

**Prescribing Information
for
TUSSEND® and
TUSSEND® EXPECTORANT**

CONTRAINDICATIONS:
Hypersensitivity to any of the
formula ingredients.

INDICATIONS: Tussend and
Tussend Expectorant anti-
tussive-decongestants are
indicated when exhausting
cough spasm accompanies
upper respiratory tract con-
gestion. They are useful in the
symptomatic relief of upper
respiratory congestion due to
allergic conditions, the com-
mon cold, sinusitis and acute
bronchitis.

PRECAUTIONS: Tussend and
Tussend Expectorant should
be used cautiously in individ-
uals with severe hypertension,
diabetes mellitus, hyper-
thyroidism or urinary reten-
tion. Continuous use over an
extended period is generally
contraindicated since hydro-
codone may cause addiction.

ADVERSE REACTIONS: As
with any narcotic analgesic,
hydrocodone may cause
gastrointestinal upset in
children and nausea in adults.
These reactions have been
reported, although rarely,
following the administration
of Tussend or Tussend
Expectorant.

**DOSAGE AND ADMINISTRA-
TION:** Adults, and children
over 90 lb., one tablet or one
teaspoonful; children 50 to
90 lb., ½ teaspoonful; children
25 to 50 lb., ¼ teaspoonful.
May be given 3 or 4 times
a day as needed.

CAUTION: Federal law
prohibits dispensing without
prescription.

and Drug Act by Congress in 1962. The court
then voided the injunction and gave the case
back to the FDA for "further determination."

Now the FDA had to either allow inclusion
of conflicting opinions about the oral hy-
poglycemics drug warning or revise the
regulation. They decided to revise the regula-
tion.

According to the 1962 Food and Drug Act:

"If an article is alleged to be misbranded
because the labeling is misleading, then in de-
termining whether the labeling is misleading
there shall be taken into account (among
other things) not only representations made
or suggested by statement, word, design, de-
vice, or any combination thereof, but also the
extent to which the labeling fails to reveal
facts material in the light of such representa-
tions or material with respect to conse-
quences which may result from the use of the
article to which the labeling relates under the
conditions of use prescribed in the labeling
thereof or under such conditions of use as are
customary or usual."

And:

"Unless its labeling bears (1) adequate direc-
tions for use; and (2) such adequate warnings
against use in those pathological conditions or
by children where its use may be dangerous
to health, or against unsafe dosage or methods
or duration of administration or application, in
such manner and form, as are necessary for
the protection of users: Provided, That where
any requirement of clause (1) of this
paragraph, as applied to any drug or device, is
not necessary for the protection of the public
health, the Secretary shall promulgate
regulations exempting such drug or device
from such requirement."

The law also (as everyone probably knows
by now) states that a new drug may not be ap-
proved for marketing if it is unsafe or ineffec-
tive for the conditions for which it is supposed
to be used.

The FDA finds the use of the word "may"
(underlined in the quotation above) particu-
larly significant, since it implies lack of univer-
sal agreement among experts. The word
"may" thus is supposed to make it unnecessary
to include the specific medical controversy
surrounding the warning. The FDA comments
that warnings have been required on drug

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DOW PHARMACEUTICALS
The Dow Chemical Company
Indianapolis, Ind. 46268