

DNRB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 343

[Docket No. 77N-094A]

**Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-The-Counter Human Use; Final Rule for Professional Labeling of Aspirin, Buffered Aspirin, and Aspirin in Combination With Antacid Drug Products; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; correction.

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**SUMMARY:** The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of October 23, 1998 (63 FR 56802). The document provided for professional labeling for over-the-counter (OTC) internal analgesic, antipyretic, and antirheumatic drug products containing aspirin, buffered aspirin, and aspirin in combination with an antacid. The document published with some inadvertent editorial errors. This document corrects those errors.

**EFFECTIVE DATE:** The regulation is effective October 25, 1999.

**FOR FURTHER INFORMATION CONTACT:** Ida I. Yoder, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

**SUPPLEMENTARY INFORMATION:** In FR Dec. 98-285 19, appearing on page 56802, in the **Federal Register** of October 23, 1998, the following corrections are made:

1. On page 56809, in Table 5, in the second entry in the fourth column, “-3.9” is corrected to read “-39”.

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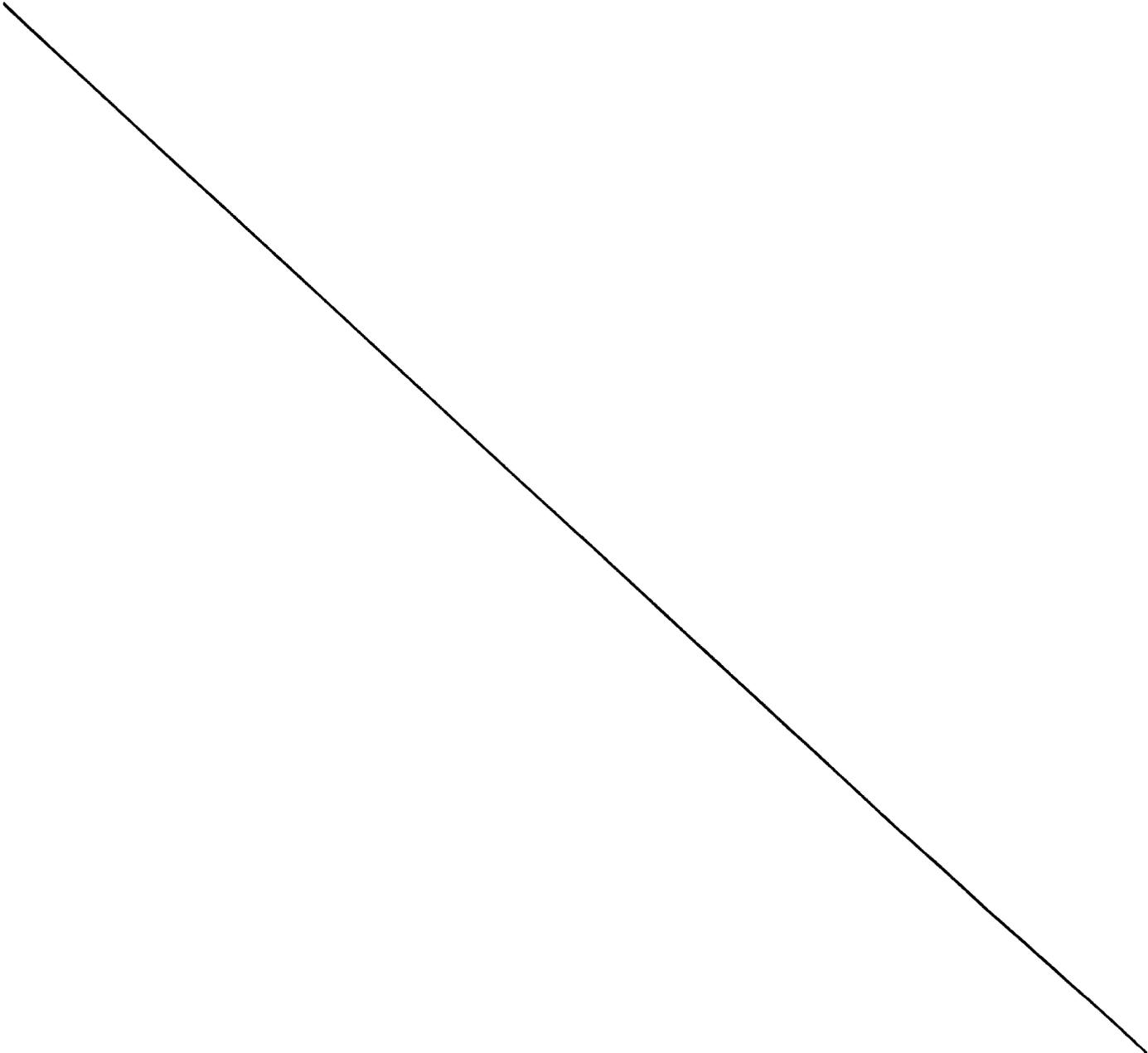
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2. On page **56810**, in the third column, in the eighteenth line, “preoperative” is corrected to read ‘ ‘perioperative”.

3. On page 56812, in the first column, in the third paragraph, in the eighteenth line, “were” is corrected to read “was”.

