

This order shall become effective June 27, 1977, except that the effective date for rearrangement of the nonproprietary name from "zinc bacitracin" to "bacitracin zinc" shall be November 22, 1977. Any bacitracin zinc preparation labeled after November 22, 1977 that does not bear the name "bacitracin zinc" is misbranded.

(Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357).)

Dated: May 18, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 77-14966 Filed 5-26-77; 8:45 am]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS,
AND RELATED PRODUCTS

[Docket No. 77N-0014]

PART 539—BULK ANTIBIOTIC DRUGS
SUBJECT TO CERTIFICATION

PART 548—CERTIFIABLE PEPTIDE ANTI-
BIOTIC DRUGS FOR ANIMAL USE BACI-
TRACIN AND BACITRACIN-CONTAIN-
ING DRUGS; CONFORMING AMEND-
MENTS

AGENCY: Food and Drug Administra-
tion.

ACTION: Final rule.

SUMMARY: This rule amends the regu-
lations regarding certification of baci-
tracin drug products for animal use to
conform with amendments to regulations
on bacitracin drug products for human
use being published elsewhere in this is-
sue of the FEDERAL REGISTER.

EFFECTIVE DATE: June 27, 1977.

FOR FURTHER INFORMATION CON-
TACT:

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nary Medicine (HFV-238), Food and
Drug Administration, Department of
Health, Education, and Welfare, 5600
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SUPPLEMENTARY INFORMATION: This
regulation is not substantive, nor
does it affect presently approved new
animal drug applications (NADA's), the
labeling contained therein or the re-
quirements for certification of the named
antibiotic drug products. Revised label-
ing requirements will be the subject of a
future proposal.

Therefore, under the Federal Food,
Drug, and Cosmetic Act (sec. 512, 82
Stat. 343-351 (21 U.S.C. 360b)) and un-
der authority delegated to the Commis-
sioner (21 CFR 5.1), Parts 539 and 548
are amended as follows:

1. Part 539 is amended in § 539.310 by
revising paragraphs (a) (1) (ii), (iii),
and (4) (i) and (b) to read as follows:

§ 539.310 Bacitracin methylene disali-
cylate.

(a) * * *

(1) * * *

(ii) It passes the safety test.

(iii) Its loss on drying is not more
than 7 percent.

(4) * * *

(i) In addition to complying with the
requirements of § 514.50 of this chapter,
a person who requests certification of a
batch shall submit with his request a
statement showing the batch mark, the
number of packages of each size in the
batch, the number of units of bacitracin
activity per gram, and the number of
grams of bacitracin activity per pound.
Such request shall be accompanied or
followed by the results of tests and as-
says made by him on the batch for po-
tency, safety, loss on drying, and pH.

(b) Tests and methods of assay—(1)
Potency. Proceed as directed in § 436.105
of this chapter, preparing the sample as
follows: Place an accurately weighed
sample of approximately 1 gram in a
blending jar, add 99 milliliters of an
aqueous solution of 2-percent sodium bi-
carbonate and 1 milliliter of polysorbate
80, and blend for 3 minutes in a high-
speed blender. Allow the foam to sub-
side, remove an aliquot of the solution,
and dilute to 1 unit per milliliter with 1-
percent phosphate buffer.

(2) Safety. Proceed as directed in
§ 436.33 of this chapter.

(3) Loss on drying. Proceed as directed
in § 436.200(b) of this chapter.

(4) pH. Proceed as directed in § 436.-
202 of this chapter, using a saturated
aqueous solution containing approxi-
mately 50 milligrams per milliliter.

2. Part 548 is amended as follows:

a. In § 548.110, paragraphs (a) (1),
(4) (ii) (a), (b), and (iii) (b), and (b)
(1), (2) are revised to read as follows:

§ 548.110 Bacitracin powder.

(a) Requirements for certification—
(1) Standards of identity, strength,
quality, and purity. Bacitracin powder is
bacitracin, with or without suitable and
harmless buffer substances, preservatives,
diluents, colorings, and flavorings. It
contains the equivalent of not less than
10 grams of the bacitracin master stand-
ard per pound. Its loss on drying is not
more than 5 percent. The bacitracin used
conforms to the standards prescribed
therefor by § 448.10(a) (1) of this chap-
ter. Each other substance used, if its
name is recognized in the *United States
Pharmacopeia* or *National Formulary*,
conforms to the standards prescribed
therefor by such official compendium.

(4) * * *

(ii) * * *

(a) The batch: units of bacitracin per
gram, and loss on drying.

(b) The bacitracin used in making the
batch: potency, safety, loss on drying,
pH, and identity.

(iii) * * *

(b) The bacitracin used in making the
batch: six packages, each containing ap-
proximately equal portions of not less
than 500 milligrams.

(b) Tests and methods of assay—(1)
Potency. Proceed as directed in § 436.105
of this chapter, preparing the sample
as follows: Place an accurately weighed

sample of approximately 1 to 5 grams
in a 100-milliliter volumetric flask; dis-
solve in 1 percent phosphate buffer, and
dilute to 100 milliliters with 1 percent
phosphate buffer. Dilute a suitable ali-
quot with 1-percent phosphate buffer to
a concentration of 1 unit per milliliter
(estimated). Its potency is satisfactory
if it contains not less than 85 percent of
the number of units of bacitracin per
pound that it is represented to contain.

(2) Loss on drying. Proceed as directed
in § 436.200(b) of this chapter.

b. In § 548.111, paragraphs (a) (1)
and (2), (b) (1), (2), and (3) (ii) are
revised to read as follows:

§ 548.111 Feed grade manganese baci-
tracin powder oral.

(a) Requirements for certification—
(1) Standards of identity, strength,
quality, and purity. Feed grade man-
ganese bacitracin powder oral is a mix-
ture of the manganese salt of a kind
of bacitracin or a mixture of two or more
such salts, with or without one or more
essential vitamins and mineral sub-
stances for nutritive purposes and with
or without one or more suitable and
harmless diluents. It contains the equiva-
lent of not less than 5 grams of the
bacitracin master standard per pound.
Its loss on drying is not more than 8.0
percent. The manganese bacitracin used
in making the batch has a potency of
not less than 2.0 units per milligram, it
contains not more than 1.0 gram of man-
ganese for each gram of bacitracin, and
its loss on drying is not more than 6.0
percent. Each other substance used, if
its name is recognized in the *United
States Pharmacopeia* or *National For-
mulary*, conforms to the standards pre-
scribed therefor by such official com-
pendium.

