producing animals shall include ade-
quate data to assure that edible prod-
ucts from treated animals are safe for
human consumption under the labeled
conditions of use.

[42 FR 37725, July 1, 1977; 42 FR 37975, July 26,
1977]

§ 500.50 Propylene glycol in or on cat
food.
The Food and Drug Administration
has determined that propylene glycol
in or on cat food is not generally recog-
nized as safe and is a food additive sub-
ject to section 409 of the Federal Food,
Drug, and Cosmetic Act (the act). The
Food and Drug Administration also has
determined that this use of propylene
glycol is not prior sanctioned.

[61 FR 19544, May 2, 1996]

Subpart C—Animal Drug Labeling
Requirements

§ 500.51 Labeling of animal drugs; mis-
branding.
(a) Among the representations on the
label or labeling of an animal drug
which will render the drug misbranded
are any broad statements suggesting or
implying that the drug is not safe and
effective for use when used in accord-
ance with labeling direction, or sug-
gesting or implying that the labeling
does not contain adequate warnings or
adequate directions for use. Such state-
ments include, but are not limited to:
(1) Any statement that disclaims li-
ability when the drug is used in accord-
ance with directions for use contained
on the label or labeling.
(2) Any statement that disclaims li-
ability when the drug is used under
"abnormal" or "unforeseeable" condi-
tions.
(3) Any statement limiting the war-
ranty for the products to a warranty
that the drug in the package contains
the ingredients listed on the label.
(b) This regulation is not intended to
prohibit any liability disclaimer that
purports to limit the amount of dam-
ages or that sets forth the legal theory
under which damages are to be recov-
ered.
(c) Any person wishing to obtain an
evaluation of an animal drug liability
disclaimer under this regulation may
submit it to Division of Compliance,
(HFV–230), Center for Veterinary Medi-
cine, Food and Drug Administration,
7500 Standish Pl., Rockville, MD 20855.
A supplemental NADA providing appro-
priately revised labeling shall be sub-
mittted for any approved new animal
drug the labeling of which is not in
compliance with this regulation.

[41 FR 8473, Feb. 27, 1976, as amended at 54
FR 18279, Apr. 28, 1989; 57 FR 6475, Feb. 25,
1992]

§ 500.52 Use of terms such as “tonic”,
“tone”, “toner”, or “conditioner” in
the labeling of preparations in-
tended for use in or on animals.
(a) The use of terms such as tonic,
tone, toner, and similar terms in the la-
beling of a product intended for use in
or on animals implies that such prod-
uct is capable of a therapeutic effect(s)
and causes such a product to be a drug
within the meaning of section 201(g) of
the Federal Food, Drug, and Cosmetic
Act. The unqualified use of such terms
in a product’s labeling fails to provide
adequate directions and indications for
use of such product and causes it to be
misbranded within the meaning of sec-
tion 502(a) and (f)(1) of the act. The
terms tonic, tone, toner, and similar
terms may be used in labeling only
when appropriately qualified so as to
fully inform the user regarding the in-
tended use(s) of the product.
(b) The unqualified use of the term
conditioner and similar terms in the la-
beling of a product intended for use in
or on animals implies that such prod-
uct is capable of a therapeutic effect(s)
and causes such a product to be a drug
within the meaning of section 201(g) of
the act. The unqualified use of such
terms in a product’s labeling fails to
provide adequate directions and indica-
tions for use of such product and
causes it to be misbranded within the
meaning of section 502(a) and (f)(1) of
the act. The term conditioner and simi-
lar terms may be used in labeling only
when appropriately qualified so as to
tfully inform the user regarding the in-
tended use(s) of the product. A product
labeled as a "conditioner" or with a
similar term can be either a food or
drug depending upon the manner in