

Est. 196
1711-10

OUTLINE OF PRODUCTION

for

**NEWCASTLE DISEASE VACCINE
B1 TYPE, B1 STRAIN, LIVE VIRUS**

CODE 1711.10

U.S. VETERINARY LICENSE NO. 196
LOHMANN ANIMAL HEALTH INTERNATIONAL
WINSLOW, MAINE 04901

March 3, 2009
Supersedes P.O. dated March 5, 2008
Complete Revision

FILED with
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APR 24 2009

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U.S. Veterinary License No. 196

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Complete Revision

**NEWCASTLE DISEASE VACCINE
B1 TYPE, B1 STRAIN, LIVE VIRUS
CODE 1711.10**

IV. PREPARATION OF THE PRODUCT (continued)

G. Method and Technique of [redacted] The vaccine is kept [redacted] during the filling operation. A filling machine with a [redacted] is used to fill the final containers. [redacted] are placed loosely in the vials. [redacted] are applied after [redacted]

H. [redacted]

1. [redacted]
2. [redacted]

I. [redacted] Amount Per Dose In Final Container: The product shall contain a minimum of [redacted] expiration.

V. TESTING

A. [redacted] Tests:

1. [redacted]

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B1 TYPE, B1 STRAIN, LIVE VIRUS
CODE 1711.10**

V. A. TESTING (continued)

2. [redacted] Final
container samples are tested as prescribed in [redacted]. The
volume of media to be used is [redacted].
[redacted]

a. [redacted]
were accepted by [redacted] (b)(6) on February 22, 2000, based
on [redacted]

s/b "b" → d.
d. [redacted]
were accepted by [redacted] (b)(6) on May 10, 2007,
based on [redacted]

3. [redacted] Final container samples are
tested as prescribed in [redacted]

4. [redacted] Final container samples are
tested as prescribed in [redacted]

✓ 113.327
5. [redacted] Final
container samples are tested as prescribed in [redacted] except as
provided in [redacted] may be conducted in the
event of a [redacted]

6. [redacted] Final container samples are tested as prescribed in
[redacted]

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B1 TYPE, B1 STRAIN, LIVE VIRUS
CODE 1711.10**

V. TESTING (continued)

B. Safety Test: Final container samples are tested as prescribed in [redacted]

1. [redacted]

2. [redacted]

C. [redacted] Test:

1. Final container samples are tested as prescribed in [redacted]

2. [redacted] Tests:

a. [redacted]

(1) Route: [redacted]

(a) Age of Chickens: 2 weeks

(b) [redacted]

(c) Date Completed: May 5, 1977

(d) Date Accepted: February 1, 1978

(2) Route: [redacted]

(a) Age of Chickens: 2 weeks

(b) [redacted]

(c) Date Completed: May 5, 1977

(d) Date Accepted: February 1, 1978

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B1 TYPE, B1 STRAIN, LIVE VIRUS
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V. C. 2. a. TESTING (continued)

(3) Route: [REDACTED]

(a) Age of Chickens: 5 weeks

(b) [REDACTED]

(c) Date Completed: June 30, 1976

(d) Date Accepted: August 12, 1976

b. [REDACTED]

(1) Route: [REDACTED]

(a) Age of Chickens: 2 weeks

(b) [REDACTED]

(c) Date Completed: August 29, 1979

(d) Date Accepted: September 24, 1979

(2) Route: [REDACTED]

(a) Age of Chickens: 2 weeks

(b) [REDACTED]

(c) Date Completed: August 29, 1979

(d) Date Accepted: September 24, 1979

c. [REDACTED]

(1) Route: [REDACTED]

(a) Age of Chickens: 1 day

(b) [REDACTED]

(c) Date Completed: December 4, 1980

(d) Date Accepted: February 13, 1996

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V. C. 2. c. TESTING (continued)

(2) Route: [REDACTED]

(a) Age of Chickens: 2 weeks

(b) [REDACTED]

(c) Date Completed: June 7, 1994

(d) Date Accepted: December 21, 1994

3. [REDACTED] Requirements:

a. The minimum [REDACTED]

b. The minimum [REDACTED]

