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Letterhead of the *AIFA - Agenzia Italiana del Farmaco* (Italian Medicines Agency)
GMP INSPECTION AND AUTHORISATION OFFICE - MEDICINAL PRODUCTS

Rome, 22/05/2019
No. aM – 76/2019

THE DIRECTOR

IN VIEW OF Art. 48 of Law Decree No. 269 dated 30 September 2003 converted into Law No. 326 dated 24 November 2003 establishing the *Agenzia Italiana del Farmaco* (Italian Medicines Agency);
IN VIEW OF Legislative Decree No. 219 dated 24 April 2006 implementing "Directive 2001/83/EC (and subsequent amending directives) on a Community code relating to medicinal products for human use, as well as Directive 2003/94/EC";
IN VIEW OF Legislative Decree No. 211 dated 24 June 2003, implementing "Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use";
IN VIEW OF Legislative Decree No. 200 dated 6 November 2007, indicating "Implementation of directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products";
IN VIEW OF Ministerial Decree dated 18 March 1996, that envisages the submission by the companies holding manufacturing authorisations for medicinal products, of precise and exhaustive documentation relating to the production activities of each pharmaceutical plant;
IN VIEW OF the documents on file relating to the manufacturing authorisations for MEDICINAL PRODUCTS previously issued in favour of the company **FINE FOODS & PHARMACEUTICALS N.T.M. S.P.A.;**
IN VIEW OF the application sent by said company, on 29 Oct. 2018, Index No. 118949, for its pharmaceutical plant located in BREMBATE (BG), VIA GRIGNANO 43, regarding the authorisation of new departments for granule production, with the installation of equipment transferred from the Nembro site and a new washroom, with annexed storage room with clean equipment and the authorisation of the production of hard gelatine capsules for the entire production cycle, with installation of equipment transferred from the Nembro site;
IN VIEW OF the outcome of the inspection carried out in the period from 25/02/2019 - 27/02/2019 at the pharmaceutical plant of the foregoing company located in BREMBATE (BG), VIA GRIGNANO 43;

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IN VIEW OF the documentation received on 15/03/2019, Prot. No. 30684, concerning the response to the infractions observed during inspection,

IN VIEW OF the report to the Public Prosecutor at the Bergamo Tribunal on 20/03/2019, Prot. No. AIFA/GMPMED/P/32206;

IN VIEW OF the authorisation letter of 05/04/2019 Prot. No. AIFA/GMPMED/P/39289, concerning the authorisation of a new department for the packaging of granulated products in sachets (line Marchesini M10);

CONSIDERING it possible to give consent for the requests made by said company

HEREBY AUTHORISES

the Company:

FINE FOODS & PHARMACEUTICALS N.T.M. S.P.A.
VIA BERLINO 39, ZINGONIA
24040 – VERDELLINO (BG)
Tax reg. code: 09320600969

to manufacture MEDICINAL PRODUCTS at its pharmaceutical plant:

FINE FOODS & PHARMACEUTICALS N.T.M. S.P.A.
VIA GRIGNANO, 43
24041 BREMBATE (BG)

as indicated in the manufacturing authorisation No. aM - 76/2019 dated 22/05/2019 attached hereto.

The foregoing Authorisation is issued exclusively pursuant to the regulations pertaining to the production of medicinal products and in no case exonerates the authorisation holder from complying with all other applicable regulations.

The attached Authorisation is issued in 2 originals, one of which stays filed with this Office while the other is served to the company holding the authorisation; it replaces any previously issued authorisations, rendering them null and void.

Rome, 22/05/2019

The Director
Renato Massimi
(signed)
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MANUFACTURING AUTHORISATION

1. Authorisation number:	aM – 76/2019
2. Name of the authorisation holder:	FINE FOODS & PHARMACEUTICALS N.T.M. S.P.A.
3. Address(es) of the production plant(s):	FINE FOODS & PHARMACEUTICALS N.T.M. S.P.A. – VIA GRIGNANO, 43 - 24041 BREMBATE (BG) BRANCH – VIA BERLINO, 39 – 24040 – VERDELLINO (BG)
4. Legal address of the authorisation holder:	VIA BERLINO 39, ZINGONIA 24040 – VERDELLINO (BG)
5. Purpose of the authorisation and pharmaceutical formats:	Manufacturing activity: see Annex 1, Part 1 Production of Experimental Medicinal Products: Annex 2 Part 1
6. Legal grounds for authorisation:	Directive 2001/83/EC, Directive 2001/20/EC, Directive 2005/28/EC, implemented through Legislative Decree No. 219 dated 24 April 2006 and subsequent amendments and additions, Legislative Decree No. 211 of 24 June 2003, Legislative Decree No. 200 of 6 November 2007
7. Name of the official of the Competent Authority of the Member State issuing the manufacturing authorisation:	Dott. Renato Massimi *Round stamp*: Italian Medicines Agency
8. Signature:	*(signed)*
9. Date:	22/05/2019
10. Annexes:	Annex 1 and Annex 2 Annex 5 (Name of Qualified Person) Annex 7 (Date of inspection for issuance of the authorisation, purpose of last inspection)

