



The Role of the FDA

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October 26, 2004



Examples of Violations

- Minimization of risk information
- Unsubstantiated claims of efficacy or safety
- Unsubstantiated comparative claims
- Promotion of unapproved uses of drugs



Diovan Warning Letter

- Sales aid
- Unsubstantiated effectiveness claim
 - Diovan delays progression to end stage renal disease (ESRD) in type 2 diabetic patients with hypertension
 - No substantial evidence; other drugs have substantial evidence for this claim



Diovan WL (cont.)

- Data on reducing urine albumin excretion; returning patients to normoalbuminuria
 - Not correlated with preventing ESRD
- Presented with statements re: recommendations for using ARBs in hypertensive diabetics; diabetes and hypertension being the two leading causes of ESRD, etc.



Cubicin Warning Letter

- Journal advertisement and website
- Broadens the indication
 - treatment of all infections caused by Staph aureus
- PI states it is not indicated for pneumonia
 - In Phase 3 studies of community-acquired pneumonia, death rate was higher



Xeloda Warning Letter

- Sales aid
- Promotion of unapproved uses
 - Failed to convey specific indications
 - Mechanism of action claims



Xeloda Warning Letter

- Mechanism of action claims
 - Prominently featured bar graph depicting distribution of TP and listing of various tissues types
 - Claim above graph
 - Because TP activity is higher in most tumor tissue than in normal tissue, final conversion of drug to 5-FU occurs preferentially in the tumor
- Relationship of mechanism of action to efficacy and safety outcomes has not been demonstrated



Pravachol Warning Letter

- DTC ads and labeling pieces
- Healthcare professional directed labeling pieces
- Promotion of unapproved uses



Pravachol: Promotion of Unapproved Uses

- Not indicated to reduce risk of strokes in patients who do not have clinically evident CHD
- Claims
 - WORRIED ABOUT HAVING A HEART ATTACK?
WORRIED ABOUT HAVING A STROKE?
 - PRAVACHOL IS THE ONLY CHOLESTEROL LOWERING DRUG PROVEN TO HELP PROTECT 1ST AND 2ND HEART ATTACKS AND STROKE



WORRIED ABOUT HAVING
A HEART ATTACK?

WORRIED ABOUT HAVING
A STROKE?

**PRAVACHOL IS THE ONLY CHOLESTEROL LOWERING DRUG
PROVEN TO HELP PROTECT AGAINST
1st AND 2nd HEART ATTACK AND STROKE.**


IMPORTANT CONSIDERATIONS:

Pravachol® (pravastatin sodium), a prescription drug, is not for everyone, including women who are pregnant or nursing or may become pregnant, or people with liver problems. And because serious side effects can result, tell your doctor about any unexplained muscle pain or weakness you experience while on Pravachol, and about any other medications you are taking. Your doctor may do blood tests to check for liver problems. Some mild side effects, such as slight rash or stomach upset, occur in 2-4% of patients.

Ask your doctor if Pravachol is right for you.

Please see product information following this advertisement.

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 Bristol Myers Squibb Company
Pravachol, 30 09547 U.S.A.

www.pravachol.com



DDMAC Information

- Web addresses:
 - www.fda.gov/cder/ddmac
 - Warning and untitled letters : Posted on www.fda.gov/cder/warn
 - Guidances: Posted on www.fda.gov/cder/guidance
- Phone numbers:
 - (301) 827-2831 or (301) 827-2828