D. [REDACTED] Not applicable. [REDACTED]

E. Any Other Tests: Not applicable.

VI. POST PREPARATORY STEPS

A. Form and Size of Final Containers - The product is marketed in the following containers:

1. [REDACTED]

a. [REDACTED]

b. [REDACTED]

2. [REDACTED]

3. [REDACTED]

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Est. 196
17P510

OUTLINE OF PRODUCTION
FOR
**NEWCASTLE-PARAMYXOVIRUS VACCINE
TYPE 3, KILLED VIRUS**
Code 17P5.10

U.S. VETERINARY LICENSE NO. 196
LOHMANN ANIMAL HEALTH INTERNATIONAL
WINSLOW, MAINE 04901

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**NEWCASTLE-PARAMYXOVIRUS VACCINE, TYPE 3, KILLED VIRUS
CODE 17P5.10**

V. TESTING

A. [redacted] Tests:

1. [redacted] Pre-inactivation samples are tested as prescribed in [redacted]
2. [redacted] Final container samples are tested as prescribed in [redacted]
[redacted]
[redacted] accepted by [redacted] (b)(6) on July 31, 2007, based on [redacted]
3. [redacted] All samples are exempt from [redacted] The exemption was granted by [redacted] (b)(6) in an Outline of Production dated February 8, 1991.
4. All samples are exempt from [redacted] in accordance with [redacted] The exemption for [redacted] was granted to [redacted] but the date and authorizing official are unknown at this time. An exemption was granted to [redacted] (b)(6) [redacted] (b)(6) in a letter dated July 6, 1988 based on a study dated May 16, 1988. The study is applicable to this product.
5. All samples are exempt from [redacted] in accordance with [redacted] The exemption for [redacted] was granted to [redacted] but the date and authorizing official are unknown at this time. An exemption was granted to [redacted] (b)(6) [redacted] in a letter dated July 6, 1988 based on a study dated May 16, 1988. The study is applicable to this product.

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incorporated
a. into 2. ✓*

added ✓

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**NEWCASTLE-PARAMYXOVIRUS VACCINE, TYPE 3, KILLED VIRUS
CODE 17P5.10**

V. TESTING (continued)

B. Safety Tests:

1. [redacted] Final container samples are tested as prescribed in
[redacted] and the results are evaluated in accordance with
[redacted] *added ✓*

✓ Deleted a. + b. →

2. [redacted] The [redacted]
in paragraph C of this section will constitute a safety test. The results are
evaluated in accordance with [redacted] *added ✓*

✓ Deleted a. + b. →

C. [redacted] Tests:

1. [redacted] Final container samples are tested as prescribed in

a. [redacted]

b. [redacted]

2. [redacted] Final container samples of completed
product are tested as follows:

a. [redacted]

b. [redacted]

c. [redacted]

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CODE 17P5.10**

V. C. 2. TESTING (continued)

- d. [Redacted]
- e. [Redacted]
- f. [Redacted]
- g. [Redacted]
- h. [Redacted]
- i. [Redacted]

3. [Redacted]

4. [Redacted] Tests:

a. [Redacted]
study and date approved by APHIS are unknown.

b. [Redacted]
Efficacy study and date approved by APHIS are unknown.

D. [Redacted] Not applicable.

E. Other Tests: [Redacted] on completed bulk or final
containers in accordance with [Redacted]
[Redacted]

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Est. 196

S.O. 47

SPECIAL OUTLINE NO. 47

**MICROTEST METHOD FOR DETERMINING HI TITERS FOR
AVIAN PARAMYXOVIRUS VACCINE, TYPE 1, KILLED VIRUS AND
AVIAN PARAMYXOVIRUS VACCINE, TYPE 3, KILLED VIRUS**

U.S. VETERINARY LICENSE NO. 196
LOHMANN ANIMAL HEALTH INTERNATIONAL
WINSLOW, MAINE 04901

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**SPECIAL OUTLINE NO. 47
MICROTEST METHOD FOR DETERMINING HI TITERS
FOR AVIAN PARAMYXOVIRUS VACCINE, TYPE 1, KILLED VIRUS
AND AVIAN PARAMYXOVIRUS VACCINE, TYPE 3, KILLED VIRUS**

I. REAGENTS:

A. [Redacted]

1. [Redacted]

[Redacted]

2. Preparation:

a. [Redacted]

b. [Redacted]

c. [Redacted]

d. [Redacted]

e. [Redacted]

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**SPECIAL OUTLINE NO. 47
MICROTEST METHOD FOR DETERMINING HI TITERS
FOR AVIAN PARAMYXOVIRUS VACCINE, TYPE 1, KILLED VIRUS
AND AVIAN PARAMYXOVIRUS VACCINE, TYPE 3, KILLED VIRUS**

I. REAGENTS (continued)

from 1. ✓

B.

