Maintenance of Drawback Information

Throughout the staged consolidation period, claimants would be required to provide Customs with advance notification of any changes in the information provided regarding a drawback claim. This notification must be provided in accordance with part 191 of the Customs Regulations (19 CFR part 191).

Explanation of Amendments

Section 101.3(b)(1) of the Customs Regulations lists the Customs ports of entry. Eight ports are denoted with an asterisk that designates their status as a ''Drawback unit/office.'' This document proposes to amend § 101.3(b)(1) to delete the asterisks in § 101.3(b)(1) next to the port listings for Boston, Miami and New Orleans.

Comments

Before adopting this proposal as a final rule, consideration will be given to any written comments timely submitted to Customs, including comments on the clarity of this proposed rule and how it may be made easier to understand. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4 of the Treasury Department Regulations (31 CFR 1.4), and § 103.11(b) of the Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9 a.m. and 4:30 p.m. at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 799 9th Street, NW., Washington, DC.

The Regulatory Flexibility Act and Executive Order 12866

Although this document is being issued with notice for public comment, because it relates to agency management and organization, it is not subject to the notice and public procedure requirements of 5 U.S.C. 553. Accordingly, this document is not subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Agency organization matters, such as this proposed closing of three Customs Drawback Centers, are not subject to Executive Order 12866.

Drafting Information

The principal author of this document was Ms. Suzanne Kingsbury, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 101

Customs duties and inspection, Customs ports of entry.

Proposed Amendments to the Regulations

For the reasons stated above, it is proposed to amend part 101 of the Customs Regulations (19 CFR part 101) as follows:

PART 101—GENERAL PROVISIONS

1. The general authority citation for part 101 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 2, 66, 1202 (General Note 23, Harmonized Tariff Schedule of the United States), 1623, 1624, 1646a.

Section 101.3 and 101.4 also issued under 19 U.S.C. 1 and 58b;

* * * * *

2. In § 101.3, the table in paragraph (b)(1) is amended by removing the plus sign in the ''Ports of entry'' column before the column listings for ''Miami'' under the state of Florida, ''New Orleans'' under the state of Louisiana, and ''Boston'' under the state of Massachusetts.

Robert C. Bonner,

Commissioner of Customs.

Approved: August 15, 2002.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 02–21111 Filed 8–20–02; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket Numbers 98N–0496 and 00N–1633]

RIN 0910–AB24 and 0910–AB95

Import for Export; Reporting and Recordkeeping Requirements for Unapproved or Violative Products Imported for Further Processing or Incorporation and Subsequent Export; Marking Requirements for and Prohibitions on the Reimportation of Imported Food Products That Have Been Refused Admission Into the United States; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rules; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of two proposed rules. One proposed rule, which appeared in the **Federal Register** on November 24, 1998 (63 FR 64930), would have established reporting and recordkeeping requirements for certain products that are imported into the United States for further processing or incorporation into products that are then exported. The second proposed rule, which appeared in the **Federal Register** on January 22, 2001 (66 FR 6502), would have established requirements for marking imported food that has been refused entry into the United States for safety reasons. FDA is withdrawing these proposed rules due to recent changes in Federal law.

DATES: The proposed rules are withdrawn August 21, 2002.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy, Planning, and Legislation (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION: On November 24, 1998, FDA published a proposed rule in the **Federal Register** (63 FR 64930) that would have established reporting and recordkeeping requirements for certain products that are imported under section 801(d)(3) and (d)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(d)(3) and (d)(4)). These sections of the act allowed the importation of certain unapproved or otherwise noncompliant products or articles provided that those products or articles are further processed or incorporated into other products and then exported from the United States.

On January 22, 2001, FDA and the Department of the Treasury jointly prescribed a proposed rule in the **Federal Register** (66 FR 6502) that would have allowed FDA to require food importers or consignees to mark imported foods if, for safety reasons, FDA had refused to allow such foods to enter the United States. The mark would have stated, ''UNITED STATES REFUSED ENTRY,'' and the proposed rule would have established the mark's size and required the mark to be affixed on packing containers holding the refused food and on invoices, bills of lading, and any other documentation accompanying the food when it is exported from the United States.

We received comments on both rules and also held public meetings to discuss the proposed rule on the marking of refused food imports. After reviewing the comments, we wrote and intended to issue final rules in 2002.

On June 12, 2002, the President signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188). The new law contains provisions that change the legal context of the two proposed FDA regulations

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.

[FR Doc. 02–21264 Filed 8–20–02; 8:45 am]

BILLING CODE 4160–01–S

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 ''§ 201.3239(c)''.

Dated: August 15, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02–21265 Filed 8–20–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 343

[Docket No. 77N–094I]

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.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

Ibuprofen is benzeneacetic acid, α-methyl-4-(2-methylpropyl), (±)-, 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)