(2) Packaging; labeling; requests for
certification; samples. Feed grade man-
ganese bacitracin powder oral conforms
to all requirements and procedures pre-
scribed for feed grade bacitracin zinc
powder oral by § 548.113(a) (1), except:
(i) Its expiration date shall be 12
months.

(ii) Its labeling is such that, when the
drug is mixed with animal feed accord-
ing to the directions contained therein,
such medicated feed complies with the
requirements of § 510.510 of this chapter
and the requirements of regulations in
Part 558 of this chapter.

(b) Tests and methods of assay—(1)
Proceed as directed in § 436.105 of this
chapter, preparing the sample as follows:

(i) Place 2 grams of the sample in a
150-milliliter beaker, add 5 milliliters of
10 percent HCl and stir 1 minute. Check
pH with test paper. If pH is greater than
2 add more acid until pH 2 is reached.
Add 45 milliliters of pyridine-buffer
solution (mix 9 volumes pyridine and
31 volumes pH 6.0 buffer) and transfer
the mixture to a centrifuge tube. Shake
well for 5 minutes then centrifuge for
15 minutes at 2,000 r.p.m. Dilute an ali-
quot of the clear solution with enough
pH 6.0 buffer to obtain an estimated con-
centration of 0.20 unit per milliliter.

(ii) Prepare the following dilutions in 0.1 M pH 6 buffer from the stock solution for the standard curve: 0.025, 0.05, 0.1, 0.2, 0.4, and 0.8 unit per milliliter with 0.2 unit per milliliter as the reference concentration. Also add 10 milliliters of agar to each petri dish instead of 21 milliliters. Its potency is satisfactory if it contains not less than 85 percent of the number of grams of manganese bacitracin per pound that it is represented to contain.

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(3) * * *
(ii) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

c. In § 548.112a, paragraph (a) (1) is amended in the third sentence by deleting "moisture content" and inserting "loss on drying"; paragraph (b) (1) is amended by revising the introductory portion of the text; and paragraphs (b) (2) and (3) are revised to read as follows:

§ 548.112a Soluble bacitracin methylene disalicylate.

(a) * * *
(1) * * * Its loss on drying is not more than 8.5 percent. * * *

(b) * * *
(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample as follows: * * *

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using a solution containing 200 units per milliliter.

d. In § 548.112b, paragraphs (a) (3) (1) introductory text and (b) (2) and (3) are revised to read as follows:

§ 548.112b Tablets bacitracin methylene disalicylate and streptomycin sulfate oral.

(a) * * *
(3) * * *

(i) For potency and loss on drying:

(b) * * *

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(3) *Disintegration time.* Proceed as directed in § 436.212 of this chapter.

e. In § 548.112c, paragraph (b) (2) is revised to read as follows:

§ 548.112c Capsules bacitracin methylene disalicylate and streptomycin sulfate oral.

(b) * * *

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

f. In § 548.112d, paragraph (a) (1) is amended by revising the third sentence and paragraphs (a) (4) (ii) (b) and (b) are revised to read as follows:

§ 548.112d Powder bacitracin methylene disalicylate and streptomycin sulfate oral.

(a) * * *
(1) * * * Its loss on drying is not more than 7.5 percent. * * *

(4) * * *
(ii) * * *
(b) The bacitracin methylene disalicylate and the streptomycin sulfate oral veterinary used in making the batch; potency, loss on drying, and pH.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Bacitracin content.* Proceed as directed in § 436.105 of this chapter, preparing the sample as follows: Place an accurately weighed sample of approximately 5 grams in a blending jar. Add sufficient dimethylformamide so that when the sample is diluted to its reference point the concentration of dimethylformamide in the final blank is no greater than 20 percent. Blend for 3 to 5 minutes. Filter through filter paper immediately. Remove an aliquot of the filtrate at once and dilute to 1 unit per milliliter with 1.0 percent phosphate buffer, pH 6.0. Add sufficient dimethylformamide to the working solution of the standard so that the concentration of dimethylformamide is the same as that in the sample being tested. In lieu of the test organisms prescribed by § 436.105(a), use either of the test organisms R or V described in § 436.103(a) of this chapter.

NOTE.—Pyridine may be substituted for dimethylformamide in the procedure described in paragraph (b) (1) (i).

Its potency is satisfactory if it contains not less than 85 percent of the units of bacitracin activity that it is represented to contain.

(ii) *Streptomycin content.* Proceed as directed in § 444.70a(b) (1) of this chapter. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams of streptomycin activity per gram that it is represented to contain.

(2) *Loss on drying.* Using a 1.0-gram sample, proceed as directed in § 436.200 (b) of this chapter.

g. In § 548.113, the section heading and paragraphs (a) (1), (a) (3) (i) (a) and (b), (b), and (c) are revised to read as follows:

§ 548.113 Crude, unrefined, feed grade bacitracin/bacitracin zinc powder oral.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Feed grade bacitracin powder oral is bacitracin with or without one or more essential vitamins and mineral substances for nutritive purposes and with or without one or more suitable and harmless diluents. Feed grade bacitracin zinc powder oral is a mixture of bacitracin zinc and zinc proteinates, with or without one or more essential vitamins and mineral substances for nutritive purposes and with

or without one or more suitable and harmless diluents. They contain the equivalent of not less than 2.5 grams of the bacitracin master standard per pound, except that if it is bacitracin zinc powder it contains the equivalent of not less than 5 grams of the bacitracin master standard per pound. Their loss on drying is not more than 5 percent. The bacitracin used in making the batch has a potency of not less than 5 units per milligram, and its loss on drying is not more than 5 percent. The bacitracin zinc used in making the batch has a potency of not less than 2 units per milligram nor more than 2 grams of zinc for each gram of bacitracin, and its loss on drying is not more than 6 percent. Each other substance used, if its name is recognized in the United States Pharmacopeia or National Formulary, conforms to the standards prescribed therefor by such official compendium.

(3) * * *
(ii) * * *

(a) The batch: Grams of bacitracin per pound and loss on drying.

(b) The bacitracin used in making the batch: Potency, loss on drying, and zinc content if the bacitracin used is bacitracin zinc.

