *Drug Product*is sold by *Customer;*(b) due to packaging or labeling defects for which *Supplier*has no responsibility; or (c) due to any other breach by *Customer*of its duties under this *Contract,*unless such *Recall*is due to a breach by both *Supplier*and *Customer*of their duties under this *Contract.*

10.2 If any *of Supplier, Customer*or any governmental authority having jurisdiction requires or reasonably requests *a Recall*due to a defect in the manufacture, processing, packaging or labeling of the *Contracted Product*or *Drug Product*caused in whole or in part by *Supplier*(a**Recall Defect),**the most diligent Party shall immediately notify the other Party thereof. Prior to commencing *any Recall, Customer*shall review with *Supplier*the cause for *a Recall,*and if such *Recall*is the responsibility of *Supplier*as a result of a *Recall*Defect caused by *Supplier,*the proposed manner in which *Customer*shall conduct the *Recall.*If the *Recall*is caused in whole or in part by *Supplier, Supplier*shall assist *Customer*in the *Recall*in the manner agreed upon in as expeditious a manner as possible and in such a way as to cause the least disruption to business, and to preserve the goodwill and reputation of their respective customers.

10.3 With respect to *any Recall*caused by the negligence, mistake, fault, error or omission of *Supplier,*its *Affiliates,*or subcontractors (including any adulteration or misbranding of the *Contracted Product by Supplier,*or any introduction of the *Contracted Product*into commerce in violation of any applicable rule, statute, regulation or governmental requirement *by Supplier),*with respect to *any Recall*resulting from *a Recall*Defect caused by *Supplier, Supplier*shall:

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| (i) | reimburse *Customer*and its *Affiliates*for any and all losses and reasonable *Costs*directly incurred by *Customer*or its *Affiliates*in connection with the *Recall;*and |

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| (ii) | indemnify, save and hold *Customer*and its *Affiliates*harmless from and against any and all damages to or claims by third parties associated with or resulting from any such *Recall.* |

10.4 With respect to *any Recall*caused by the negligence, mistake, fault, error or omission of *Customer*or its *Affiliates*(including any adulteration or misbranding of the *Contracted Product by Customer,*or any introduction of the *Drug Product*into commerce in violation of any applicable rule, statute, regulation or governmental requirement *by Customer), Customer*shall:

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| (i) | reimburse *Supplier*and its *Affiliates*and subcontractors for any and all losses and reasonable *Costs*directly incurred by *Supplier*in connection with the *Recall;*and |

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| (ii) | indemnify, save and hold *Supplier* and its *Affiliates* and subcontractors harmless from and against any and all damages to or claims by third parties associated with or resulting from any such *Recall*. |

10.5 With respect to any*Recall*caused by the shared negligence, mistake, fault, error, or omission of *Supplier*and *Customer*or their *Affiliates*or subcontractors, the Parties shall share the losses and reasonable *Costs*of the *Recall*in the proportion of their relative negligence, mistake, fault, error or omission, and they shall indemnify one another and their*Affiliates*and subcontractors with respect to third party claims associated with or resulting from the *Recall*in the same proportion.

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| [\*] | Confidential treatment requested. |

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**Article 11**

**Indemnification**

11.1 *Supplier*shall indemnify, defend and hold harmless *Customer*and its *Affiliates,*and their respective officers, directors and employees from any liability (including liability for death or injury), damage, deficiency, loss, judgments, assessments and, *Costs*arising from or attributable to: *(a) Supplier’s*negligent acts or omissions, willful wrongful acts or breach of any of its representations, warranties, covenants or other obligations hereunder, or (b) product liability claims including personal injury and death resulting from the manufacture, use, or sale of the *Contracted Product*to the extent attributable to the responsibility of *Supplier.*The indemnification is to be limited as follows: [\*] per claim per year and up to a maximum of [\*] per year, including liability for death or injury.

