§ 112.8

(3) Clostridium botulinum Type C. “Re-
vaccinate breeders 1 month before
breeding.”

(g) In the case of a liquid product au-
thorized in a filed Outline of Produc-
tion to be used as a diluent in a com-
bination package, the carton labels and
enclosures used for serials which are ei-
ther not tested for bactericidal or viri-
cidal activity or have been found un-
satisfactory by such test shall contain
the statement: “CAUTION: DO NOT
USE AS DILUENT FOR LIVE VAC-
CINES.”

(h) In the case of wart vaccine, rec-
ommendations shall be limited to use
in cattle. Indications for use shall be
for prophylactic use only, as an aid in
the control of viral papillomas (warts).
All labels shall include a dosage rec-
ommendation of at least 10 ml to be
given subcutaneously and the dose re-
peated in 3 to 5 weeks.

(i) Unless otherwise authorized in an
Outline of Production filed subsequent
to the effective date of these amend-
ments, all but very small final con-
tainer labels for Feline Panleukopenia
Vaccines shall contain the following
recommendations for use:

(1) Killed virus vaccines. Vaccinate
healthy cats of any age with one dose
except that if the animal is less than 12
weeks of age, a second dose should be
given at 12 to 16 weeks of age. Annual
revaccination with a single dose is rec-
ommended.

(2) Modified live virus vaccines. Vac-
cinate healthy cats of any age with one
dose except that if the animal is less
than 12 weeks of age, a second dose
should be given at 12 to 16 weeks of
age. Annual revaccination with a sin-
gle dose is recommended. Do not vac-
cinate pregnant cats.

(j) In the case of normal serum, anti-
serum, or antiserum derivatives, the
type of preservative used shall be indi-
cated on all labels.

(k) Unless acceptable data has been
filed with Animal and Plant Health In-
spection Service, to show that develop-
ment of corneal opacity is not associ-
ated with the product, carton labels and
enclosures used with biological prod-
ucts containing modified live ca-
nine hepatitis virus or modified live ca-
nine adenovirus Type 2 shall bear the
following statement: “Occasionally,
transient corneal opacity may occur
following the administration of this
product.”

(l) All labels for autogenous biologics
shall bear the following statement:
“Potency and efficacy of autogenous
biologics have not been established.
This product is prepared for use only
by or under the direction of a veteri-
narian or approved specialist.”

(m) In the case of biological products
containing Marek’s disease virus, all
labels shall specify the Marek’s disease
virus serotype(s) used in the product.

(Approved by the Office of Management and
Budget under control number 0579–0013)

[38 FR 12094, May 9, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER ci-
tations affecting § 112.7, see the List of CFR
Sections Affected, which appears in the
Finding Aids section of the printed volume
and on GPO Access.

§ 112.8 For export only.

The applicable regulations for pack-
aging and labeling a biological product
produced in the United States shall
apply to such biological product if ex-
ported from the United States except
as otherwise provided in this section.
Only labels approved as provided in
§ 112.5 shall be used.

(a) Biological products which have
been packaged and labeled for export
or which have been exported, shall be
subject to the applicable provisions in
this paragraph.

(1) After leaving the licensed estab-
lishment, a biological product shall not
be bottled, repackaged, relabeled, or
otherwise altered in any way while in
the United States; and

(2) An exported biological product
shall not be returned to the United
States: Provided, That, in the case of a
biological product exported in labeled
final containers, the Administrator
may authorize by permit the importa-
tion of a limited number for research
and evaluation by the producing li-
censee; and

(3) An exported biological product
which is bottled, rebottled, or altered
in any way in a foreign country shall
not bear a label which indicates by es-
tablishment license number that it has
been prepared in the United States.
§ 112.10 Special packaging and labeling.

A biological product, which requires special packaging and/or labeling not provided for in this part, shall be packaged and/or labeled in accordance with requirements written into the approved outline for such product.

PART 113—STANDARD REQUIREMENTS

APPLICABILITY

Sec.
113.1 Compliance.
113.2 Testing aids.
113.3 Sampling of biological products.
113.4 Exemptions to tests.
113.5 General testing.
113.6 Animal and Plant Health Inspection Service testing.
113.7 Multiple fractions.
113.8 In vitro tests for serial release.
113.9 New potency test.
113.10 Testing of bulk material for export or for further manufacture.

STANDARD PROCEDURES

113.25 Culture media for detection of bacteria and fungi.
113.26 Detection of viable bacteria and fungi except in live vaccine.
113.27 Detection of extraneous viable bacteria and fungi in live vaccines.
113.28 Detection of mycoplasma contamination.
113.29 Determination of moisture content in desiccated biological products.
113.30 Detection of Salmonella contamination.
113.31 Detection of avian lymphoid leukosis.
113.32 Detection of Brucella contamination.
113.33 Mouse safety tests.
113.34 Detection of hemagglutinating viruses.
113.35 Detection of virucidal activity.
113.36 Detection of pathogens by the chicken embryo inoculation test.
113.37 Detection of pathogens by the chicken embryo inoculation test.
113.38 Guinea pig safety test.
113.39 Cat safety tests.
113.40 Dog safety tests.
113.41 Calf safety test.
113.42 Detection of lymphocytic choriomeningitis contamination.
113.43 Detection of chlamydial agents.
113.44 Swine safety test.
113.45 Sheep safety test.
113.46 Detection of cytopathogenic and/or hemadsorbing agents.
113.47 Detection of extraneous viruses by the fluorescent antibody technique.

§ 112.9 Biological products imported for research and evaluation.

A biological product imported for research and evaluation under a permit issued in accordance with §104.4, with the exception of products imported under §104.4(d), shall be labeled as provided in this section.

(a) The label shall identify the product and the name and address of the manufacturer and shall provide instructions for proper use of the product, including all warnings and cautions needed by the permittee to safely use the product.

(b) Labels on each product to be further distributed in accordance with §103.3 shall bear the statement “Notice! For Experimental Use Only—Not for Sale!”

(c) The labeling shall contain any other information deemed necessary by the Administrator and specified on the permit.