

described previously in this document. For example, the new law gives FDA express authority to require marking on any food product that had been refused admission into the United States whereas the proposed rule would have required marking on food refused admission for safety reasons only.

The new law also significantly revises section 801(d)(3) of the act; it prescribes new reporting requirements that differ from those in the FDA proposed rule.

Because of the changes brought about by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, FDA is withdrawing both proposed rules. FDA will consider whether new rulemakings or other actions are necessary to implement the new statutory requirements.

Dated: August 13, 2002.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 201

[Docket No. 02N-0241]

#### Amendment of Regulations on Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition; Correction

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

**ACTION:** Proposed rule; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a proposed rule that appeared in the **Federal Register** of August 12, 2002 (67 FR 52429). The document proposed to amend FDA's regulations to change the labeling requirements concerning aluminum in small volume parenterals and pharmacy bulk packages used in total parenteral nutrition. The document was published with an inadvertent error. This document corrects that error.

**DATES:** Submit written or electronic comments by October 28, 2002.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments at <http://www.fda.gov/dockets/ecomments>. All comments should be identified with the

docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Doris B. Tucker, Office of Policy, Planning, and Legislation (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 02-20300, appearing on page 52429 in the **Federal Register** of Monday, August 12, 2002, the following correction is made:

1. On page 52429, in the third column, in the seventh line “§ 201.323©” is corrected to read “§ 201.323(c)”.

Dated: August 15, 2002.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 201 and 343

[Docket No. 77N-0941]

RIN 0910-AA01

#### Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph, and Related Labeling

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend the tentative final monograph (TFM) for over-the-counter (OTC) internal analgesic, antipyretic, and antirheumatic (IAAA) drug products to include ibuprofen as a generally recognized safe and effective analgesic/antipyretic active ingredient for OTC use. FDA is also proposing to amend its regulations to include consistent allergy warnings for OTC IAAA drug products containing nonsteroidal anti-inflammatory active ingredients. These proposals are in response to a citizen petition (Ref. 1) and to a comment submitted in response to that petition (Ref. 2) and are part of the ongoing review of OTC drug products conducted by FDA.

**DATES:** Submit written or electronic comments by November 19, 2002. Submit written or electronic comments

on the agency's economic impact determination by November 19, 2002. Please see section XII of this document for the effective date of any final rule that may publish based on this proposal.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**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.

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##### I. Background

Ibuprofen is benzenecarboxylic acid,  $\alpha$ -methyl-4-(2-methylpropyl), ( $\pm$ ), a member of the propionic acid class of nonsteroidal anti-inflammatory drugs (NSAIDs). The commercially available drug is a racemic mixture of two optical isomers (S-[+] and R-[-] ibuprofen). The racemic mixture is recognized in the U.S. Pharmacopeia (U.S.P.) (Ref. 3). Ibuprofen has been available as a prescription drug for the treatment of osteoarthritis and rheumatoid arthritis at a dose of 1,200 to 3,200 milligrams (mg) per (/) day since 1974 in the United States and since 1969 in the United Kingdom. Ibuprofen has also been marketed by prescription and OTC in numerous countries throughout the world (Ref. 4).

Safety and effectiveness data submitted to the agency to support the approval of the OTC marketing of a 200-mg ibuprofen tablet were considered by the Arthritis Advisory Committee (AAC)