(b) *Tests and methods of assay*—(1) *Feed grade bacitracin or bacitracin zinc powder oral*—(i) *Potency.* Proceed as directed in § 548.110(b) (1), except if it is feed grade bacitracin zinc powder oral proceed as directed in § 448.13(b) (1) of this chapter. Their potency is satisfactory if they contain not less than 85 percent of the number of grams of bacitracin or bacitracin zinc per pound that they are represented to contain.

(ii) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(2) *Bacitracin or bacitracin zinc used in making the batch*—(i) *Potency.* Proceed as directed in § 448.10(b) (1) of this chapter, except if it is bacitracin zinc proceed as directed in § 448.13(b) (1) of this chapter.

(ii) *Zinc content* (if bacitracin zinc is used). Proceed as directed in § 448.13 (b) (5) of this chapter.

(iii) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(c) *Conditions of marketing.* If it is feed grade bacitracin powder, its conditions of marketing are described in § 548.110(c). If it is feed grade bacitracin zinc powder, oral, its conditions of marketing are described in § 548.114(c).

h. In § 548.114, the section heading and paragraphs (a), (b), and (c) (1) and (3) are revised to read as follows:

§ 548.114 Bacitracin zinc oral.

(a) *Requirements for certification.* The requirements for certification for bacitracin zinc oral are described under § 548.113(a).

(b) *Tests and methods of assay.* The tests and methods of assay for bacitracin

cin zinc oral are described under § 548.113(b).

(c) *Conditions of marketing*—(1) *Specifications.* Bacitracin zinc is the zinc salt of the antibiotic substance produced by growth of *Bacillus subtilis* var. *Tracy* or the same antibiotic substance produced by any other means, and for the purposes of this section refers to bacitracin zinc or feed grade bacitracin zinc.

(3) *Special considerations.* Quantities of bacitracin zinc expressed in paragraph (c) (5) of this section refer to the weight of an appropriate antibiotic standard.

i. Section 548.212 is revised to read as follows:

§ 548.212 Bacitracin methylene disalicylate tablets; bacitracin/bacitracin zinc implantation pellets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Bacitracin methylene disalicylate tablets, bacitracin tablets, and bacitracin zinc tablets are tablets composed of bacitracin methylene disalicylate, bacitracin or bacitracin zinc with or without one or more suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings, and with or without a suitable amebicidal agent. The potency of each tablet is not less than 1,000 units or more than 10,000 units. Its loss on drying content is not more than 5 percent. Tablets not exceeding 15 millimeters in diameter shall disintegrate within 1 hour. The bacitracin methylene disalicylate used conforms to the standards prescribed therefor by § 539.310(a) (1) of this chapter. The bacitracin used conforms to the standards prescribed therefor by § 448.10(a) (1) of this chapter. The bacitracin zinc used conforms to the requirements of § 448.13(a) (1) of this chapter. Each other substance used, if its name is recognized in the United States Pharmacopeia or National Formulary, conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* Unless each tablet is enclosed in a foil or plastic film and such enclosure is a tight container as defined by the United States Pharmacopeia, except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* It shall be labeled in ac-

cordance with the requirements of § 510.55 of this chapter, and its label and labeling shall bear the statement, "Warning—not for use in animals raised for food production".

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark; the number of packages of each size in such batch; the batch mark and, unless it was previously submitted, the date on which the latest assay of the bacitracin methylene disalicylate, bacitracin, or bacitracin zinc used in making such batch was completed; the number of units in each tablet; the quantity of each ingredient used in making the batch; the date on which the latest assay of the drug comprising such batch was completed; and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(ii) Except as otherwise provided in paragraph (a) (4) (iv) of this section, such person shall submit in connection with his request, results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(a) The batch: Average potency per tablet, average loss on drying, and if required by paragraph (a) (1) of this section, disintegration time.

(b) The bacitracin methylene disalicylate, bacitracin, or bacitracin zinc used in making the batch: potency; safety; loss on drying; pH; identity if it is bacitracin; and zinc content if it is bacitracin zinc.

(iii) Except as otherwise provided by paragraph (a) (4) (iv) of this section, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(a) The batch:

(i) For potency and loss on drying: One tablet for each 5,000 tablets in the batch, but in no case less than 30 tablets, collected by taking single tablets throughout the entire time of tableting so that the quantities tableted during the intervals are approximately equal.

(2) For disintegration time: six tablets.

(b) The bacitracin methylene disalicylate used in making the batch: five packages, each containing approximately equal portions of not less than 5 grams.

(c) The bacitracin used in making the batch: six packages, each containing approximately equal portions of not less than 500 milligrams.

(d) The bacitracin zinc used in making the batch: six packages, each containing approximately equal portions of not less than 1.0 gram.

(e) In case of an initial request for certification, each other substance used in making the batch: one package of each containing approximately 5 grams.

(iv) No result referred to in paragraph (a) (4) (ii) (b) of this section and no

sample referred to in paragraph (a) (4) (iii) (b), (c), (d) or (e) of this section are required if such result or sample has been previously submitted.

(b) *Tests and methods of assay*—(1) *Potency:* (i) If it is bacitracin or bacitracin zinc, proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: If it is bacitracin, place a representative sample (usually five tablets) in a blending jar containing 250 milliliters of 1-percent phosphate buffer, pH 6.0. If it is bacitracin zinc, use 250 milliliters of 0.01N HCl. If it is bacitracin, after blending for 1 minute with a high-speed blender, add 250 milliliters of buffer to the blender, and if it is bacitracin zinc, add 250 milliliters of 0.01N HCl to the blender. Blend again for 1 minute and make the proper estimated dilutions in 1-percent phosphate buffer, pH 6.0. If it is bacitracin zinc, make all dilutions for the assay so that the final dilution contains the same ratio of 1.01N HCl to 1-percent phosphate buffer, pH 6.0, as the sample under test. The content of bacitracin, or bacitracin zinc is satisfactory if it contains not less than 85 percent of the number of units per tablet that it is represented to contain.

(ii) If it is bacitracin methylene disalicylate, proceed as directed in § 436.105 of this chapter, preparing the sample as follows: Place a representative sample (usually five tablets) into a high-speed glass blender jar containing 99 milliliters of an aqueous solution of 2-percent sodium bicarbonate and 1 milliliter of polysorbate 80. Blend 3 to 5 minutes. Allow the foam to subside. Dilute an aliquot of the resultant solution with 1 percent sodium phosphate buffer, pH 6.0, to the reference concentration of 1 unit of bacitracin per milliliter (estimated). Its potency is satisfactory if it contains not less than 85 percent of the number of units of bacitracin per tablet that it is represented to contain.

