III. Statutory Basis

The amendments to Rule 31–1 under the Exchange Act are being adopted pursuant to 15 U.S.C. 78a et seq., particularly sections 23(a) and 31 of the Exchange Act.

IV. Text of Final Amendments

List of Subjects in 17 CFR Part 240

Reporting and record keeping requirements, Securities.

Text of Rule Amendment

For the reasons set forth above, the Commission amends Part 240 of Chapter II, Title 17 of the Code of Federal Regulations as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for Part 240 continues to read in part as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l*, 78m, 78n, 78o, 78p, 78q, 78s, 78u–5, 78w, 78x, 78*ll*, 78mm, 79q, 79t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4 and 80b–11, unless otherwise noted.

* * * * *

2. Section 240.31–1 is revised to read as follows:

§ 240.31–1. Securities transactions exempt from transaction fees.

Preliminary Note

The section 31 fee for options transactions occurring on a national securities exchange, or transactions in options subject to prompt last sale reporting occurring otherwise than on an exchange (with the exception of sales of options on securities indexes other than narrow-based security indexes) is to be paid by the exchange or the national securities association itself, respectively, or by the Options Clearing Corporation on behalf of the exchange or association, and such fee is to be computed on the basis of the option premium (market price) for the sale of the option. In the event of the exercise of an option, whether such option is traded on an exchange or otherwise, a section 31 fee is to be paid by the exchange or the national securities association itself, or the Options Clearing Corporation on behalf of the exchange or association, and such fee is to be computed on the basis of the exercise price of the option. The following shall be exempt from section 31 of the Act:

(a) Transactions in securities offered pursuant to an effective registration statement under the Securities Act of 1933 (except transactions in put or call options issued by the Options Clearing Corporation) or offered in accordance with an exemption from registration afforded by section 3(a) or 3(b) thereof (15 U.S.C. 77c(a) or 77c(b)), or a rule thereunder.

(b) Transactions by an issuer not involving any public offering within the meaning of section 4(2) of the Securities Act of 1933 (15 U.S.C. 77d(2));

(c) The purchase or sale of securities pursuant to and in consummation of a tender or exchange offer;

(d) The purchase or sale of securities upon the exercise of a warrant or right (except a put or call), or upon the conversion of a convertible security; and

(e) Transactions which are executed outside the United States and are not reported, or required to be reported, to a transaction reporting association as defined in § 240.11Aa3–1 (Rule 11Aa3–1 under the Act) and any approved plan filed thereunder.

By the Commission.

Dated: January 16, 2002.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 02–1620 Filed 1–22–02; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 10

[T.D. 02—05]

RIN 1515–AC85

Extension of Deadline To File a Wool Duty Refund Claim for Claim Year 2000

AGENCY: Customs Service, Department of the Treasury.

ACTION: Interim rule.

SUMMARY: This document amends the Customs Regulations on an interim basis to extend the deadline to file a wool duty refund claim for calendar year 2000, as authorized by section 505 of the Trade and Development Act of 2000. The regulations currently require that claims for a wool duty refund for calendar year 2000, except for certain amended claims, should already have been received by Customs by December 31, 2001. This deadline is extended until December 31, 2002, to reflect the fact that proposed legislation is currently pending before Congress which would significantly alter the scope of section 505 in regard to the amount of payment manufacturers would be eligible to receive, as well as the documents that a manufacturer would need to file to be entitled to a refund and, in part, because of the destruction of records at the New York Customshouse on September 11, 2001. The deadline extension is also intended to spare manufacturers from the filing of unnecessary documentation, again, in part, due to the destruction of records in New York. Additionally, Customs is amending the regulations to reflect the new Customs location to which all wool duty refund documentation should be sent.

DATES: This interim rule is effective January 23, 2002. The deadline to file a wool duty refund claim for calendar year 2000 is extended to December 31, 2002. Comments must be received on or before February 7, 2002.

ADDRESSES: Written comments (preferably in triplicate) may be submitted to and inspected at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, NW., 3rd Floor, Washington, DC 20229. Wool duty refund documentation should be sent to the U.S. Customs Service, Office of Field Operations, Wool Duty Refund Unit, 1300 Pennsylvania Avenue, NW., 5th Floor, Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Bruce Ingalls, Chief, Entry and Drawback Management (202) 927–1082.

SUPPLEMENTARY INFORMATION:

Background

On May 18, 2000, President Clinton signed into law the Trade and Development Act of 2000 (''the Act''), Public Law 106–200, 114 Stat. 251. Title V of the Act concerns imports of certain wool articles and sets forth provisions intended to provide tariff relief to U.S. manufacturers of specific wool products. Within Title V, section 505 permits eligible U.S. manufacturers to claim a limited refund of duties paid on imports of select wool articles.

On December 26, 2000, Customs published in the **Federal Register** (65 FR 81344), as T.D. 01–01, the final rule adding the eligibility, documentation and procedural requirements for obtaining a wool duty refund to § 10.184 of the Customs Regulations (19 CFR 10.184).