**§ 343.80 [Corrected]**

4. On page **56817**, in §343.80(a)(1), the last paragraph is corrected to read “REV: October 23, 1998”.



5. On page **56818**, in § 343.80(a)(2), the entire page “**HIGHLIGHTS OF PRESCRIBING INFORMATION**” is corrected to read as follows:

[Insert graphic]

Dated: Nov 16, 1998

November 20, 1998



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William K. Hubbard  
Associate Commissioner for Policy Coordination

[FR Dec. 98-???? Filed ??-??-98; 8:45 am]

**BILLING CODE 41 60-01-F**

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL.**



**HIGHLIGHTS OF PRESCRIBING INFORMATION**

ASPIRIN (FORMULATION)  
(acetylsalicylic acid)

**PROFESSIONAL INDICATIONS AND USAGE**

**Vascular Indications:**

- Ischemic Stroke and Transient Ischemic Attacks (TIA)
- Suspected Acute Myocardial Infarction (MI)
- Prevention of Recurrent MI
- Unstable Angina Pectoris
- Chronic Stable Angina Pectoris

**Revascularization Procedures in Select Patients:**

- Coronary Artery Bypass Graft (CABG)
- Percutaneous Transluminal Coronary Angioplasty (PTCA)
- Carotid Endarterectomy

**Rheumatologic Disease Indications:**

- Rheumatoid Arthritis
- Juvenile Rheumatoid Arthritis
- Spondyloarthropathies
- Osteoarthritis
- Arthritis and Pleurisy of Systemic Lupus Erythematosus (SLE)

**Warnings Regarding Use In Pregnancy**

Pregnant women should only take aspirin if clearly needed. Because of the known effects of nonsteroidal anti-inflammatory drugs on the fetal cardiovascular system (closure of the ductus arteriosus), use during the third trimester of pregnancy should be avoided. Salicylate products have also been associated with alterations in maternal and neonatal hemostasis mechanisms, decreased birth weight, and with perinatal mortality. Salicylate is excreted in breast milk. (See "Pregnancy," "Labor and Delivery" and "Nursing Mothers" in the "Precautions" section of the Comprehensive Prescribing Information.)

Patients with a pre-existing condition for which aspirin is already indicated. See "Revascularization Procedures" under the "Indications and Usage" and "Clinical Studies" Sections in the Comprehensive Prescribing Information.

**Dosage and Administration**

General Each dose should be taken with a full glass of water unless contraindicated. Doses may need to be individualized depending on indication.

Indications	Recommended Daily Dose	Duration of Therapy
<b>Vascular Indications:</b>		
Ischemic Strokes and TIA	50-325 milligrams (mg) daily	Indefinitely
Suspected Acute MI	160-1625 mg taken as soon as infarction is suspected, then once daily	For 30 days post infarction (after 30 days consider further treatment based on indication for previous MI)
Prevention of Recurrent MI	75-325 mg daily	Indefinitely
Unstable Angina Pectoris	75-325 mg daily	Indefinitely
Chronic Stable Angina Pectoris	75-325 mg daily	Indefinitely
<b>Revascularization Procedures in Select Patients:</b>		
CABG	325 mg daily starting 6 hrs post procedure	1 year
PTCA	325 mg 2 hours presurgery Maintenance therapy: 160-325 mg daily	Indefinitely
Carotid Endarterectomy	30 mg daily to 650 mg twice a day started presurgery	Indefinitely
<b>Rheumatologic Disease Indications:</b>		
Rheumatoid Arthritis	Initial dose 3 g daily Target plasma salicylate levels 150-300 micrograms/mL	As indicated
Juvenile Rheumatoid Arthritis	Initial dose 90-130 mg/kg/day Target plasma salicylate levels 150-300 µg/mL	As indicated
Spondyloarthropathies	Up to 4 grams (g) daily	As indicated
Osteoarthritis	Up to 3 g daily	As indicated
Arthritis and Pleurisy of SLE	Initial dose 3 g daily Target plasma salicylate levels 150-300 µg/mL	As indicated

**CONTRAINDICATIONS**

Aspirin is contraindicated in patients with known allergy to nonsteroidal anti-inflammatory drugs and in patients with the syndrome of asthma, rhinitis, and nasal polyps. Aspirin shouldn't be used in children or teenagers for viral infections, with or without fever, because of the risk of Reye's syndrome with concomitant use of aspirin in certain viral illnesses.

**PRECAUTIONS**

**General**

**Renal Failure**

**Hepatic Insufficiency**

**Sodium Restricted Diets**

**Laboratory Tests**

**Drug Interactions:**

**Angiotensin Converting Enzyme (ACE) Inhibitors**

**Acetazolamide**

**Anticoagulant Therapy**

**Anticonvulsants**

**Beta Blockers**

**Diuretics**

**Methotrexate**

**Nonsteroidal Anti-inflammatory Drugs (NSAID's)**

**Oral Hypoglycemics**

**Uricosuric Agents**

**Carcinogenesis, Mutagenesis, Impairment of fertility**

**Pregnancy, Labor and Delivery, Nursing Mothers**

**Pediatric Use**

**WARNINGS**

**Alcohol Warning**

**Coagulation Abnormalities**

**Gastrointestinal Side Effects**

**Peptic Ulcer Disease**

**ADVERSE REACTIONS (Most common)**

**Gastrointestinal (Abdominal Pain, Ulceration, Bleeding)**

**Inhibition of Platelet Aggregation (Bleeding)**

**Tinnitus**

**Dizziness**

**Hearing Loss**

To report SERIOUS adverse drug reactions, call (manufacturer) at (phone number) or MED WA TCH at 1-8(X-FDA-1088)

**HOW SUPPLIED**

(Insert specific information regarding strength, dosage form, units in which the dosage form is generally available, and information to facilitate identification of the dosage form.) Store in a tight container at 25 °C (77 °F), excursions permitted to 15-30 °C (59-86 °F)

**These highlights do not include all the information needed to prescribe aspirin safely and effectively. See aspirin's comprehensive prescribing information.**