[Redacted]
[Redacted]
[Redacted]

*✓ format
of B.I. & a.c. and
2. a.c.*

2. d. ①

II. PROCEDURE:

A.

[Redacted]

1.

[Redacted]

2.

[Redacted]

3.

[Redacted]

4.

[Redacted]

5.

[Redacted]

6.

[Redacted]

7.

[Redacted]

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**SPECIAL OUTLINE NO. 47
MICROTEST METHOD FOR DETERMINING HI TITERS
FOR AVIAN PARAMYXOVIRUS VACCINE, TYPE 1, KILLED VIRUS
AND AVIAN PARAMYXOVIRUS VACCINE, TYPE 3, KILLED VIRUS**

II. A. PROCEDURE (continued)

8.

[Redacted]

9.

[Redacted]

10.

[Redacted]

- a.
- b.
- c.
- d.
- e.
- f.

[Redacted]

[Redacted]

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**SPECIAL OUTLINE NO. 47
MICROTEST METHOD FOR DETERMINING HI TITERS
FOR AVIAN PARAMYXOVIRUS VACCINE, TYPE 1, KILLED VIRUS
AND AVIAN PARAMYXOVIRUS VACCINE, TYPE 3, KILLED VIRUS**

II. PROCEDURE (continued)

B.

1. [Redacted]
2. [Redacted]
3. [Redacted]
4. [Redacted]
5. [Redacted]
6. [Redacted]
7. [Redacted]
8. [Redacted]

C. Confidentiality Statement: This entire special outline contains procedures and techniques developed by Lohmann Animal Health International and are considered confidential.

(b)(6)

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(b)(6)

Est. 196
12G5.43

OUTLINE OF PRODUCTION

for

**BURSAL DISEASE-NEWCASTLE DISEASE VACCINE
KILLED VIRUS**

Code 12G5.43

U.S. VETERINARY LICENSE NO. 196
LOHMANN ANIMAL HEALTH INTERNATIONAL
WINSLOW, MAINE 04901

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**BURSAL DISEASE-NEWCASTLE DISEASE VACCINE, KILLED VIRUS
CODE 12G5.43**

IV. PREPARATION OF THE PRODUCT (continued)

F. Volume of Fill – Final containers have the following recoverable fill:

- 1.
- 2.
- 3.

[Redacted]

G. Method and Technique of [Redacted]

[Redacted] during the filling operation. A filling machine with a [Redacted]
[Redacted] is used to fill the final containers. [Redacted] are placed in the final
containers and [Redacted] onto the containers.

H. [Redacted] Not applicable.

I.

[Redacted]

- 1.
- 2.

[Redacted]

[Redacted]

V. TESTING

A. [Redacted] Tests:

- 1.

[Redacted] samples are tested
for [Redacted]

NEW YORK STATE
DEPARTMENT OF HEALTH
DIVISION OF VETERINARY MEDICINE

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**BURSAL DISEASE-NEWCASTLE DISEASE VACCINE, KILLED VIRUS
CODE 12G5.43**

V. A. TESTING (continued)

2.

[Redacted]
Final container samples are tested for [Redacted] as prescribed in [Redacted]
[Redacted]
[Redacted]

"a."

accepted by [Redacted] (b)(6) on July 31, 2007, based on
[Redacted]

3.

[Redacted] Samples are tested as prescribed
in [Redacted]

4.

All samples are exempt from [Redacted]
[Redacted] in accordance with [Redacted] The exemption for
[Redacted] was granted to [Redacted]
[Redacted] but the date and authorizing official are
unknown at this time. An exemption was granted to [Redacted] (b)(6)
[Redacted] in a letter dated
July 6, 1988 based on a study dated May 16, 1988. The study is applicable
to this product.

