cheeses resulting in no more than 20 ppm of natamycin in these cheeses, demonstrated that the additive will achieve its intended technical effect. The application of natamycin in dry form does not change the chemical composition of the additive, the uses in food, the use levels and, therefore, the dietary exposure to natamycin. Furthermore, the use of natamycin in the dry form does not result in any manufacturing changes that would affect the safety of the additive for this proposed use. The use of comparable levels of other safe and suitable anticaking agents, in addition to cellulose, would not change this conclusion. Therefore, the agency's safety evaluation of natamycin for the approved use in an aqueous application by dipping or spraying (47 FR 26823, June 22, 1982, as amended at 50 FR 49536, December 3, 1985) supports this proposed use of natamycin in dry form. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 172.155 should be amended.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

–The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 8A4581 (63 FR 6945, February 11, 1998). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

–This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before December 31, 1998, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

–Food additives, Reporting and recordkeeping requirements.

–Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Foods and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

–1. The authority citation for 21 CFR part 172 continues to read as follows:

–Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

–2. Section 172.155 is amended by revising paragraph (c)(1) to read as follows:

§ 172.155 Natamycin (pimaricin).

* * * * *

(c) * * *

(1) The additive may be applied as a dry mix containing the additive and safe and suitable anticaking agents, resulting in no more than 20 parts per million of the additive in the finished product, or by dipping or spraying, using an aqueous solution containing 200 to 300 parts per million of the additive.

* * * * *

Dated: November 7, 1998.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–31855 Filed 11–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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.

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 Doc. 98–28519, 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''.

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:

Dated: November 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc 98–31854 Filed 11–30–98; 8:45 am]

BILLING CODE 4160–01–F

HIGHLIGHTS OF PRESCRIBING INFORMATION
ASPIRIN (FORMULATION)
(acetylsalicylic acid)

PROFESSIONAL INDICATIONS AND USAGE
Vascular Indications:
· Ischemic Strokes 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
Vascular Indications:		
Ischemic Strokes and TIA	50-325 milligrams (mg) daily	Indefinitely
Suspected Acute MI	160-162.5 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
Revascularization Procedures in Select Patients:		
CABG	325 mg daily starting 6 hrs. postprocedure	1 year
PTCA	325 mg 2 hours presurgery Maintenance therapy: 160-325 mg daily	Indefinitely
Carotid Endarterectomy	80 mg daily to 650 mg twice a day started presurgery	Indefinitely
Rheumatologic Disease Indications:		
Rheumatoid Arthritis	Initial dose 3 g daily. Target plasma salicylate levels 150-300 micrograms/milliliter (μg/mL)	As indicated
Juvenile Rheumatoid Arthritis	Initial dose 90-130 mg/kilograms/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 should not 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 MEDWATCH at 1-800-FDA-1088
HOW SUPPLIED
(Insert specific information regarding, strength of 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.

[FR Doc. 98–31854 Filed 11–30–98; 8:45 am]
BILLING CODE 4160–01–C