§ 331.20 Determination of percent contribution of active ingredients.

To determine the percent contribution of an antacid active ingredient,
place an accurately weighed amount of
the antacid active ingredient equal to
the amount present in a unit dose of
the product into a 250-milliliter (mL)
beaker. If wetting is desired, add not
more than 5 mL of alcohol (neutralized
to an apparent pH of 3.5), and mix to
wet the sample thoroughly. Add 70 mL
of water, and mix on a magnetic stirrer
at 300 ±30 r.p.m. for 1 minute. Analyze
the acid neutralizing capacity of the
sample according to the procedure pro-
vided in the United States Pharma-
copia 23-National Formulary 18 and
calculate the percent contribution of
the antacid active ingredient in the
total product as follows:
Percent contribution = (Total mEq.
Antacid Active Ingredient x 100)/(Total
mEq. Antacid Product).

[61 FR 4823, Feb. 8, 1996]

§ 331.21 Test modifications.
The formulation or mode of adminis-
tration of certain products may require
a modification of the United States
Pharmacopeia 23-National Formulary 18
acid neutralizing capacity test. Any
proposed modification and the data to
support it shall be submitted as a peti-
tion under the rules established in
§ 10.30 of this chapter. All information
submitted will be subject to the disclo-
sure rules in part 20 of this chapter.

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Subpart D—Labeling

§ 331.30 Labeling of antacid products.
(a) Statement of identity. The labeling
of the product contains the established
name of the drug, if any, and identifies
the product as an “antacid.”
(b) Indications. The labeling of the
product states, under the heading “Indica-
tions,” the following: “For the re-

Relief of” (optional, any or all of the
following): “heartburn,” “sour stomach,”
and/or “acid indigestion” (which may
be followed by the optional statement:)
“and upset stomach associated with”
(optional, as appropriate) “this symp-
tom” or “these symptoms.” Other
truthful and nonmisleading state-
ments, describing only the indications
for use that have been established and
listed in this paragraph (b), may also
be used, as provided in § 330.1(c)(2) of
this chapter, subject to the provisions
of section 502 of the act relating to
misbranding and the prohibition in sec-
tion 301(d) of the act against the intro-
duction or delivery for introduction
into interstate commerce of unap-
proved new drugs in violation of sec-
tion 505(a) of the act.
(c) Warnings. The labeling of the
product contains the following warn-
ings, under the heading “Warnings,”
which may be combined but not rear-
ranged to eliminate duplicative words
or phrases if the resulting warning is
clear and understandable:
(1) “Do not take more than (maximum
recommended daily dosage, broken
down by age groups if appropriate,
expressed in units such as tablets or
teaspoonfuls) in a 24-hour period, or
use the maximum dosage of this prod-

uct for more than 2 weeks, except
under the advice and supervision of a
physician.”
(2) For products which cause con-

stipation in 5 percent or more of per-
sons who take the maximum re-

ommended dosage: “May cause con-

stipation.”
(3) For products which cause laxation
in 5 percent or more of persons who
take the maximum recommended dos-

age: “May have laxative effect.”
(4) For products containing more
than 5 gm per day lactose in a max-
imum daily dosage: “Do not use this
product except under advice and supervi-
sion of a physician if you are allergic
to milk or milk products.”
(d) Drug interaction precaution. The
labeling of the product contains the
following statement “Ask a doctor or
pharmacist before use if you are [bul-
let]1 presently taking a prescription
drug. Antacids may interact with cer-

tain prescription drugs.”
(e) Directions for use. The labeling of
the product contains the recommended
dosage, under the heading “Direc-
tions”, per time interval (e.g., every 4
hours) or time period (e.g., 4 times a
day) broken down by age groups if ap-
propriate, followed by “or as directed
by a physician.”
(f) Exemption from the general acci-
dental overdose warning. The labeling
for antacid drug products containing

1See § 201.66(b)(4) of this chapter.