(2) *Loss on drying.* Proceed as directed in § 436.200 of this chapter.

(3) *Disintegration time.* Proceed as directed in § 436.212 of this chapter, using the procedure described in paragraph (e) (1) of that section.

j. Section 548.310a is amended to read as follows:

§ 548.310a Bacitracin ophthalmic.

(a) *Requirements for certification*—(1) *Standards of identity, quality, and purity.* Bacitracin ophthalmic is bacitracin, with or without one or more suitable and harmless preservatives, local anesthetics, buffer substances, and diluents. It is sterile. Its loss on drying is not more than 5 percent. The bacitracin is of such quantity that when dissolved as directed in its labeling the potency of such solution is not less than 500 units per milliliter and maintains its labeled potency after it has been kept for 7 days at room temperature. Such solution has a pH of 6.5 ± 0.5 . The bacitracin used conforms to the requirements of § 448.10 (a) (1) of this chapter. Each other ingredient used, if its name is recognized

in the United States Pharmacopeia or National Formulary, conforms to the standards prescribed therefor by such official compendium.

(2) **Packaging.** The immediate container of bacitracin ophthalmic shall be a tight container as defined by the United States Pharmacopeia; its closure shall be one through which a hypodermic needle cannot be introduced; and the immediate container and closure shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not less than 5,000 units, and each may be packaged in combination with a container of the solvent, sterile distilled water U.S.P.

(3) **Labeling.** In addition to the labeling requirements prescribed by § 510.55 of this chapter, each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container, the statement "Warning—not for injection".

(ii) If a local anesthetic is present, after the name "bacitracin ophthalmic", wherever it appears, the words "with _____", (the blank being filled in with the established name of the local anesthetic) in juxtaposition with such name.

(4) **Requests for certification; samples.** (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the bacitracin used in making such batch was completed, the number of units in each immediate container, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each other ingredient used in making the batch, and a statement that each such ingredient used conforms to the requirements prescribed therefor by this section. If such batch or any part thereof is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(ii) Except as otherwise provided in paragraph (a) (4) (iv) of this section, such person shall submit in connection with his request, results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(a) The batch: potency, sterility, loss on drying, and pH of the solution prepared as directed in its labeling;

(b) The bacitracin used in making the batch, potency, safety, loss on drying, pH, and identity.

(iii) Except as otherwise provided by paragraph (a) (4) (iv) of this section, such person shall submit in connection with his request in the quantities hereinafter indicated, accurately representative samples of the following:

(a) The batch:

(1) For all tests except sterility: One immediate container for each 5,000 immediate containers in the batch, but in no case less than five immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch so that the quantities packaged during the intervals are approximately equal.

(2) For sterility testing: 20 immediate containers collected at regular intervals throughout each filling operation.

(b) The bacitracin used in making the batch: 6 packages, each containing approximately equal portions of not less than 500 milligrams.

(c) In case of an initial request for certification, each other ingredient used in making the batch; one package of each, containing approximately 5.0 grams.

(iv) No result referred to in paragraph (a) (4) (i) (b) of this section and no sample referred to in paragraph (a) (4) (iii) (b) of this section are required if such result or sample has been previously submitted.

(b) **Tests and methods of assay.**—(1) **Potency.** Proceed as directed in § 448.10 (b) (1) of this chapter.

(2) **Loss on drying.** Proceed as directed in § 436.200 (b) of this chapter.

(3) **pH.** Proceed as directed in § 436.202 of this chapter, using a solution prepared as directed in the labeling for the drug.

(4) **Sterility.** Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e) (1) of that section.

k. Section 548.310b is revised to read as follows:

§ 548.310b Bacitracin-polymyxin B sulfate-neomycin sulfate ointment.

(a) **Requirements for certification.** The requirements for certification for bacitracin-polymyxin B sulfate-neomycin sulfate ointment are described under § 448.510e(a) of this chapter.

(b) **Tests and methods of assay.** The tests and methods of assay for bacitracin-polymyxin B sulfate-neomycin sulfate ointment are described under § 448.510e(b) of this chapter.

1. Section 548.313a is revised to read as follows:

§ 548.313a Bacitracin - neomycin - polymyxin powder topical; bacitracin zinc - neomycin - polymyxin powder topical.

(a) **Requirements for certification.**—(1) **Standards of identity, strength, quality, and purity.** Bacitracin-neomycin-polymyxin powder topical and bacitracin zinc-neomycin-polymyxin powder topi-

cal are bacitracin or bacitracin zinc neomycin, and polymyxin B, with or without suitable and harmless diluents, preservatives, and lubricants, and with or without hyaluronidase, chymotrypsin, and polyvinylpyrrolidone. Unless it is packaged with one or more suitable and harmless inert gases, each gram contains not less than 200 units of bacitracin or bacitracin zinc not less than 1,600 units of polymyxin B, and not less than 3.5 milligrams of neomycin. It contains not more than an average of 10 microorganisms per gram. Its moisture content is not more than 7.0 percent, unless it is packaged with one or more suitable and harmless inert gases, in which case its moisture content is not more than 0.5 percent. The bacitracin used conforms to the standards prescribed therefor by § 448.10(a) (1) of this chapter.

The bacitracin zinc used conforms to the standards prescribed by § 448.13(a) (1) of this chapter. The neomycin used conforms to the standards prescribed by § 444.2a(a) (1) (i), (iv), (v), and (vi) of this chapter. The polymyxin B used conforms to the standards prescribed therefor by § 444.170a(a) (1) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) **Packaging.** In all cases the immediate container shall be a tight container as defined by the U.S.P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container may contain one or more suitable and harmless inert gases; in which case it shall contain not less than 8,000 units of bacitracin zinc, not less than 70 milligrams of neomycin, and not less than 100,000 units of polymyxin B.

(3) **Labeling.** In addition to the labeling requirements prescribed by § 510.55 of this chapter, each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(a) The statement "Expiration date _____", the blank being filled in with the date that is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date that is 18 months, or 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) (1) of this section.

(b) The statement "Not sterile".

(iii) If it contains, in addition to the antibiotic drug, one or more other active ingredients specified in paragraph (a) (1) of this section, after the name "bacitracin-neomycin-polymyxin powder topical" or "bacitracin zinc-neomycin-polymyxin powder topical", wherever such name appears, the words "with-----", in juxtaposition with such name, the blank being filled in with the established name of each such other ingredient.

