

Subpart B—Active Ingredients

Subpart C—Labeling

§ 343.10 [Reserved]

§§ 343.50–343.60 [Reserved]

§ 343.12 Cardiovascular active ingredients.

(a) Aspirin.
 (b) Buffered aspirin. Aspirin identified in paragraph (a) of this section may be buffered with any antacid ingredient(s) identified in §331.11 of this chapter provided that the finished product contains at least 1.9 milliequivalents of acid-neutralizing capacity per 325 milligrams of aspirin as measured by the procedure provided in the United States Pharmacopeia 23/National Formulary 18.

§ 343.13 Rheumatologic active ingredients.

(a) Aspirin.
 (b) Buffered aspirin. Aspirin identified in paragraph (a) of this section may be buffered with any antacid ingredient(s) identified in §331.11 of this chapter provided that the finished product contains at least 1.9 milliequivalents of acid-neutralizing capacity per 325 milligrams of aspirin as measured by the procedure provided in the United States Pharmacopeia 23/National Formulary 18.

§ 343.20 [Reserved]

§ 343.22 Permitted combinations of active ingredients for cardiovascular-rheumatologic use.

Combinations containing aspirin must meet the standards of an acceptable dissolution test, as set forth in §343.90. The following combinations are permitted: Aspirin identified in §§343.12 and 343.13 may be combined with any antacid ingredient identified in §331.11 of this chapter or any combination of antacids permitted in accordance with §331.10(a) of this chapter provided that the finished product meets the requirements of §331.10 of this chapter and is marketed in a form intended for ingestion as a solution.

§ 343.80 Professional labeling.

The labeling of an over-the-counter drug product written for health professionals (but not for the general public) shall consist of the following:

(a) *For products containing aspirin identified in §§343.12 and 343.13 or permitted combinations identified in §343.22.* (These products must meet United States Pharmacopeia (USP) standards for dissolution or drug release in §343.90.)

(1) The labeling contains the following prescribing information under the heading “Comprehensive Prescribing Information” and the subheadings “Description,” “Clinical Pharmacology,” “Clinical Studies,” “Animal Toxicology,” “Indications and Usage,” “Contraindications,” “Warnings,” “Precautions,” “Adverse Reactions,” “Drug Abuse and Dependence,” “Overdosage,” “Dosage and Administration,” and “How Supplied” in the exact language and the exact order provided as follows:

COMPREHENSIVE PRESCRIBING
 INFORMATION
 DESCRIPTION

(Insert the proprietary name and the established name (if any) of the drug, type of dosage form (followed by the phrase “for oral administration”), the established name(s) and quantity of the active ingredient(s) per dosage unit, the total sodium content in milligrams per dosage unit if the sodium content of a single recommended dose is 5 milligrams or more, the established name(s) (in alphabetical order) of any inactive ingredient(s) which may cause an allergic hypersensitivity reaction, the pharmacological or therapeutic class of the drug, and the chemical name(s) and structural formula(s) of the drug.) Aspirin is an odorless white, needle-like crystalline or powdery substance. When exposed to moisture, aspirin hydrolyzes into salicylic and acetic acids, and gives off a vinegary-odor. It is highly lipid soluble and slightly soluble in water.

CLINICAL PHARMACOLOGY

Mechanism of Action: Aspirin is a more potent inhibitor of both prostaglandin synthesis and platelet aggregation than other salicylic acid derivatives. The differences in activity between aspirin and salicylic acid are thought to be due to the acetyl group on