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ANNEX 1

PURPOSE OF AUTHORISATION

Name and address of the production site: FINE FOODS & PHARMACEUTICALS N.T.M. S.P.A. - VIA GRIGNANO, 43 - 24041 BREMBATE (BG)

Human Medicinal Products

Authorised Activities	
Manufacturing Activities (Part 1)	
Part 1 – MANUFACTURING ACTIVITIES	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products 1.2.1.1 Hard capsules 1.2.1.8 Other solid pharmaceutical formats 1.2.1.13 Tablets *1.2.2 Lot certification*
1.3	**Organic medicinal products**
	1.3.1 Organic medicinal products 1.3.1.6 Made from human or animal extracts *1.3.2 Lot certification* 1.3.2.6 Made from human or animal extracts
1.4	**Other products or other production activities**
	1.4.1 Production of 1.4.1.1 Plant products
1.5	**Packaging**
	1.5.1 Primary packaging 1.5.1.1 Hard capsules 1.5.1.8 Other solid pharmaceutical formats 1.5.1.13 Tablets *1.5.2 Secondary packaging*
1.6	**Quality control tests**
	1.6.2 Microbiological: different from sterility *1.6.3 Chemical/physical*

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Restrictions or clarifications regarding manufacturing operations

1.2.1.8 Other solid pharmaceutical formats: powders and granules; also products made from human or animal extracts

1.3.1.6: Products made from human or animal extracts: products made from animal extracts: powders and granules

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1.3.2.6 Products made from human or animal extracts: products made from animal extracts: powders and granules
1.4.1.1 Plant products: powders and granules
1.5.1.8 Other solid pharmaceutical formats: powders and granules

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ANNEX 1

PURPOSE OF AUTHORISATION

Name and address of the production site: BRANCH – VIA BERLINO, 39 – 24040 VERDELLINO (BG)

Human Medicinal Products

Authorised Activities	
Manufacturing Activities (Part 1)	
Part 1 – MANUFACTURING ACTIVITIES	
1.6	**Quality control tests**
	1.6.2 Microbiological: different from sterility *1.6.3 Chemical/physical*

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ANNEX 2

PURPOSE OF AUTHORISATION

Name and address of the production site: FINE FOODS & PHARMACEUTICALS N.T.M. S.P.A. – VIA GRIGNANO, 43, 24041 BREMBATE (BG)

Human Medicinal Products

Authorised Activities Manufacturing Activities (Part 1)	
Part 1 – MANUFACTURING ACTIVITIES FOR EXPERIMENTAL MEDICINAL PRODUCTS	
1.2	**Non-sterile products**
	1.2 *Non-sterile products* 1.2.1.1 Hard capsules 1.2.1.8 Other solid pharmaceutical formats 1.2.1.13 Tablets *1.2.2 Lot certification*
1.5	**Packaging**
	1.5.1 Primary packaging 1.5.1.1 Hard capsules 1.5.1.8 Other solid pharmaceutical formats 1.5.1.13 Tablets *1.5.2 Secondary packaging*
1.6	**Quality control tests**
	1.6.2 Microbiological: different from sterility *1.6.3 Chemical/Physical*

Restrictions or clarifications regarding manufacturing operations

1.2.1.8 Other solid pharmaceutical formats: powders and granules;

1.5.1.8 Other solid pharmaceutical formats: powders and granules;

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ANNEX 2

PURPOSE OF AUTHORISATION

Name and address of the production site: BRANCH – VIA BERLINO, 39 – 24040 VERDELLINO (BG)

Human Medicinal Products

Authorised Activities	
Manufacturing Activities (Part 1)	
Part 1 – MANUFACTURING ACTIVITIES FOR EXPERIMENTAL MEDICINAL PRODUCTS	
1.6	**Quality control tests**
	1.6.2 Microbiological: different from sterility *1.6.3 Chemical/physical*

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ANNEX 5

Name(s) of qualified person(s): - MARIO BARBINI, born in PISA on 02/10/1956

- CESARE DOGNINI born in COLLEBEATO (BS) on 18/06/1960

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ANNEX 7

Date of inspection regarding authorisation issuance: 27/02/2019

Purpose of last inspection: General revision/Extension

MUNICIPALITY OF VERDELLINO (BG)

AUTHENTICATION OF COPIES, OF DEEDS AND DOCUMENTS

(Art. 18 of the Consolidated Act)

This is to certify that this copy, consisting of 10 sheets of paper, conforms to the original presented by Mr. RAMO FABIO, born in CAGLIARI on APRIL 15, 1977, identified through ID card Nr. AY957011 issued on 23/8/2018 – Municipality of BOLTIERE, warned of the penal sanctions he might be submitted to in case of false deed or deed containing data that are no longer correspondent to the truth.

Verdellino, 11 June 2019

Reg. No. 1572 THE OFFICIAL IN CHARGE Angela Grazia Grasselli

(*signed*)

Secretarial fees. € 0.52

Stamp duty paid: € 16.00

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On the right side of each page:

- *Stamp*: The Official in charge Angela Grazia Grasselli (*signed*)
- *Round stamp*: Municipality of Verdellino (BG)

Between pages:

- *Round stamp*: Italian Medicines Agency
- *Round stamp*: Municipality of Verdellino (BG)

PC- File Code: aM530/2018

Trento, 17.06.2019