(4) *Request for certification; samples.*
(i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless they were previously submitted) the dates on which the latest assays of the bacitracin or bacitracin zinc neomycin, and polymyxin used in making such batch were completed, the number of units of bacitracin or bacitracin zinc and polymyxin B, and the number of milligrams of neomycin in each immediate container, the date on which the latest assays of the drugs comprising such batch were completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(ii) Except as otherwise provided in paragraph (a) (4) (iv) of this section such person shall submit in connection with his request results of the tests and assays listed after each of the following made by him on an accurately representative sample of:

(a) The batch: The number of units of bacitracin or bacitracin zinc the number of units of polymyxin, and the number of milligrams of neomycin, a microorganism count, and moisture.

(b) The bacitracin or bacitracin zinc used in making the batch: Potency, safety, loss on drying, pH, and zinc content if it is bacitracin zinc.

(c) The neomycin used in making the batch: Potency, toxicity, moisture, and pH.

(d) The polymyxin B used in making the batch: Potency and toxicity.

(iii) Except as otherwise provided by paragraph (a) (4) (iv) of this section such person shall submit in connection with his request, in the quantities hereinafter indicated accurately representative samples of the following:

(a) The batch: For all tests except microorganism count, one immediate container for each 5,000 immediate containers in the batch, but in no case less than seven immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(b) For microorganism testing: Five immediate containers.

(c) The bacitracin or bacitracin zinc used in making the batch: Six packages, containing approximately equal portions of not less than 0.5 gram.

(d) The neomycin used in making the batch: Five packages containing approximately equal portions of not less than 0.5 gram.

(e) The polymyxin B used in making the batch: Five packages containing approximately equal portions of not less than 0.5 gram.

(f) In case of an initial request for certification, each other substance used in making the batch: One package of each containing approximately 5 grams.

(iv) The results referred to in paragraph (a) (4) (ii) (b), (c), and (d) of this section and the samples referred to in paragraph (a) (4) (iii) (c), (d), (e), and (f) of this section are not required if such results or samples have been previously submitted.

(b) *Tests and methods of assay—(1) Potency. (i) Dry powder—(a) Bacitracin content.* Proceed as directed in § 448.10 (b) (1). Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) *Bacitracin zinc content.* Proceed as directed in § 448.13 (b) (1). Its content of zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(c) *Neomycin content.* Proceed as directed in § 436.517 (b) (1) of this chapter. Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(d) *Polymyxin B content.* Proceed as directed in § 444.170a (b) (2) (1) of this chapter. Its content of polymyxin B is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(ii) *Powder packaged with inert gases.* Spray, as directed in the labeling, the entire contents of each container to be tested into a separate 2-liter Erlenmeyer flask, held in a horizontal position. Add 500 milliliters of 0.01N HCl and shake to dissolve the contents. Immediately remove aliquots of this solution and using the appropriate buffer solutions to make further dilutions, proceed as directed in paragraph (b) (1) (i) of this section. Calculate the average total amount of each antibiotic expelled from the containers. The total potency is satisfactory if it contains not less than 85 percent of the number of units of bacitracin zinc and polymyxin and not less than 85 percent of the number of milligrams of neomycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *Microorganism count—(i) Conduct of test for bacteria—(a) Dry powder.* Using approximately 200 milligrams of powder from each of five separate immediate containers, proceed as directed in § 436.20 (e) (1) of this chapter, except after the three washings transfer the entire filter membrane to the surface of medium G as described in § 436.20 (c) (7) of this chapter. Incubate the plate for 5 days at 30° C to 32° C. Count the number of colonies appearing on the filter

pad and calculate therefrom the number of viable microorganisms per gram of powder.

(b) *Powder packaged with inert gases.* Thoroughly cleanse the valve of each container to be tested with a suitable disinfectant. Into an empty, sterile Erlenmeyer flask, stoppered with a cotton plug, spray about one-half on the contents of each of five separate immediate containers by removing the cotton plug temporarily and using aseptic technique. Allow the propellant to evaporate. To the dry residue, which should not exceed 1 gram, add 500 milliliters of diluting fluid C as described in § 436.20 (c) (3) of this chapter, and swirl the flask to dissolve the contents. Then proceed as described in paragraph (b) (3) (i) (a) of this section.

(ii) *Conduct of test for molds and yeasts—(a) Dry powder.* Proceed as directed in § 436.20 (e) (1) of this chapter, using approximately 200 milligrams from each of the five containers tested, except use the agar medium H as described in § 436.20 (b) (8) of this chapter, and incubate at 22° C—25° C for 5 days. Count the number of colonies appearing on the filter pad and calculate therefrom the number of viable microorganisms per gram of powder.

(b) *Powder packaged with inert gases.* Proceed as directed in paragraph (b) (3) (i) (b) of this section, use agar medium H as described in § 436.20 (c) (8) of this chapter, and incubate at 25° C for 5 days.

(iii) *Evaluation of results.* The microorganism count of the sample is satisfactory if the average number of viable microorganisms is not more than 10 per gram of powder, or per container if it is packaged with inert gases.

§ 548.313b [Amended]

m. In § 548.313b, the section heading is revised to read "§ 548.313b Bacitracin/bacitracin zinc ointment, the introductory text of paragraph (a) and paragraph (b) are amended by changing "zinc bacitracin" to read "bacitracin zinc", and paragraph (a) (2) (i) is amended in the last sentence by changing "§ 448.510a(a)(3)" to read "448.510a(a)(2)".

n. In § 548.314a, the section heading and paragraph (a) are revised to read as follows:

§ 548.314a Bacitracin zinc, polymyxin B sulfate, neomycin sulfate ophthalmic ointment.

(a) *Specifications.* The drug conforms to the provisions of § 448.313b of this chapter.

o. In § 548.314b, the section heading and paragraphs (a), (b), and (c) (1) are revised to read as follows:

§ 548.314b Bacitracin zinc, polymyxin B sulfate, neomycin sulfate, hydrocortisone acetate, ophthalmic ointment.

(a) *Requirements for certification.* The requirements for certification for bacitracin zinc, polymyxin B sulfate, neomycin sulfate, hydrocortisone ace-

tate, ophthalmic ointment are described under § 448.313b(a) of this chapter.

(b) *Tests and methods of assay.* The tests and methods of assay for bacitracin zinc, polymyxin B sulfate, neomycin sulfate, hydrocortisone acetate, ophthalmic ointment are described under § 448.313b of this chapter.

