of such drug, even though such drug or
animal feed containing such drug when
used in another dosage, or another
method or duration of administration
or application, or different condition,
is not a new animal drug.

(j) Animals used only for laboratory re-
search and laboratory research animals
mean individual animals or groups of
animals intended for use and used sole-
ly for laboratory research purposes, re-
gardless of species, and does not in-
clude animals intended to be used for
any food purposes or animals intended
to be kept as livestock.

(k) Sponsor means the person request-
ing designation for a minor-use or
minor-species drug as defined in part
516 of this chapter, who must be the
real party in interest of the develop-
ment and the intended or actual pro-
duction and sales of such drug (in this
context, the sponsor may be an indi-
vidual, partnership, organization, or
association). Sponsor also means the
person responsible for an investigation
of a new animal drug. In this context,
the sponsor may be an individual, part-
nership, corporation, or Government
agency or may be a manufacturer, sci-
entific institution, or an investigator
regularly and lawfully engaged in the
investigation of new animal drugs.
Sponsor also means the person submit-
ting or receiving approval for a new
animal drug application (in this con-
text, the sponsor may be an individual,
partnership, organization, or associa-
tion). In all contexts, the sponsor is re-
sponsible for compliance with applica-
table provisions of the act and regula-
tions.

§510.4 Biologies; products subject to
license control.

An animal drug produced and distrib-
uted in full conformance with the ani-
mal virus, serum, and toxin law of
March 4, 1913 (37 Stat. 832; 21 U.S.C. 151
et seq.) and any regulations issued
thereunder shall not be deemed to be subject to section 512 of the Federal

§510.7 Consignees of new animal
drugs for use in the manufacture of
animal feed.

(a) A new animal drug intended for
use in the manufacture of animal feed
shall be deemed to be unsafe unless at
the time of its removal from the estab-
ishment of a manufacturer, packer, or
distributor of such drug, such manufac-
turer, packer, or distributor has an
unrevoked written statement from the
consignee of such drug, or a notice
from the Secretary, to the effect that
with respect to the use of such drug in
animal feed the consignee:

(1) Holds a license issued under
§515.20 of this chapter; or

(2) Will, if the consignee is not the
user of the drug, ship such drug only to
a holder of an approved application
under §515.10 of this chapter.

(b) The requirements of paragraph (a)
of this section do not apply:

(1) Where such drugs are intended for
export and/or

(2) When the use of such drug in the
manufacture of a finished feed has been
exempted from the requirements of
section 512(m) of the act under the con-
ditions specified by regulations pub-
lished in part 558 of this chapter.

[40 FR 13807, Mar. 27, 1975, as amended at
64 FR 63203, Nov. 19, 1999]

§510.95 [Reserved]

Subpart B—Specific Administrative
Rulings and Decisions

§510.105 Labeling of drugs for use in
milk-producing animals.

(a) Part 526 of this chapter provides
for new animal drugs intended for
intramammary use in animals and in-
cludes conditions of use intended to
prevent the contamination of milk
from the use of such drugs.

(b) Preparations containing anti-
biotics and other potent drugs labeled
with directions for use in milk-pro-
ducing animals will be misbranded
under section 502(f)(2) of the act unless
their labeling bears appropriate warn-
ings and directions for use to avoid
adulteration of milk under section
402(a)(2)(c)(ii) of the act.

(c) It is the position of the Food and
Drug Administration that the labeling