5.

All samples are exempt from [Redacted]
[Redacted] in accordance with [Redacted] The exemption for [Redacted]
[Redacted] was granted to [Redacted]
[Redacted], but the date and authorizing official are unknown at this
time. An exemption was granted to [Redacted]
[Redacted] based on a study dated November 20, 1986.
The approval letter cannot currently be found. The study is applicable to
this product.

*format chg -
incorporated
a. into 2.*

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**BURSAL DISEASE-NEWCASTLE DISEASE VACCINE, KILLED VIRUS
CODE 12G5.43**

V. TESTING (continued)

B. [redacted] Test:

1. [redacted] Final container samples are tested as prescribed in 9 CFR 113.212(d)(1) and the results are evaluated in accordance with [redacted] *added ✓*

2. [redacted] Final container samples are tested as prescribed in [redacted] and the results are evaluated in accordance with [redacted] *added ✓*

Deleted "3." →

C. [redacted] Tests:

1. [redacted] Final container samples are tested as prescribed in [redacted]

2. [redacted] Final container samples are tested as prescribed in [redacted]

3. [redacted]

D. [redacted] Not applicable.

E. Other Tests: [redacted] is determined on completed bulk or final containers in accordance with [redacted]

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Est. 196
1705.11

OUTLINE OF PRODUCTION

for "FOR"

**NEWCASTLE DISEASE VACCINE
KILLED VIRUS**

Code 1705.11

U.S. VETERINARY LICENSE NO. 196
LOHMANN ANIMAL HEALTH INTERNATIONAL
WINSLOW, MAINE 04901

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NEWCASTLE DISEASE VACCINE, KILLED VIRUS
Code 1705.11

IV. PREPARATION OF THE PRODUCT (continued)

H. [redacted] Not applicable.

I. [redacted]

V. TESTING

A. [redacted] Tests:

1. [redacted]
2. [redacted]

[redacted] were accepted by [redacted] (b)(6)
[redacted] (b)(6) on July 31, 2007, based on [redacted]

3. All samples are exempt from [redacted]
[redacted] in accordance with [redacted]. The exemption for
[redacted] was granted to [redacted]
[redacted] but the date and authorizing official are
unknown at this time. An exemption was granted to [redacted] (b)(6)
[redacted] (b)(6)
in a letter dated July 6, 1988 based on a study dated May 16, 1988. The
study is applicable to this product.

*split 3.
into 3. + 4.
added info*

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NEWCASTLE DISEASE VACCINE, KILLED VIRUS
Code 1705.11

V. A. TESTING (continued)

*added
part 7 "3"*

4. All samples are exempt from [redacted]
[redacted] in accordance with [redacted]. The exemption for [redacted]
[redacted] was granted to [redacted]
[redacted] but the date and authorizing official are
unknown at this time. An exemption was granted to [redacted]
[redacted] based on a study dated
November 20, 1986. The approval letter cannot currently be found. The
study is applicable to this product.

B. [redacted] Test: Final container samples are tested as prescribed in [redacted]
[redacted]

1. [redacted]

2. [redacted]

C. [redacted] Test:

from "C" ① Final container samples are tested as prescribed in [redacted]

*format
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a. [redacted]

b. [redacted]

from "C" ②

D. [redacted] Not applicable.

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NEWCASTLE DISEASE VACCINE, KILLED VIRUS
Code 1705.11

V. TESTING (continued)

E. Other tests: [redacted] is determined on final containers in accordance with [redacted]

VI. POST PREPARATORY STEPS

A. Form and Size of Final Containers - The product is marketed in the following containers:

1. [redacted]
 - a. [redacted]
 - b. [redacted]
 - c. [redacted]
2. [redacted]
 - a. [redacted]
 - b. [redacted]
 - c. [redacted]
3. [redacted]

B. [redacted]

C. [redacted]

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
CENTER FOR VETERINARY BIOLOGICS

JUN 29 2009

REGISTRY, EVALUATION, AND LICENSING
NO ENDORSEMENT
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