(c) *Conditions of marketing—(1) Specifications.* The drug conforms to the specification requirements in § 448.313b of this chapter and is subject to the tests and methods of assay prescribed in § 448.310b of this chapter. Each gram of the drug contains the following active ingredients: 400 units of bacitracin zinc, 5,000 units of polymyxin B sulfate, 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), and 10 milligrams of hydrocortisone acetate.

Effective date: This regulation shall become effective June 27, 1977.

(Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b).)

Dated: May 18, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 77-14965 Filed 5-26-77; 8:45 am]

Title 32—National Defense

CHAPTER V—DEPARTMENT OF THE ARMY

[Army Reg. 340-21]

PART 505—PERSONAL PRIVACY AND RIGHTS OF INDIVIDUALS REGARDING THEIR PERSONAL RECORDS

Privacy Act of 1974

AGENCY: Department of the Army.

ACTION: Final rule.

SUMMARY: This rule adopts prescribed exemptions which may be claimed under the Privacy Act for the system of records ID: A0709.01aDAPE, entitled: United States Military Academy Candidate Files. This action is being taken in order to protect information sources, evaluative material, and investigatory and testing techniques.

DATE: This rule is effective May 10, 1977.

FOR FURTHER INFORMATION CONTACT:

Mr. Cyrus Fraker (202-693-0973).

SUPPLEMENTARY INFORMATION: In FR Doc. 77-10574 published in the FEDERAL REGISTER issue of April 11, 1977 (42 FR 18863), the Department of the Army published a proposed exemption rule as a proposed amendment to 32 CFR 505.9 for system of records identified above. Comments were received from the Office of Management and Budget and the House of Representatives concerning necessity for claiming a (k) (6) exemption for the Candidate Summary Sheet. It was suggested that the Army consider separating information furnished by the candidate from the values (scores) assigned such information by the Academy so that a person could see his/her scores.

This suggestion was considered infeasible since a candidate could be supplying ten or more papers containing self-prepared information about oneself. The Academy does not verify all information reported by the candidate. Thus, if a candidate knows the weight assigned to a given item of information, he/she could obtain undue advantage. For example, a candidate may report having lettered in football or track when, in reality, the person may have only participated in these sports. Another may report being Editor-in-Chief of a high school newspaper when the person was only a reporter. The Academy develops quantified scores from the information provided. To permit an individual to see his/her scores on the Candidate Summary Sheet would give the candidate the opportunity to derive a close approximation of the values assigned to each event or category of accomplishment reported and therefore jeopardize the objectivity of the evaluation in fairness to all candidates.

ROME D. SMYTH,
Colonel, GS, Director,
Administrative Management.

MAURICE W. ROCHE,
Director, Correspondence and
Directives, Office of the
Assistant Secretary of Defense (Comptroller).

MAY 17, 1977.

The following exemption rule is added and should be inserted before exemption rule ID-A0709.03aDAPE, SYSNAME—United States Military Academy Cadet Files (41 FR 30905).

§ 505.9 Exemption rules for Army systems of records.

EXEMPTED RECORD SYSTEM (SPECIFIC EXEMPTIONS)

ID-A0709.01aDAPE.
SYSNAME: United States Military Academy Candidate Files.

EXEMPTION: All portions of this system which fall within 5 U.S.C. 552a(k) (5), (6), or (7) are exempt from the following provisions of Title 5 U.S.C. section 552a: (d).

AUTHORITY: 5 U.S.C. 552a(k) (5), (6), and (7).

REASONS: From subsection (d) because access might reveal investigatory and testing techniques. The exemption from access necessarily includes exemption from amendment, certain agency requirements relating to access and amendment of records, and civil liability predicated upon agency compliance with those specific provisions of the Privacy Act.

Exemption is necessary to protect the identity of individuals who furnished information to the United States Military Academy which is used in determining suitability, eligibility, or qualifications for military service and which was provided under an express promise of confidentiality.

Exemption is needed for the portion of records compiled within the Academy which pertain to testing or examination material used to rate individual qualifications, the disclosure of which would compromise the objectivity or fairness of the testing or examination process.

Exemption is required for evaluation material used by the Academy in determining

potential for promotion in the armed services, to protect the identity of a source who furnished information to the Academy under an express promise of confidentiality.

[FR Doc. 77-15029 Filed 5-26-77; 8:45 am]

Title 36—Parks, Forests and Public Property

CHAPTER II—FOREST SERVICE, DEPARTMENT OF AGRICULTURE

PART 261—NATIONAL FOREST SYSTEM PROHIBITIONS

Permits for Chattooga River

AGENCY: Forest Service, Department of Agriculture.

ACTION: Interim regulations applicable to Region 8, Southern Region, and Notice of Proposed Rulemaking.

SUMMARY: This action requires private and commercial users to obtain a permit to float the Chattooga Wild and Scenic River. Permits will include conditions of use to protect river values and provide for floater safety. Safety regulations have drastically reduced the high number of fatalities occurring prior to regulations.

DATES: Effective date May 27, 1977. Comments must be received on or before August 25, 1977.

ADDRESS: Sent comments to: USDA, Forest Service, Fiscal and Accounting Management Staff, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT:

Forest Supervisor John Orr, Francis Marion & Sumter National Forests, 1801 Assembly Street, Second Floor, Columbia, South Carolina 29201, 803-765-5222.

SUPPLEMENTARY INFORMATION: The number of people annually floating and canoeing the Chattooga River has increased over 7,000 percent since 1967.

The river was designated a Wild and Scenic River in 1974. The river is located on the border of Georgia-South Carolina and is one of the largest rivers in the Southeast with challenging whitewater rapids.

The number of accidents, including drownings, also increased at an alarming rate, averaging seven per year. In 1974, regulations to provide for user safety were adopted. Principal among these was the required wearing of life jackets. The fatality rate has been lowered drastically. No fatalities have occurred since October 1975. Safety regulations and more experienced users are thought to account for this improved record. This action provides these regulations to continue as a condition of the permit required to float or canoe the river. There is immediate need for the regulations as the warmer weather increases use on the river. They will be issued as interim regulations for ninety days during which time comments may be submitted. After ninety days, the regulations will be issued as permanent reg-

ulations or modified depending upon comments received.