On April 23, 2001, Customs published in the **Federal Register** (66 FR 20392), as T.D.01–33, an interim rule amending § 10.184 regarding the description of the wool products that are eligible to provide the basis for a wool duty refund and the tariff provisions that eligible wool products must be entered under to substantiate a refund.

Extension of Deadline To File a Wool Duty Refund Claim for Calendar Year 2000

Section 10.184(g) of the Customs Regulations sets forth the procedures for filing a wool duty refund claim. Paragraph (g)(1) provides, in pertinent part, that all refund claims, whether original or amended in the absence of a Customs notice of insufficiency or defect, must be received by Customs no later than December 31st of the year following the calendar claim year for which a wool duty refund is being sought. Therefore, pursuant to the existing regulations, all original claims and certain amended claims for calendar year 2000 must be received by Customs no later than December 31st, 2001.

Customs has learned that proposed legislation is currently pending before Congress which would significantly alter the scope of section 505 in regard to the amount of payment manufacturers would be eligible to receive, as well as the documents that a manufacturer would need to file to be entitled to a refund. For this reason, Customs has opted to extend the deadline to file calendar year 2000 claims until December 31, 2002, in an effort to spare manufacturers seeking refunds from the filing of unnecessary documentation.

If legislation is soon passed by Congress that amends section 505 to institute new procedures for filing a claim, Customs will publish another document in the **Federal Register** that amends § 10.184 to reflect the terms of the legislation, unless the legislation is self-effectuating. If legislation is not passed in the near future, Customs will inform potential claimants how to expedite the refund process under current law. In any event, the document published today should relieve manufacturers of concern that they must file claims by December 31st, 2001, to receive refunds for duties that they paid in the year 2000.

New Customs Address for the Submission of Wool Duty Refund Documentation

Section 10.184(g)(2) directs claimants to submit wool refund claims to Customs at the Residual Liquidation and Protest Branch located at 6 World Trade Center, New York, NY. Due to the events of September 11, 2001, that address no longer functions as a Customs office. This document amends § 10.184(g)(2) to reflect the fact that wool duty refund documentation should be submitted to the U.S. Customs Service, Office of Field Operations, Wool Duty Refund Unit, 1300 Pennsylvania Avenue, NW., 5th Floor, Washington, DC 20229.

Comments

Before adopting this interim regulation as a final rule, consideration will be given to any written comments timely submitted to Customs, including comments on the clarity of this interim 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, 1300 Pennsylvania Avenue, NW., 3rd Floor, Washington, DC.

Inapplicability of Prior Public Notice and Comment Procedures and Delayed Effective Date

Because these regulations confer a benefit to the public by extending the deadline to file a wool duty refund claim for calendar year 2000 and redesignate the location to which such claims should be sent, Customs has determined, pursuant to the provisions of 5 U.S.C. 553(b)(B), that prior public notice and comment procedures on this regulation are unnecessary and contrary to the public interest. These regulatory amendments inform the public of changes to the procedures for filing a wool duty refund claim. For this reason, pursuant to the provisions of 5 U.S.C. 553(d)(3), Customs finds that there is good cause for dispensing with a delayed effective date.

Executive Order 12866

This document does not meet the criteria for a ''significant regulatory action'' as specified in Executive Order 12866.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this interim regulation, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Paperwork Reduction Act

The collection of information involved in this interim rule has already been approved by the Office of Management and Budget (OMB) in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) and assigned OMB control number 1515–0227. This rule does not substantively change the existing approved information collection.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB.

Drafting Information

The principal author of this document was Suzanne Kingsbury, Regulations Branch, 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 10

Customs duties and inspection, Imports, Reporting and recordkeeping requirements, Trade agreements.

Amendments to the Regulations

For the reasons stated above, 19 CFR part 10 is amended as follows:

PART 10—ARTICLES CONDITIONALLY FREE, SUBJECT TO A REDUCED RATE, ETC.

1. The general authority citation for part 10 and the specific authority for § 10.184 continue to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1321, 1481, 1484, 1498, 1508, 1623, 1624, 3314.

* * * * *

Section 10.184 is also issued under Sec. 505, Pub. L. 106–200, 114 Stat. 251;

* * * * *

2. In § 10.184, paragraph (g)(1), the third sentence is amended by removing the period after the word ''sought'' and adding the words '', with the exception of claims for calendar claim year 2000 which may be filed no later than December 31, 2002.''

3. In § 10.184, paragraph (g)(2) is revised to read as follows:

§ 10.184 Refund of duties on certain wool imports.

* * * * *

(g) * * *

(2) *Place to file.* A claim for a refund of duties paid on imports of eligible wool products must be submitted to: U.S. Customs Service, Office of Field Operations, Wool Duty Refund Unit,

1300 Pennsylvania Avenue, NW., 5th Floor, Washington, DC 20229.

* * * * *

Robert C. Bonner,

Commissioner of Customs.