11.2 *Customer*shall indemnify, defend and hold harmless *Supplier*and its *Affiliates,*its officers, directors and employees from *Costs*directly or indirectly arising from or attributable to: (a) *Customer’s*negligent acts or omissions, willful wrongful acts, breach of any of its representations, warranties, covenants or other obligations hereunder, or (b) product liability claims including personal injury and death resulting from the manufacture, use, or sale of the *Contracted Product*to the extent attributable to the responsibility of *Customer.*The indemnification is to be limited as follows: [\*] per claim per year and up to a maximum of [\*] per year, including liability for death or injury.

11.3 Promptly after the receipt by any Party entitled to indemnity hereunder of (i) any claim or (ii) the commencement of any action or proceeding, such person (the **Aggrieved Party)**will, if a claim with respect thereto is to be made against any Party obligated to provide indemnification pursuant to this Article 11 (the **Indemnifying Party),**give such Indemnifying Party written notice of such claim or the commencement of such action or proceeding and shall permit the Indemnifying Party to assume the defense of any such claim or any litigation resulting from such claim, and, upon such assumption, shall reasonably cooperate with the Indemnifying Party in the conduct of such defense. Failure by the Indemnifying Party to notify in writing the Aggrieved Party of its election to defend any such action within a reasonable time, but in no event more than fifteen (15) days after notice thereof shall have been given to the Indemnifying Party, shall be deemed a waiver by the Indemnifying Party of its right to defend such action. If the Indemnifying Party assumes the defense of any such claim or litigation resulting therefrom, the obligations of the Indemnifying Party as to such claim shall be limited to taking all steps necessary in the defense or settlement of such claim or litigation resulting therefrom. The Aggrieved Party may participate, at its expense, in the defense of such claim or litigation provided that the Indemnifying Party shall direct and control the defense of such claim or litigation. The Indemnifying Party shall not, in the defense of such claim or any litigation resulting therefrom, consent to entry of any judgment, except with the written consent of the Aggrieved Party (which shall not be unreasonably delayed or withheld), or enter into any settlement, except with the written consent of the Aggrieved Party (which shall not be unreasonably delayed or withheld), which does not include as an unconditional term thereof the giving by the claimant or the plaintiff to the Aggrieved Party of a release from all liability in respect of such claim or litigation. In addition, all awards and costs payable by a third party to the Aggrieved Party or the Indemnifying Party shall belong to the Indemnifying Party.

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| [\*] | Confidential treatment requested. |

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11.4 If the Indemnifying Party shall not assume the defense of any such claim or litigation resulting therefrom, the Aggrieved Party may defend against such claim or litigation in such manner as it may deem appropriate and, unless the Indemnifying Party shall deposit with the Aggrieved Party a sum equivalent to the total amount demanded in such claim or litigation, or shall deliver to the Aggrieved Party a surety bond in form and substance reasonably satisfactory to the Aggrieved Party in such amount, the Aggrieved Party may settle such claim or litigation on such terms as it may deem appropriate, and the Indemnifying Party shall promptly reimburse the Aggrieved Party for the amount of all expenses, legal or otherwise, incurred by the Aggrieved Party in connection with the defense against or settlement of such claim or litigation. If no settlement of such claim or litigation is made, the Indemnifying Party shall promptly reimburse the Aggrieved Party for the amount of any judgment rendered with respect to such claim or in such litigation and of all expenses, legal or otherwise, incurred by the Aggrieved Party in the defense against such claim or litigation.

11.5 The indemnification provided in this Article 11, subject to the limitations set forth herein, shall be the exclusive remedy for damages available to any Aggrieved Party and shall survive indefinitely the expiration or termination of this *Contract.*

**Article 12**

**Final Clauses**

12.1 *Supplier*shall give *Customer*prompt notice of any governmental audit of *Supplier*as it relates to the manufacture, production or testing of the *Contracted Product.*Further, *Supplier*shall provide *Customer*with any relevant documentation provided to it relating to any such audit. *Customer*shall have the right to audit and inspect the manufacturing facility of *Supplier*provided that such audit visits occur no more than once each calendar year per site and that *Customer*gives *Supplier*notice of a minimum of 8 weeks or as otherwise agreed to by the Parties prior to such visits, unless quality problems arise of such seriousness as to justify an unforeseen audit visit.