INTERIM REGULATIONS

Pursuant to 36 CFR 261.70, the Regional Forester, Region 8, Southern Region, has determined that advanced notice of proposed rulemaking and public participation thereon relative to the interim regulations hereinafter set forth is impracticable, unnecessary, or contrary to the public interest. Accordingly, the following interim regulations, prohibiting acts or omissions within the areas of the Sumter National Forest and the Chattahoochee National Forest described below for the purposes of public safety and establishing reasonable rules of public conduct, are hereby issued with the concurrence of the Chief of the Forest Service, United States Department of Agriculture. The prohibitions set forth below become effective on May 27, 1977, and shall remain effective for not more than 90 days unless readopted as permanent regulations as hereinafter proposed.

NOTICE OF PROPOSED RULE MAKING

Notice is hereby given that the Department of Agriculture, by and through the Regional Forester, Region 8, Southern Region, Forest Service, is considering re-adopting the interim regulations set forth below, 36 CFR 261.77, as permanent regulations pursuant to 36 CFR 261.70 for the purposes of public safety, and establishing reasonable rules of public conduct on the areas mentioned in the interim regulations.

It is proposed that the said interim regulations being published concurrently herein become permanent regulations and that § 261.77, as set forth in the interim regulations, become permanent regulations.

All persons wishing to submit written data, views, or objections pertaining to the proposed new permanent section § 261.77, may do so by submitting them to the U.S. Department of Agriculture, Forest Service, Fiscal and Accounting Management Staff, Washington, D.C. 20250 on or before August 25, 1977.

All written submissions made pursuant to this notice will be available for public inspection in Room 4007, South Building, U.S. Department of Agriculture, 14th Street and Independence Avenue, SW., Washington, D.C., during regular business hours (7 CFR 1.27(b)).

Subpart C is amended by adding a new interim regulation section, § 261.77, as follows:

§ 261.77 Prohibitions in Region 8, Southern Region.

(a) Using or occupying any area of the Sumter National Forest or the Chattahoochee National Forest abutting the Chattooga River for the purpose of entering or going upon the River in, on, or upon any floatable object or craft of every kind or description, unless authorized by permit obtained through registration at Forest Service Registration Stations abutting the Chattooga River located at Highway 28, Low-Water Bridge, Earl's Ford, Sandy Ford, High-

way 76, Woodall Shoals, or Overflow Bridge or unless authorized under special use permit.

(b) Using or occupying within the scope of any commercial operation or business any area of the Sumter National Forest or the Chattahoochee National Forest abutting the Chattooga River for the purpose of entering or going upon the River in, on, or upon any floatable object or craft of every kind or description, unless authorized by special use permit.

(c) Violating or failing to comply with any of the terms or conditions of any permit authorizing the occupancy and use specified in paragraphs (a) or (b) of this section is prohibited.

(d) Entering, going, riding, or floating upon any portion or segment of the Chattooga River within the boundaries of the Chattahoochee National Forest in, on, or upon any floatable object or craft of every kind or description, unless authorized by a permit obtained through registration at Forest Service Registration Stations abutting the Chattooga River located at Highway 28, Low-Water Bridge, Earl's Ford, Sandy Ford, Highway 76, Woodall Shoals, or Overflow Bridge or unless authorized under special use permit.

(e) Entering, going, riding, or floating within the scope of any commercial operation or business upon any portion or segment of the Chattooga River within the boundaries of the Chattahoochee National Forest in, on, or upon any floatable object or craft of every kind or description, unless authorized by special use permit.

(f) Violating or failing to comply with any of the terms or conditions of any permit authorizing the occupancy and use specified in paragraph (d) or (e) of this section is prohibited.

Dated: May 20, 1977.

JAMES E. WEBB,
Deputy Regional Forester for
Administration, Region 8,
Southern Region, Forest
Service, Department of Agriculture.

[FR Doc. 77-15148 Filed 5-26-77; 8:45 am]

Title 38—Pensions, Bonuses and Veterans' Relief

CHAPTER I—VETERANS ADMINISTRATION

PART 1—GENERAL PROVISIONS

United States Flag for Burial Purposes

AGENCY: Veterans Administration.

ACTION: Final rule.

SUMMARY: This amended regulation would eliminate the preference being given to sons and fathers in the disposition of a United States Flag for burial purposes. It would permit the eldest child to be eligible to receive the flag if there is no spouse, and it would combine the eligibility of mothers and fathers into one category of parents. In addition minor editorial changes have been made to reflect agency policy concerning

use of precise terms denoting gender. These actions are being taken in the interests of fairness and in conformity with recent decisions of the United States Supreme Court. It is intended that this rule will eliminate sex discrimination with regard to this regulation.

EFFECTIVE DATE: May 20, 1977.

FOR FURTHER INFORMATION CONTACT:

Charles M. Ott, Veterans Assistance Specialist (272), Veterans Assistance Service, Veterans Administration, Washington, D.C. 20420, telephone 202-389-3675.

SUPPLEMENTARY INFORMATION:

On page 54777 of the FEDERAL REGISTER of December 15, 1976, there was published a notice of proposed regulatory development to amend § 1.10(b) (2) and (3). This proposal concerned the elimination of preference being given to sons over daughters with regard to the disposition of a United States Flag for burial purposes. Interested persons were given 30 days in which to submit comments, suggestions, or objections regarding the proposed regulation. Twenty-one written comments were received. Four of these concurred with the proposal while the remaining seventeen not only agreed with the proposal but wished to see it extended to also eliminate the preference being given to fathers over mothers. The proposal has been reviewed in light of these comments and consequently subdivisions (iii) and (iv) of paragraph (b) (2) have been combined with the remaining subdivisions renumbered accordingly. The proposed regulation is adopted as changed and set forth below.

Inflation Impact: The Veterans Administration has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

Approved: May 20, 1977.

By direction of the Administrator

RUFUS H. WILSON,
Deputy Administrator.

1. In § 1.10, paragraph (b) (2) and (3) is revised to read as follows:

§ 1.10 Eligibility for and disposition of the United States flag for burial purposes.

(b) Disposition of burial flags. * * *

(2) The phrase "next of kin" for the purpose of disposing of the flag used for burial purposes is defined as follows, with preference to entitlement in the order listed:

- (i) Widow or widower.
- (ii) Children, according to age (minor child may be issued a flag on application signed by guardian).
- (iii) Parents, including adoptive, step-parents, and foster parents.
- (iv) Brothers or sisters, including brothers or sisters of the halfblood.