Approved: January 17, 2002.

Timothy E. Skud,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 02–1664 Filed 1–22–02; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 330

[Docket No. 96N–0277]

RIN 0910–AA01

Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing additional criteria and procedures by which over-the-counter (OTC) conditions may become eligible for consideration in the OTC drug monograph system. The criteria and procedures address how OTC drugs initially marketed in the United States after the OTC drug review began in 1972, and OTC drugs without any U.S. marketing experience, can meet the statutory definition of marketing ''to a material extent'' and ''for a material time'' and become eligible. If found eligible, the condition would be evaluated for general recognition of safety and effectiveness in accordance with FDA's OTC drug monograph regulations. FDA is also changing the current OTC drug monograph procedures to streamline the process and provide additional information in the review.

DATES: This final rule is effective February 22, 2002.

FOR FURTHER INFORMATION CONTACT: John D. Lipnicki, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION: The purpose of this final rule is to establish criteria and procedures by which OTC conditions may become eligible for consideration in the OTC drug monograph system. Currently, a sponsor wishing to introduce into the United States an OTC drug condition marketed solely in a foreign country must prepare and submit a new drug application (NDA). Likewise, companies with OTC drugs initially marketed in the United States after the 1972 initiation of the OTC drug review must have an NDA. This final rule provides procedures for these NDA drugs to become eligible for inclusion in the OTC drug monograph system by first submitting a time and extent application (TEA) to show marketing ''to a material extent'' and ''for a material time.'' Once determined eligible, safety and effectiveness data would be submitted and evaluated. This two-step process allows sponsors to demonstrate that eligibility criteria are met before having to expend resources to prepare safety and effectiveness data.

I. Background

The OTC drug monograph system was established to evaluate the safety and effectiveness of all OTC drug products marketed in the United States before May 11, 1972, that were not covered by NDAs and all OTC drug products covered by ''safety'' NDAs that were marketed in the United States before enactment of the 1962 drug amendments to the Federal Food, Drug, and Cosmetic Act (the act). In 1972, FDA began its OTC drug review to evaluate OTC drugs by categories or classes (e.g., antacids, skin protectants), rather than on a product-by-product basis, and to develop ''conditions'' under which classes of OTC drugs are generally recognized as safe and effective (GRAS/E) and not misbranded.

FDA publishes these conditions in the **Federal Register** in the form of OTC drug monographs, which consist primarily of active ingredients, labeling, and other general requirements. Final monographs for OTC drugs that are GRAS/E and not misbranded are codified in part 330 (21 CFR part 330). Manufacturers desiring to market an OTC drug covered by an OTC drug monograph need not seek FDA clearance before marketing. In a future issue of the **Federal Register**, the agency will be publishing a final call for data for OTC drug products marketed in the United States before May 11, 1972, to be reviewed as part of the original OTC drug review.

In the **Federal Register** of October 3, 1996 (61 FR 51625), FDA published an advance notice of proposed rulemaking (ANPRM) stating that it was considering proposing to amend its regulations to include criteria under which certain additional OTC drug conditions may become eligible for inclusion in the OTC drug monograph system. Interested persons were invited to submit written comments by January 2, 1997. The agency received 16 comments, which it discussed in section III of a proposed rule that was published in the **Federal Register** of December 20, 1999 (64 FR 71062 at 71067) (the proposed rule).

Under the proposal, eligibility for consideration in the OTC drug monograph system would be determined by showing a condition's use ''to a material extent'' and ''for a material time'' in compliance with the existing statutory requirements of the act. A number of ingredients have been marketed in OTC drug products under NDAs approved after May 11, 1972. The agency provided criteria and procedures in this proposal for ingredients such as these to be considered for OTC drug monograph status.

For OTC drug products without any U.S. marketing experience, this proposal represented a change in the agency's previous interpretation of ''use'' requirements in section 201(p) of the act (21 U.S.C. 321(p)). Previously, the agency interpreted the use provision to mean use in the United States only. The agency proposed this change in policy to expand ''use'' to include foreign marketing experience because it believed that under certain circumstances use outside the United States may appropriately be considered to satisfy the use requirements in section 201(p) of the act.

In the ANPRM, the agency used the term ''condition'' to refer to OTC drug active ingredients, indications, dosage forms, dosage strengths, routes of administration, and active ingredient combinations. In the proposed rule, the agency has used the term ''condition'' to refer to an active ingredient or botanical drug substance (or a combination of active ingredients or botanical drug substances), dosage form, dosage strength, or route of administration, marketed for a specific OTC use. The agency has included the reference to botanical drug substance to recognize that the information needed for consideration of a botanical substance for inclusion in the OTC drug monograph system may differ from the information needed to evaluate other types of active ingredients for this purpose.

II. Description of the Proposed Rule

The existing OTC drug regulations in part 330 do not define eligibility requirements for consideration in the OTC drug monograph system or what constitutes marketing to a material