12.2 *Supplier*and *Customer*shall keep the other fully informed in writing of any notification or other information, whether received directly or indirectly, that might (i) affect the marketability, safety or effectiveness of any *Drug Product,* (ii) result in liability issues or otherwise necessitate action on the part of either Party or (iii) result in *Recall*or seizure of any *Contracted Product*or *Drug Product.*

12.3 *Supplier*shall promptly comply with all FDA and other *Regulatory Authority’s*filing and reporting requirements with respect to the *Contracted Product. Supplier*shall be responsible for any additional study relevant to any part of the drug substance section of Module 3 of the “Common Technical Document” that may be required during the registration process.

12.4 In the event that it is not possible to obtain registration of the *Drug Product*from the FDA or other health authority by 31th December 2010, other than for either Party’s default, both Parties will be entitled to terminate this *Contract*for convenience and no compensation, indemnification, or other payment shall be due by either Party to the other in connection with such termination.

12.5 This *Contract*and any and all information provided by one Party to the other pursuant to this *Contract*(including all information relating to duration and quantity and price of the *Contracted Product)*shall be deemed to be confidential information **(Confidential Information).**Each Party will hold

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| [\*] | Confidential treatment requested. |

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Confidential Information in complete confidence and will not, without the prior written consent of the other, use or disclose it in whole or in part to any person other than to those who are directly concerned with this *Contract.*The term “Confidential Information” shall not include information:

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| --- | --- |
| (i) | which at the time of disclosure to the other is in the public domain; |

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| (ii) | which after disclosure becomes generally available to third parties from a source other than the disclosing Party: provided that such source is not bound by a confidentiality or other similar agreement with the discloser or by any other legal contractual or fiduciary obligation which prohibits the disclosure of such Confidential Information; |

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| (iii) | which was lawfully in possession of the recipient prior to disclosure as evidenced by written records and which was not acquired directly or indirectly from the discloser; or |

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| (iv) | which the recipient is required to disclose under law or under the regulations of any Governmental entity or agency. |

The obligations in this Article 12.5 shall expire on the fifth (5th) anniversary of the expiration or termination of this *Contract.*

12.6 This *Contract* may only be amended or extended in writing.

12.7 If individual clauses of this *Contract*should be or become invalid, then the remainder of the *Contract*continues to be valid. In this case, the legally admissible regulation or action that has the closest financial effect to the invalid clause shall be substituted for the invalid clause.

12.8 This *Contract*shall be binding upon and inure to the benefit of the Parties hereto and their respective permitted successors and assigns. This *Contract*may be assigned and delegated by *Customer*to *an Affiliate,*or in connection with any sale, merger or other business combination involving all or substantially all of *Customer’s*assets or capital stock. Except as set forth in the preceding sentence, neither this *Contract*nor *any*other rights or obligations hereunder shall be assigned or delegated by either Party without the prior written consent of the other Party.

12.9 This *Contract*and *any*Sale/Purchase Contracts shall be governed by and construed in accordance with the laws of Italy.

12.10 In the event of any dispute arising out of this *Contract*or any Sale/Purchase Contract, the Parties shall first seek to settle the dispute amicably by submitting such dispute to the respective Chief Executive Officers who shall seek an amicable commercial resolution to such dispute. In the event however that such dispute cannot be settled in such a way within three (3) calendar months of the dispute being brought to the attention of the respective CEO’s then the Parties shall submit such dispute to the courts as set out in Section 12.11 below.

12.11 Each of the Parties hereby submits to the exclusive jurisdiction of the Court of Milan for the determination of any question or dispute arising under or in connection with the *Contract*or any Sale/Purchase Contract.

