from the Master Seed and prepared at
the minimum preinactivation titer
specified in the Outline of Production.

(d) Test requirements for release. Each
serial and subserial shall meet the
applicable general requirements pre-
scribed in §113.200 and the special re-
quirements provided in this paragraph.
Any serial or subserial found unsatis-
factory by a prescribed test shall not
be released.

(1) Safety. Vaccinates used in the po-
tency test in paragraph (d)(2) of this
section shall be observed each day dur-
ing the prechallenge period. If unfavor-
able reactions occur, including oral le-
sions, which are attributable to the
vaccine, the serial is unsatisfactory. If
unfavorable reactions occur which are
not attributable to the vaccine, the
test is inconclusive and may be re-
peated. If the test is not repeated, the
serial is unsatisfactory.

(2) Potency. Bulk or final container
samples of completed product shall be
treated for potency as follows:

(i) Eight feline calicivirus susceptible
cats (five vaccinates and three con-
trols) shall be used as test animals.
Throat and nasal swabs shall be col-
lected from each cat and individually
tested on susceptible cell cultures for
the presence of feline calicivirus. Blood
samples shall be drawn and individual
serum samples tested for neutralizing
antibody. The cats shall be considered
suitable for use if all swabs are nega-
tive for virus isolation and all sera are
negative for calicivirus antibody at
the 1:2 final dilution in a 50 percent
plaque reduction test or other test of
equal sensitivity.

(ii) The five cats used as vaccinates
shall be administered one dose of vac-
cine by the method recommended on
the label. If two doses are rec-
ommended, the second dose shall be
given after the interval recommended
on the label.

(iii) Fourteen or more days after the
final dose of vaccine, the vaccinates
and controls shall each be challenged
intranasally with virulent feline
calicivirus furnished or approved by
Animal and Plant Health Inspection
Service and observed each day for 14
days postchallenge. The rectal tem-
perature of each animal shall be taken
and the presence or absence of clinical
signs, particularly lesions on the oral
mucosa, noted and recorded each day.

(iv) If three of three controls do not
show clinical signs of feline calicivirus
infection other than fever, the test is
inconclusive and may be repeated.

(v) If a significant difference in clin-
ical signs cannot be demonstrated be-
tween vaccinates and controls using a
scoring system approved by Animal
and Plant Health Inspection Service
and prescribed in the Outline of Pro-
duction, the serial is unsatisfactory.

§113.211 Feline Rhinotracheitis Vac-
cine, Killed Virus.

Feline Rhinotracheitis Vaccine, Killed Virus, shall be prepared from
virus-bearing cell culture fluids. Only
Master Seed which has been estab-
lished as pure, safe, and immunogenic
shall be used for preparing seeds for
vaccine production. All serials of vac-
cine shall be prepared from the first
through the fifth passage from the
Master Seed.

(a) The Master Seed shall meet the
applicable general requirements pre-
scribed in §113.200.

(b) The Master Seed shall be tested
for chlamydial agents as prescribed in
§113.43.

(c) The immunogenicity of vaccine
prepared from the Master Seed in ac-
cordance with the Outline of Produc-
tion shall be established by a method
acceptable to Animal and Plant Health
Inspection Service. Vaccine used for
this test shall be at the highest passage
from the Master Seed and prepared at
the minimum preinactivation titer
specified in the Outline of Production.

(d) Test requirements for release. Each
serial and subserial shall meet the ap-
plicable general requirements pre-
scribed in §113.200 and the special re-
quirements provided in this paragraph.
Any serial or subserial found unsatis-
actory by a prescribed test shall not
be released.

(1) Safety test. Vaccinates used in the
potency test in paragraphs (d)(2) of this

section shall be observed each day during the prechallenge period. If unfavorable reactions occur which are attributable to the vaccine, the test is inconclusive and may be repeated. If the test is not repeated, the serial is unsatisfactory.

(2) Potency test. Bulk or final container samples of completed product shall be tested for potency as follows:

(i) Eight feline rhinotracheitis susceptible cats (five vaccinates and three controls) shall be used as test animals. Throat and nasal swabs shall be collected from each cat and individually tested on susceptible cell cultures for the presence of feline rhinotracheitis virus. Blood samples shall be drawn and individual serum samples tested for neutralizing antibody. The cats shall be considered suitable for use if all swabs are negative for virus isolation and all sera are negative for rhinotracheitis virus antibody at the 1:2 final dilution in a 50 percent plaque reduction test or other test of equal sensitivity.

(ii) The five cats used as vaccinates shall be administered one dose of vaccine by the method recommended on the label. If two doses are recommended, the second dose shall be given after the interval recommended on the label.

(iii) Fourteen or more days after the final dose of vaccine, the vaccinates and controls shall each be challenged intranasally with virulent feline rhinotracheitis virus furnished or approved by Animal and Plant Health Inspection Service and observed each day for 14 days postchallenge. The rectal temperature of each animal shall be taken and the presence or absence of clinical signs noted and recorded each day.

(iv) If three of three controls do not show clinical signs of feline rhinotracheitis virus infection other than fever, the test is inconclusive and may be repeated.

(v) If a significant difference in clinical signs cannot be demonstrated between vaccinates and controls using a scoring system approved by Animal and Plant Health Inspection Service and prescribed in the Outline of Production, the serial is unsatisfactory.


§ 113.212 Bursal Disease Vaccine, Killed Virus.

Bursal Disease Vaccine, Killed Virus, shall be prepared from virus-bearing cell culture fluids or embryonated chicken eggs. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for preparing seeds for vaccine production. All serials shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable requirements prescribed in §113.200.

(b) Each lot of Master Seed shall be tested for pathogens by the chicken embryo inoculation test prescribed in §113.37, except that, if the test is inconclusive because of a vaccine virus over-ride, the chicken inoculation test prescribed in §113.36 may be conducted and the virus judged accordingly.

(c) The immunogenicity of vaccine prepared in accordance with the Outline of Production shall be established by a method acceptable to Animal and Plant Health Inspection Service. Vaccine used for this test shall be at the highest passage from the Master Seed and prepared at the minimum preinactivation titer specified in the Outline of Production. The test shall establish that the vaccine, when used as recommended on the label, is capable of inducing an immune response in dams of sufficient magnitude to provide significant protection to offspring.

(d) Test requirements for release. Each serial and subserial shall meet the applicable general requirements prescribed in §113.200 and the special requirements in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) Safety. Vaccinates used in the potency test in paragraph (d)(2) of this section shall be observed each day during the prechallenge period. If unfavorable reactions attributable to the vaccine occur, the serial is unsatisfactory. If unfavorable reactions which are not