

Boehringer Ingelheim
 Registration Number: 43-R-0014
 Customer ID: 1415

Column E Explanation

1. **Registration Number:** 43-R-0014
2. **Number** (b) (4) **of animals used in this study.**
3. **Species (common name)** (b) (4) **of animals used in this study.**
4. **Explain the procedure producing pain and/or distress.**

This testing requires (b) (4)
 (b) (4)

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For federally mandated testing, see Item 6 below)

The testing procedures for biologics (vaccines) are established by the USDA Center for Veterinary Biologics (USDA CVB) and are codified in 9 Code of Federal Regulations (CFR): Animals and Animal Products. This testing procedure is codified (b) (4) Testing is required to verify that the (b) (4)

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, (b) (4))

Agency USDA APHIS **CFR** (b) (4)

Details of the particular 9 CFR sections listed above are considered confidential business information, subject to protection from public disclosure under Exemption 4 of 5 U.S.C. §522(b)(4).

Boehringer Ingelheim
 Registration Number: 43-R-0014
 Customer ID: 1415

Column E Explanation

1. **Registration Number:** 43-R-0014
2. **Number** (b) (4) **of animals used in this study.**
3. **Species (common name)** (b) (4) **of animals used in this study.**
4. **Explain the procedure producing pain and/or distress.**
 This (b) (4) requires (b) (4)
(b) (4)
5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For federally mandated testing, see Item 6 below)**
(b) (4)
6. **What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, (b) (4))**

Agency: USDA APHIS Per: APHIS approved Outlines of Production

(b) (4)

Details of the particular 9 CFR sections listed above are considered confidential business information, subject to protection from public disclosure under Exemption 4 of 5 U.S.C. §522(b)(4).

Boehringer Ingelheim
 Registration Number: 43-R-0014
 Customer ID: 1415

Column E Explanation

1. **Registration Number:** 43-R-0014
2. **Number** (b) (4) **of animals used in this study.**
3. **Species (common name)** (b) (4) **of animals used in this study.**
4. **Explain the procedure producing pain and/or distress.**

This (b) (4) requires (b) (4)
 (b) (4)

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For federally mandated testing, see item 6 below)**

The testing procedures for biologics (vaccines) are established by the USDA Center for Veterinary Biologics (USDA CVB) and are codified in 9 Code of Federal Regulations (CFR): Animals and Animal Products. This testing procedure is codified in (b) (4)

6. **What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, (b) (4)**

(b) (4)

Agency: USDA APHIS **CFR:** (b) (4)

Details of the particular 9 CFR sections listed above are considered confidential business information, subject to protection from public disclosure under Exemption 4 of 5 U.S.C. §522(b)(4).

Boehringer Ingelheim
 Registration Number: 43-R-0014
 Customer ID: 1415

Column E Explanation

1. **Registration Number:** 43-R-0014
2. **Number** (b) (4) **of animals used in this study.**
3. **Species (common name)** (b) (4) **of animals used in this study.**
4. **Explain the procedure producing pain and/or distress.**

This (b) (4) requires (b) (4)
 (b) (4)

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For federally mandated testing, see Item 6 below)**

The testing procedures for biologics (vaccines) are established by the USDA Center for Veterinary Biologics (USDA CVB) and are codified in 9 Code of Federal Regulations (CFR): Animals and Animal Products. This testing procedure is codified in (b) (4)

(b) (4)

6. **What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, (b) (4))**

Agency: USDA APHIS CFR: (b) (4)
 (b) (4)

Details of the particular 9 CFR sections listed above are considered confidential business information, subject to protection from public disclosure under Exemption 4 of 5 U.S.C. §522(b)(4).

Boehringer Ingelheim
 Registration Number: 43-R-0014
 Customer ID: 1415

Column E Explanation

1. **Registration Number:** 43-R-0014
2. **Number** (b) (4) **of animals used in this study.**
3. **Species (common name)** (b) (4) **of animals used in this study.**
4. **Explain the procedure producing pain and/or distress.**

This (b) (4) requires (b) (4)
(b) (4)

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For federally mandated testing, see item 6 below)**

The testing procedures for biologics (vaccines) are established by the USDA Center for Veterinary Biologics (USDA CVB) and are codified in 9 Code of Federal Regulations (CFR): Animals and Animal Products. This testing procedure is codified in (b) (4)

6. **What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, (b) (4))**

Agency USDA APHIS **CFR** (b) (4)

Details of the particular 9 CFR sections listed above are considered confidential business information, subject to protection from public disclosure under Exemption 4 of 5 U.S.C. §522(b)(4).

03 DEC 2019

Boehringer Ingelheim
 Registration Number: 43-R-0014
 Customer ID: 1415

Column E Explanation

1. **Registration Number:** 43-R-0014
2. **Number** (b) (4) **of animals used in this study.**
3. **Species (common name)** (b) (4) **of animals used in this study.**
4. **Explain the procedure producing pain and/or distress.**

This (b) (4) requires (b) (4)
 (b) (4)

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For federally mandated testing, see Item 6 below)**

If the (b) (4)
 (b) (4)

6. **What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, (b) (4))**

Agency: USDA APHIS **CFR:** (b) (4)

Details of the particular 9 CFR sections listed above are considered confidential business information, subject to protection from public disclosure under Exemption 4 of 5 U.S.C. §522(b)(4).