

fiscal year, whether a bank or nonbank and whether held directly or indirectly, in which any one of the three items—total assets, sales or gross operating revenues excluding sales taxes, or net income after provision for foreign income taxes—was greater than \$3 million (positive or negative) at any time during the affiliate's 1994 fiscal year, the U.S. Reporter must file a complete Form BE-10A BANK and, as applicable, a BE-10A BANK SUPPLEMENT listing each, if any, exempt foreign affiliate, whether bank or nonbank. It must also file a Form BE-10B(SF) for each nonexempt nonbank foreign affiliate and a Form BE-10B BANK for each nonexempt foreign bank affiliate.

(ii) If the U.S. bank Reporter had no foreign affiliates for which any one of the three items listed in paragraph (d)(2)(i) of this section was greater than \$3 million (positive or negative) at any time during the affiliate's 1994 fiscal year, then only items 1-4 of Form BE-10A BANK and the BE-10A BANK SUPPLEMENT, listing all exempt foreign affiliates, should be completed.

(3) Form BE-10B BANK (Report for a foreign affiliate that is a bank).

(i) A BE-10B BANK report must be filed for each foreign bank affiliate of a bank or nonbank U.S. Reporter, whether directly or indirectly held, for which any one of the three items—total assets, sales or gross operating revenues excluding sales taxes, or net income after provision for foreign income taxes—was greater than \$3 million (positive or negative) at any time during the affiliate's 1994 fiscal year.

(i) Notwithstanding paragraph (d)(3)(i) of this section, a Form BE-10B BANK must be filed for a foreign bank affiliate of the U.S. Reporter that owns another nonexempt foreign affiliate of that U.S. Reporter, even if the foreign affiliate parent is otherwise exempt, i.e., a Form BE-10B(LF), (SF), or BANK must be filed for all affiliates upward in a chain of ownership. However, a Form BE-10B BANK is not required to be filed for a foreign bank affiliate in which the U.S. Reporter holds only an indirect ownership interest of 50 percent or less and that does not own a reportable nonbank foreign affiliate, but the indirectly owned bank affiliate must be listed on the BE-10A BANK SUPPLEMENT.

(e) Due date. A fully completed and certified BE-10 report comprising Form BE-10A or 10A BANK, BE-10A SUPPLEMENT (as required), and Form(s) BE-10B(LF), (SF), or BANK (as required) is due to be filed with BEA not later than May 31, 1995 for those U.S. Reporters filing less than 50, and June

30, 1995 for those U.S. Reporters filing 50 or more, Forms BE-10B(LF), (SF) or BANK.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 358

[Docket No. 81N-0201]

Marketing of Over-the-Counter Pediculicide Drug Products; Background Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Availability of background documents.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of background documents dealing with its response to two citizen petitions seeking actions for marketing of over-the-counter (OTC) pediculicide drug products. This action is being taken to ensure that all interested persons are aware of the issues that were raised in the two citizen petitions.

ADDRESSES: Single copies of the background documents may be requested in writing from the Freedom of Information Staff (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, at a cost of 10 cents per page. Requests should be identified with the docket number found in brackets in the heading of this document. The background documents are available for public examination at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5000.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 14, 1993 (58 FR 65452), FDA issued a final monograph for OTC pediculicide drug products (21 CFR part 358, subpart C). The final monograph becomes effective on December 14, 1994. Prior to that date, jurisdiction over pediculicide products is vested concurrently with the Environmental Protection Agency (EPA) and with FDA. EPA and FDA labeling

requirements for these products are different. After December 14, 1994, FDA will have sole jurisdiction over labeling and other requirements applicable to OTC pediculicide drug products.

On February 25, 1994, the Nonprescription Drug Manufacturers Association (NDMA) submitted a citizen petition (Ref. 1) requesting certain actions because of the dual jurisdiction over OTC pediculicide drug products that exists until December 14, 1994. On April 14, 1994, a meeting was held between FDA, EPA, and NDMA (Ref. 2). On April 22, 1994, NDMA submitted a second, more detailed citizen petition (Ref. 3). NDMA requested FDA to provide industry at least 1 1/2 years from December 14, 1993 (the date of publication of the final monograph for OTC pediculicide drug products), for a smooth transition from EPA to FDA regulations for OTC pediculicide drug products. NDMA also requested FDA agreement not to bring enforcement proceedings against OTC pediculicide drug products applied to the human body and bearing EPA-mandated labeling for 1 year after December 14, 1994. The enforcement deferral would apply to products distributed with labeling printed before December 14, 1994, or where the products shipped into interstate commerce had been in stock before December 14, 1994. NDMA also submitted a citizen petition to EPA, which responded by notice dated September 6, 1994 (Ref. 4).

FDA responded to NDMA (Refs. 5 and 6) stating that a 1 1/2 year extension to meet FDA labeling requirements would not be granted on a blanket basis for all products. The agency stated that requests for extensions would be evaluated on a case-by-case basis. The agency also indicated that any extension granted will be limited to the quantity of stock that a company has on hand prior to December 14, 1994. FDA also stated that, in its discretion, it agrees not to bring enforcement proceedings against OTC pediculicide drug products conforming with the final monograph and containing EPA-required labeling for a period of 1 year after the effective date of the final monograph on December 14, 1994.

