

Dated: November 4, 2002.

David L. Hutner,

Secretary to the Board, Federal Retirement Thrift Investment Board.

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FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Federal Trade Commission (FTC).

ACTION: Notice.

SUMMARY: The FTC has submitted to the Office of Management and Budget (OMB) for review under the Paperwork Reduction Act (PRA) information collection requirements contained in four product labeling rules enforced by the Commission. The FTC is seeking public comments on the proposal to extend through December 31, 2005 the current PRA clearance for information collection requirements contained in the regulations. That clearance expires on December 31, 2002.

DATES: Comments must be filed by December 6, 2002.

ADDRESSES: Send written comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10202, Washington, DC 20503, ATTN.: Desk Office for the Federal Trade Commission (comments in electronic form should be sent to oir_docket@omb.eop.gov), and to Secretary, Federal Trade Commission, Room H-159, 600 Pennsylvania Ave., NW., Washington, DC 20580 (comments in electronic form should be sent to apparelpprwork@ftc.gov as prescribed below). All comments should be captioned "Apparel Rules: Paperwork Comment."

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the proposed information requirements should be sent to Gary Greenfield, Attorney, Office of the General Counsel, Federal Trade Commission, 600 Pennsylvania Ave., NW., H-576, Washington, DC 20580, (202)326-2753.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. On August 20,

2002, the FTC sought comment on the information collection requirements associated with these product labeling rules. See 67 FR 53933. No comments were received. Pursuant to the OMB regulations that implement the PRA (5 CFR part 1320), the FTC is providing this second opportunity for public comment while seeking OMB approval to extend the existing paperwork clearance for the Rule.

If a comment contains nonpublic information, it must be filed in paper form, and the first page of the document must be clearly labeled "confidential." Comments that do not contain any nonpublic information may instead be filed in electronic form (in ASCII format, WordPerfect, or Microsoft Word) as part of or as an attachment to email messages directed to the following email box: apparelpprwork@ftc.gov. Such comments will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's rules of practice, 16 CFR 4.9(b)(6)(ii).

Staff's burden estimates for the four rules in question are based on data from the Bureau of Census, U.S. Customs and International Trade Commission, the Department of Labor, and data or other input from industry sources. The relevant information collection requirements within these rules and corresponding burden estimates follow.

1. Regulations Under the Fur Products Labeling Act, 15 U.S.C. 69 et seq. ("Fur Act") (Control Number: 3084-0099)

The Fur Act prohibits misbranding and false advertising of fur products. The Fur Act Regulations, 16 CFR 301, establish disclosure requirements that assist consumers in making informed purchasing decisions, and recordkeeping requirements that assist the Commission in enforcing these regulations. The Regulations also provide a procedure for exemption from certain disclosure provisions under the Act.

Estimated annual hours burden: 177,000 hours, rounded to the nearest thousand (62,400 hours for recordkeeping + 114,450 hours for disclosure).

Recordkeeping: The Regulations require that retailers, manufacturers and processors, and imports keep certain records in addition to those they may keep in the ordinary course of business. Staff estimates that 1,500 retailers incur an average recordkeeping burden of

about 13 hours per year (19,500 hours total); 225 manufacturers and fur processors combined incur an average recordkeeping burden of about 52 hours per year (11,700 total); and 1,200 importers of furs and fur products incur an average recordkeeping burden of 26 hours per year (31,200 hours total). The combined recordkeeping burden for the industry is approximately 62,400 hours annually.

Disclosure: Staff estimates that 1,710 respondents (210 manufacturers + 1,500 retail sellers of fur garments) each require an average of 20 hours per year to determine label content (34,200 hours total), and an average of five hours per year to draft and order labels (8,550 hours total). Staff estimates that manually attaching a label to an estimated 1,620,000 fur garments requires approximately two minutes per garment for a total of 54,000 hours annually. Thus, the total burden for labeling garments is 96,750 hours per year.

Staff estimates that the increment burden associated with the Regulations' invoice disclosure requirement, beyond the time that would be devoted to preparing invoices in its absence, is approximately 30 seconds per invoice.¹ The invoice disclosure requirement applies to fur garments, which are generally sold individually, and fur pelts, which are generally sold in groups of at least 50, on average. Assuming invoices are prepared for sales of 1,620,000 garments and 160,000 groups (an estimated 8 million pelts ÷ 50) each of imported and domestic pelts, the invoice disclosure requirement entails an estimated total burden of 16,167 hours.

Staff estimates that the regulations' advertising disclosure requirements impose an average burden of one hour per year for each of the approximately 1,500 domestic fur retailers, or a total of 1,500 hours.

Thus, staff estimates the total disclosure burden to be approximately 114,450 hours (96,750 hours for labeling + 16,167 hours for invoice + 1,500 hours for advertising).

Estimated annual cost burden: \$2,303,000 rounded to the nearest thousand (solely relating to labor costs).

¹ The invoice disclosure burden for PRA purposes excludes the time that respondents would spend for invoicing, apart from the Fur Act Regulations, in the ordinary course of business. See 5 CFR 1320.3(b)(2).

Task	Hourly rate	Burden hours	Labor cost
Determine label content	20.00	34,200	\$684,000
Draft and order labels	13.00	8,500	111,150
Attach labels	² 8.50	54,000	459,000
Invoice disclosures	13.00	16,167	210,171
Prepare advertising disclosures	18.00	1,500	27,000
Recordkeeping	13.00	62,400	811,200
Total			2,302,521

Staff² believes that there are no current start-up costs or other capital costs associated with the regulations. Because the labeling of fur products has been an integral part of the manufacturing process for decades, manufacturers have in place the capital equipment necessary to comply with the Regulations' labeling requirements. Industry sources indicate that much of the information required by the Fur Act and its implementing regulations would be included on the product label even absent the regulations. Similarly, invoicing, recordkeeping, and advertising disclosures are tasks performed in the ordinary course of business so that covered firms would incur no additional capital or other non-labor costs as a result of the Act or the regulations.