- (v) Uncles or aunts.
- (vi) Nephews or nieces.
- (vii) Others—cousins, grandparents, etc. (but not in-laws).

(3) The phrase "close friend or associate" for the purpose of disposing of the burial flag means any person who because of his or her relationship with the deceased veteran arranged for the burial or assisted in the burial arrangements. In the absence of a person falling in either of these categories, any person who establishes by evidence that he or she was a close friend or associate of the veteran may be furnished the burial flag. Where more than one request for the burial flag is received and each is accompanied by satisfactory evidence of relationship or association, the head of the field station having jurisdiction of the burial flag quota will determine which applicant is the one most equitably entitled to the burial flag.

2. Immediately preceding § 1.12, the following centerhead is added "Public Participation."

[FR Doc. 77-15163 Filed 5-26-77; 8:45 am]

Title 39—Postal Service

CHAPTER I—UNITED STATES POSTAL SERVICE

PART 111—GENERAL INFORMATION ON POSTAL SERVICE

Definition of Advertisements; Marking of Paid Reading Matter

AGENCY: U.S. Postal Service.

ACTION: Final rule.

SUMMARY: The rule, among other things, revises 125.52 of the Postal Service Manual to simplify and more precisely define the term "advertising." It also incorporates administrative rulings of the Postal Service to the effect that, if an advertising rate is paid for the publication of reading matter or other material in a second-class publication, such material is deemed to be "advertising." Under 125.52 articles published in scientific journals or other second-class publications would not be considered "advertising" for rate purposes, even though the author paid a fee for the publication based upon the number of printed pages. Such articles, however, continue to fit the definition of "advertisement" in 132.7, which requires disclosure that valuable consideration has been paid or promised for the publication of editorial or other reading matter. In this connection, 132.7, which deals with the marking of paid reading matter with the word "advertisement," is amended by limiting the required marking to one page of a piece of reading matter, regardless of the total number of pages.

EFFECTIVE DATE: May 27, 1977.

FOR FURTHER INFORMATION CONTACT:

Arthur S. Cahn, 202-245-4604.

SUPPLEMENTARY INFORMATION: On March 2, 1977, the Postal Service published for comment in the *FEDERAL*

REGISTER a notice of rule which, among other things, would revise 125.52 of the Postal Service Manual to simplify and more precisely define the term "advertisement" and amend 132.7 of the Postal Service Manual, which deals with the marking of paid reading matter with the word "advertisement," so that the required marking would be limited to one piece of reading matter, regardless of the total number of pages.

Interested persons were invited to submit written data, views or arguments concerning the proposed revised regulations. Comments were received from a total of 23 individuals and organizations. These comments were carefully considered by the Postal Service in adopting the amendments to the regulations set forth below.

The general areas of concern of the commenters and the Postal Service analysis of the comments follows:

(a) Labeling requirement—Many commenters suggested that the Postal Service not require that advertising matter in an editorial format be marked "advertisement." Others felt that the word "advertisement" should be permitted as an explanatory phrase at the end of a multi-page article, while others felt that our proposed regulations should clearly specify the exact location where the word "advertisement" should appear. 18 U.S.C. 1734 provides as follows:

Sec. 1734. Editorials and other matter as 'advertisements'

Whoever, being an editor or publisher, prints in a publication entered as second-class mail, editorial or other reading matter for which he has been paid or promised a valuable consideration, without plainly marking the same 'advertisement' shall be fined not more than \$500.

The Postal Service has no authority to waive this statutory requirement that any reading matter must be labeled "advertisement" if consideration is paid for its publication. Since the statute on which the regulation is based states that the matter in question is to be plainly marked, the regulation prescribes that the word "advertisement" must be on the first page of a multi-page article.

Further, the word "advertisement" may appear as part of an explanatory statement telling why the material must be marked advertisement. However, any such statement must be prominent on the first page of an article and the word "advertisement" in the statement must be in bold or italicized print, or otherwise given emphasis so it can be plainly seen. We have added this requirement to 132.73 in the final regulation.

(b) A second area of concern for several commenters concerned whether the revised regulation would apply to articles published in scientific journals which have a "voluntary page charge" policy. The Postal Service has previously stated that the provisions of part 132 of the Postal Service Manual do not apply to articles in scientific or other publications for which payment of a page charge or other consideration is not a condition of publication. However, in order for these

provisions not to apply, any payments resembling page charges must be truly voluntary contributions. Part 132 applies to all publications, scientific or otherwise, having mandatory page charges.

(c) Several commenters objected to the proposed revision on the basis that it may violate the provisions of the First Amendment of the Constitution because of vagueness and possible censorship questions. This criticism does not appear to be valid. The revised regulations do not prohibit or censor the content of a second-class publication but simply contain a more precise statement of how the Postal Service determines what is "advertising" for rate purposes, a statutory and regulatory responsibility of the Postal Service. Additionally, a commenter felt that the word "promotes" in the last sentence of proposed section 125.52 was too vague. We have changed the word "promotes" to "advertises" in the final version of the regulation.

(d) Several commenters objected to the last two sentences of proposed section 125.52 as constituting a substantive change in Postal Service regulations. However, the last two sentences of the proposed regulation are almost identical to the existing regulation and changes were made simply for clarity. No substantive changes are intended. The Postal Service received several phone inquiries concerning the meaning of the term "reader," which is a technical term used in the current regulation and in the proposed revision. To avoid any confusion concerning this term, we have used nontechnical language in the final regulation.

(e) Lastly, several commenters indicated their approval of the revised regulation.

Accordingly, having given due consideration to all comments received, the Postal Service has determined to adopt the following amendments to the Postal Service Manual, with these changes from the original proposal.

The third and fourth sentences of § 125.52 are rewritten as follows:

Articles, items, and notices in the form of reading matter are deemed to be "advertising" if they are inserted in accordance with a custom or understanding that textual matter is to be inserted for the advertiser or his products in the publication in which a display advertisement appears. If a newspaper or periodical advertises its own services or issues, or any other business of the publisher, whether in the form of display advertising or editorial or reading matter, this is deemed to be "advertising."

The following sentence has been added to 132.73:

The word "advertisement" may be part of a statement which explains why the material is marked advertisement. However, such a statement must be prominent on the first page of an article and the word "advertisement" in the statement must be in bold or italicized print, or otherwise given emphasis so it can be plainly seen.

Accordingly, the Postal Service hereby adopts the following revisions of the Postal Service Manual effective 12:01 a.m. on May 27, 1977.