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EUROPEAN BATCH RELEASE PROTOCOL

PRODUCT: **BIORAL H120 NEO**

MEMBER STATE SPECIFIC INFORMATION

Batch number of finished product: 17BLPA21A

Release date of finished product: 10-Apr-2017

Marketing authorisation number: 3718/2/16 NÉBIH ÁTI

Issued by: NÉBIH

Target species: Chickens

Total number of containers in this batch: 249 Boxes of 1 blister

Number of containers the release is applied for: 249 Boxes of 1 blister

Number of doses per container: 10 tablets of 2000 doses per blister

Number of samples for the competent authority: Available upon request

Date of expiry: 26-Jul-2018

Name and Address of Marketing Authorisation Holder:

MERIAL
29, avenue Tony Garnier
69007 LYON
France

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SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Trade name: BIORAL H120 NEO

INN / PE name / common name of product: Avian infectious bronchitis (live) vaccine

Batch number of:

Finished product:	Final batch:	Final bulk:
17BLPA21A	17BLPT3A21	17BLPT0A20

Pharmaceutical form of finished product: Effervescent tablet

Type of final container: Blister of 10 tablets

Date of start of period of validity: 26-Jan-2017

Storage: 2°C-8°C

Name and address of manufacturer:

MERIAL
Lentilly
1, chemin de Cruzols
69210 Lentilly
FRANCE

Name and address of the batch release site :

MERIAL
Lyon Porte des Alpes
Rue de l'Aviation
69800 Saint Priest
FRANCE

CERTIFICATION BY THE MANUFACTURER

I herewith certify that batch BIORAL NEO n° 17BLPA21A was manufactured and tested according to the procedures approved by the competent authorities and complies with the quality requirement and that all measures have been taken to demonstrate compliance with Directive 2001/82/EC as amended by Directive 2004/28/EC.

Date: 12-Apr-2017

Signature

Dr Véronique SARRÈRE
Substitute Deputy Qualified Person
Merial Lyon