12.12 This *Contract,*including the Appendices attached hereto constitute the entire understanding and agreement of the Parties, and shall supersede any prior written or oral

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| [\*] | Confidential treatment requested. |

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agreement or understanding between the Parties, including without limitation general terms and conditions of sale of *Supplier.*In the event of conflict between the provisions of this *Contract*and/or any of its Appendixes or any Sale/Purchase Contract the following hierarchy shall apply: (1), this *Contract,*(2) the *Specifications,*(3) the other Appendixes hereto and (4) the Sale/Purchase Contract.

12.13 *Supplier*hereby agrees that the *Specifications*as well as all the Confidential Information provided by the *Customer*to the *Supplier*regarding the *Contracted Product*are the exclusive property of *Customer*and cannot be disclosed to any third Party without prior written consent of *Customer*unless otherwise required by law and, in that case, only after giving *Customer*reasonable notice and a reasonable opportunity to move or petition the authority requiring such disclosure to implement measures to protect the Confidential Information.

12.14 The relationship between *Customer,*on the one hand, and *Supplier,*on the other hand, is that of independent contractors and nothing herein shall be deemed to constitute or create the relationship of partners, joint ventures nor of principal and agent between *Customer*and *Supplier.*Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any third party.

12.15 All communications information and notices required to be given under this *Contract*shall be sent by registered mail (return receipt requested), or delivered by hand to a duly authorised representative of the addressee. Such communications information and notices can also be sent by telefax (but in this case they must be confirmed by subsequent registered mail, return receipt requested). Such communication information and notices shall be sent to the following addresses, (or at such other address as either Party may notify to the other in the manner set forth in this Clause 12.15):

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|  | (a) | if to Supplier: |

Nordmark Arzneimittel GmbH & Co. KG

Pinnauallee 4

25436 Uetersen

Germany

Attention: Dr. Peter Tonne

Fax: 0049 4122 712 510

|  |  |  |
| --- | --- | --- |
|  | (b) | if to Customer: |

Eurand S.p.A.

Via Martin Luther King, 13

20060 Pessano con Bornago (MI)

Italy

Attention: Gearoid Faherty

Fax: 0039 02 95745018

IN WITNESS WHEREOF, the Parties have caused this *Contract*to be executed by their duly authorized representatives as of the day and year first above written.

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| [\*] | Confidential treatment requested. |

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|  |  |  |  |  |
| Uetersen, January 3, 2006 | | |  | Milan, January 3, 2006 |
| Nordmark Arzneimittel GmbH & Co. KG | | |  | Eurand S.p.A. |
|  |  | |  | |
| Mr. Franz Empl |  | Dr. Jorn Tonne |  | Mr. Gearoid Faherty |
| Chief Financial Officer |  | Vice President  Marketing & Sales |  | Chief Executive Officer |
|  |  | |  | |
| /s/ Franz Empl |  | /s/ Jom Tome |  | /s/ Gearoid Faherty |
|  |  |  |  |  |

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| [\*] | Confidential treatment requested. |

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**APPENDIX 1 - SPECIFICATIONS OF THE CONTRACTED PRODUCT**

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| [\*] | Confidential treatment requested. |

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**APPENDIX 2 - DETERMINATION OF THE PRICES**

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| (i) | The price of the *Contracted Product*(the Price) shall be agreed upon by the Parties in good faith by the Effective Date. Negotiations will start six months before the expected Effective Date. |

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| (ii) | [\*] |

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| --- | --- |
| (iii) | [\*] |

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| --- | --- |
| (iv) | The Price of the *Contracted Product* will be denominated and paid in US$. |

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| (v) | The Parties agree that the Price offered *by Supplier*to *Customer*will be calculated according to: |

[\*]

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| --- | --- |
| [\*] | Confidential treatment requested. |

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**APPENDIX 3 - LEAD TIME**

Provided that there is no other agreement made for any *Orders,*the standard delivery date for the *Contracted Product*shall be [\*] calendar months from the date of receipt of the *Customer’s*Order by *Supplier.*

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| [\*] | Confidential treatment requested. |

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