



PIC QUESTION OF THE WEEK: 04/18/05

Q: Why is Fiorinal® considered a controlled substance while Fioricet® is not?

A: The Controlled Substance Act regulates five classes of drugs: narcotics, depressants, hallucinogens, stimulants, and anabolic steroids. These compounds are then placed into categories known as “Schedules”, based on their potential for abuse. Each varies in its ability to produce physical dependence and addiction. Schedule I contains substances that have the highest potential for abuse, but have no currently accepted medical use in the United States and little safety data is available. Unlike Schedule I, Schedule II consists of drugs with high abuse potential that currently have an accepted medical use in the United States. Schedules III through V have progressively less abuse potential and produce limited physical dependence.

Exceptions from the above scheduling have been made if the drug meets the requirements of section 201(g) (3) (A) of the Controlled Substances Act. This section relates to combination products such as Fiorinal® and Fioricet®. The exemption requires that one of the active ingredients be a non-narcotic controlled substance and one of the others be a non-scheduled compound. The potential for abuse is decreased if a sufficient amount of a non-controlled substance (aspirin, acetaminophen, and ibuprofen) is added. The ratio required for exemption is 70 mg of acetaminophen to 15 mg of butalbital. In contrast, the ratio of aspirin to butalbital is 188 mg to 15 mg. Fioricet® contains 325 mg acetaminophen, 50 mg butalbital, and 40 mg caffeine. Therefore, the acetaminophen to butalbital ratio is approximately 97mg to 15 mg. This is greater than the 70mg:15mg ratio, thus the drug is exempt from scheduling. On the other hand, Fiorinal® contains 325 mg aspirin, 50 mg butalbital, and 40 mg caffeine. Therefore, the aspirin to butalbital ratio is approximately 97mg to 15mg. This combination is less than the 188mg:15mg ratio, so the drug is classified as a Schedule III substance.

References:

- www.usdoj.gov/dea (accessed 4/11/05)
- The United States Pharmacopeial Convention, INC. It's a Question of Control. Drug Product Quality Review. 1991;22.

Abbie L. McGowan and Karen E. Predmore, Pharmacy Clerkship Students