(2) The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements of 40 CFR part 82 and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase.

(d) This section does not replace or relieve a person from any requirements imposed under 40 CFR part 82.

[61 FR 20100, May 3, 1996]

§ 201.322 Over-the-counter drug products containing internal analgesic/antipyretic active ingredients; required alcohol warning.

(a) People who regularly consume large quantities of alcohol (three or more drinks every day) have an increased risk of adverse effects (possible liver damage or gastrointestinal bleeding). OTC drug products containing internal analgesic/antipyretic active ingredients may cause similar adverse effects. FDA concludes that the labeling of OTC drug products containing internal analgesic/antipyretic active ingredients should advise consumers with a history of heavy alcohol use to consult a physician. Accordingly, any OTC drug product, labeled for adult use, containing any internal analgesic/antipyretic active ingredients (including, but not limited to, acetaminophen, aspirin, carbaspirin calcium, choline salicylate, ibuprofen, ketoprofen, magnesium salicylate, naproxen sodium, and sodium salicylate) alone or in combination shall bear an alcohol warning statement in its labeling as follows:

(1) *Acetaminophen.* ''Alcohol Warning'' [heading in boldface type]: ''If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.''

(2) *Nonsteroidal anti-inflammatory analgesic/antipyretic active ingredients—including but not limited to aspirin, carbaspirin calcium, choline salicylate, ibuprofen, ketoprofen, magnesium salicylate, naproxen sodium, and sodium salicylate.* ''Alcohol Warning'' [heading in boldface type]: ''If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take [insert one nonsteroidal anti-inflammatory analgesic/antipyretic active ingredient] or other pain relievers/fever reducers. [Insert one nonsteroidal anti-inflammatory analgesic/antipyretic active ingredient] may cause stomach bleeding.''

(3) *Combinations of acetaminophen with nonsteroidal anti-inflammatory analgesic/antipyretic active ingredients—including but not limited to aspirin, carbaspirin calcium, choline salicylate, ibuprofen, ketoprofen, magnesium salicylate, naproxen sodium, and sodium salicylate.* ''Alcohol Warning'' [heading in boldface type]: ''If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take [insert acetaminophen and one nonsteroidal anti-inflammatory analgesic/antipyretic active ingredient—including, but not limited to aspirin, carbaspirin calcium, choline salicylate, magnesium salicylate, or sodium salicylate] or other pain relievers/fever reducers. [Acetaminophen and (insert one nonsteroidal anti-inflammatory analgesic/antipyretic ingredient—including, but not limited to aspirin, carbaspirin calcium, choline salicylate, magnesium salicylate, or sodium salicylate] may cause liver damage and stomach bleeding.''

(b) *Requirements to supplement approved application.* Holders of approved applications for OTC drug products that contain internal analgesic/antipyretic active ingredients that are subject to the requirements of paragraph (a) of this section must submit supplements under § 314.70(c) of this chapter to include the required warning in the product's labeling. Such labeling may be put into use without advance approval of FDA provided it includes the exact information included in paragraph (a) of this section.

(c) Any drug product subject to this section that is not labeled as required and that is initially introduced or initially delivered for introduction into interstate commerce after April 23, 1999, is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) and is subject to regulatory action.

[63 FR 56801, Oct. 23, 1998]