FDA has placed all of the correspondence on this subject in docket no. 81N-0201 for OTC pediculicide drug products, to enable interested persons to see the correspondence. The documents may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

References

- (1) Citizen petition from the Nonprescription Drug Manufacturers Association to FDA, coded CP1, Docket No. 81N-0201, Dockets Management Branch.
- (2) Memorandum of Meeting, coded MM1, Docket No. 81N-0201, Dockets Management Branch.
- (3) Citizen petition from the Nonprescription Drug Manufacturers Association to FDA, coded CP2, Docket No. 81N-0201, Dockets Management Branch.
- (4) Pesticide Regulation Notice 94-6, dated September 6, 1994, Notice to Manufacturers, Producers, Formulators, and Registrants of Pesticide Products, Office of Pesticides and Toxic Substances, Environmental Protection Agency, coded REF1, Docket No. 81N-0201, Dockets Management Branch.
- (5) Letter from W. E. Gilbertson, FDA, to R. W. Soller, Nonprescription Drug Manufacturers Association, coded LET18, Docket No. 81N-0201, Dockets Management Branch.
- (6) Letter from R. G. Chesemore, FDA, to R. W. Soller, Nonprescription Drug Manufacturers Association, coded PAV1, Docket No. 81N-0201, Dockets Management Branch.

Dated: November 30, 1994.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8570]

RIN 1545-AS96

Nonbank Trustee Net Worth Requirements

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations that provide guidance to nonbank trustees with respect to the adequacy of net worth requirements of § 1.401-12(n) (6) and (7) of the Income Tax Regulations. The text of these temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the *Federal Register*.

DATES: These regulations are effective December 6, 1994.

FOR FURTHER INFORMATION CONTACT: Judith E. Alden, (202) 622-6030 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) under section 401(d)(1). Sections 1022(c), 1022(d), and 2002(a)(2) of the Employee Retirement Income Security Act of 1974 (ERISA), Pub. L. 93-406 (1974), amended sections 401(d), 401(f), and 408 of the Internal Revenue Code (Code) to permit an entity that is not a bank to be a trustee or a custodian for purposes of those Code sections if such entity demonstrates to the satisfaction of the Secretary of the Treasury that it will administer the trust and hold assets in a manner consistent with the law. Although section 401(d)(1) was repealed by section 237(a) of the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248 (1982), the regulations under section 401(d)(1) remain in force and effect to the extent that they govern the determination of whether an entity can be a nonbank trustee or custodian for purposes of Treasury Regulation §§ 1.401(f)-1 and 1.408-2(d). Section 1.401-12(n)(6)(ii) of the regulations, proposed in 1975 and finalized in 1979 under section 401(d)(1) of the Code, sets forth net worth requirements for nonbank trustees based on the greater of a specified dollar amount or a percentage of the value of all assets held by the nonbank trustee in fiduciary accounts. A primary objective of this adequacy of net worth requirement has been to ensure that nonbank trustees maintain a level of solvency commensurate with their financial and fiduciary responsibilities.

Pursuant to the existing net worth requirements, nonbank trustees may not accept new accounts unless their net worth exceeds the greater of \$100,000 or four percent of the value of all assets held in fiduciary accounts. Additionally, nonbank trustees must take whatever steps are necessary (including the relinquishment of fiduciary accounts) to ensure that their net worth exceeds the greater of \$50,000 or two percent of the value of assets held in their fiduciary accounts. While similar requirements apply to passive nonbank trustees (qualified nonbank entities that have no discretion to direct the investment of assets), the percentage requirements for these trustees are lower. Specifically, passive nonbank trustees may not accept new accounts unless their net worth exceeds the greater of \$100,000 or two percent of the value of all assets held in fiduciary accounts and they must take appropriate action (including the relinquishment of fiduciary accounts) to ensure that their net worth exceeds the greater of \$50,000

or one percent of the value of assets held in their fiduciary accounts.

The IRS has received comments that this requirement is unduly restrictive in the case of passive trustees who are broker-dealers regulated by the Securities and Exchange Commission (SEC) and who are required to have their fiduciary accounts protected by the Securities Investor Protection Corporation (SIPC). SIPC, established by Congress in 1970, insures customer assets and funds held by a U.S. broker-dealer in the case of an insolvency in an amount of up to \$500,000 per customer, of which \$100,000 may be cash. Thus, with respect to SIPC protected assets, the on-going net worth requirement provides little if any increase in protection of assets held in fiduciary accounts. Accordingly, these temporary regulations provide that SIPC protected assets will be disregarded in determining the value of assets held in fiduciary accounts by passive trustees for purposes of the percentage prong of the net worth requirement.

These temporary regulations also increase the initial net worth requirement for all nonbank trustees to better assure that enterprises are sound and well-funded during their start-up period. Under the existing net worth requirements, every nonbank trustee must have an initial net worth that exceeds \$100,000. Under these temporary regulations, all entities applying for nonbank trustee status must have a net worth of not less than \$250,000 for the most recent taxable year preceding the applicant's initial application. The existing net worth requirements, as modified for SIPC protected assets, will continue to apply on an on-going basis after a nonbank trustee has obtained the approval of the IRS.

In the absence of evidence that the on-going net worth requirements fail to meet the underlying objectives, these requirements (except with respect to SIPC protected assets) remain unchanged. However, the IRS recognizes that the nonbank trustee requirements have been in effect since 1979. Accordingly, the IRS and Treasury would welcome comments concerning the net worth requirements generally, as well as other aspects of the 1979 regulations.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5