2. Regulations Under the Wool Products Labeling Act, 15 U.S.C. 68 et seq. ("Wool Act") (Control Number: 3084-0100)

The Wool Act prohibits misbranding of wool products. The Wool Act Regulations, 16 CFR part 300, establish disclosure requirements that assist consumers in making informed purchasing decisions and recordkeeping requirements that assist the Commission in enforcing the Regulations.

Estimated annual hours burden: 556,000 hours, rounded to the nearest thousand (125,000 recordkeeping hours + 430,556 disclosure hours).

Recordkeeping: Staff estimates that approximately 5,000 wool firms are subject to the Regulations' recordkeeping requirements. Based on an average annual burden of 25 hours per firm, the total recordkeeping burden is 125,000 hours.

Disclosure: Approximately 10,000 wool firms, producing or importing about 500,000,000 wool products annually, are subject to the Regulations'

disclosure requirements. Staff estimates the burden of determining label content to be 20 hours per year per respondent, or a total of 200,000 hours, and the burden of drafting and ordering labels to be 5 hours per respondent per year, or a total 50,000 hours. Staff believes that the process of attaching labels is now fully automated and integrated into other production steps for about 35 percent of all affected products. For the remaining 325,000,000 items (65 percent of 500,000,000), the process is semi-automated and requires an average of approximately two seconds per item, for total of 180,556 hours per year. Thus, the total estimated annual burden for all respondents is 430,556 hours. Staff believes that any additional burden associated with advertising disclosure requirements would be minimal (less than 10,000 hours) and can be subsumed within the burden estimates set forth above.

Estimated annual cost burden: \$6,817,000, rounded to the nearest thousand (solely relating to labor costs).

Task	Hourly rate	Burden hours	Labor cost
Determine label content	\$20.00	200,000	\$4,000,000
Draft and order labels	13.00	50,000	650,000
Attach labels	³ 3.00	180,556	541,668
Recordkeeping	13.00	125,000	1,625,000
Total			6,816,668

³For products that are imported, this work generally is done in the country where they are manufactured. According to information compiled by an industry trade association using data from the International Trade Commission, the U.S. Customs Service, and the U.S. Census Bureau, approximately 90% of apparel and other textile products used in the United States is imported. With the remaining 10% attributable to U.S. production at an approximate domestic hourly wage of \$8.50 to attach labels, staff has calculated a weighted average hourly wage of \$3 per hour attributable to U.S. and foreign labor combined. The estimated percentage of imports supplied by particular countries is based on trade data for 2001 compiled by the Office of Textiles and Apparel, International Trade Administration, U.S. Department of Commerce. Wages in major textile exporting countries, factored into the above hourly wage estimate, were based on data published in February 2000 by the U.S. Department of Labor, Bureau of International Labor Affairs. (See "Wages, Benefits, Poverty Line, and Meeting Workers' Needs in the Apparel and Footwear Industries of Selected Countries," Table I-2: "Prevailing or Average Wages in the Manufacturing Sector and in the Footwear and Apparel Industries in Selected Countries, Latest Available Year").

Staff believes that there are no current start-up costs or other capital costs associated with the regulations. Because the labeling of wool products has been an integral part of the manufacturing process for decades, manufacturers have in place the capital equipment necessary to comply with the

regulations. Based on knowledge of the industry, staff believes that much of the information required by the Wool Act and its implementing regulations would be included on the product label even absent their requirements. Similarly, recordkeeping and advertising disclosures are tasks performed in the

ordinary course of business so that covered firms would incur no additional capital or other non-labor costs as a result of the regulations.

²Per industry sources, most fur labeling is done in the U.S. and this rate is reflective of an average

domestic hourly wage for such tasks. Conversely, attaching labels with regard to the others

regulations discussed herein is mostly performed by foreign labor, as detailed in note 3.

3. Regulations Under the Textile Fiber Products Identification Act, 15 U.S.C. 70 et seq. ("Textile Act") (Control Number: 3084-0101)

The Textile Act prohibits misbranding and false advertising of textile fiber products. The Textile Act Regulations, 16 CFR part 303, establish disclosure requirements that assist consumers in making informed purchasing decisions, and recordkeeping requirements that assist the Commission in enforcing the regulations. The regulations also contain a petition procedure for requesting the establishment of generic names for textile fibers.

Estimated annual hours burden: approximately 7,547,000 hours, rounded to the nearest thousand

(537,500 recordkeeping hours + 7,009,722 disclosure hours).

Recordkeeping: Staff estimates that approximately 21,500 textile firms are subject to the Textile Regulations' recordkeeping requirements. Based on an average burden of 25 hours per firm, the total recordkeeping burden is 537,500 hours.

Disclosure: Approximately 31,500 textile firms, producing or importing about 17.2 billion textile fiber products annually, are subject to the regulations' disclosure requirements.⁴ Staff estimates the burden of determining label content to be 20 hours per year per respondent, or a total of 630,000 hours and the burden of drafting and ordering labels to be 5 hours per respondent per year, or a total of 157,500 hours. Staff believes that the process of attaching

labels is now fully automated and integrated into other production steps for about 35 percent of all affected products. For the remaining 11.2 billion items (65 percent of 17.2 billion), the process is semi-automated and requires an average of approximately two seconds per item, for a total of 6,222,222 hours per year. Thus, the total estimated annual burden for all respondents is 7,009,722 hours. Staff believes that any additional burden associated with advertising disclosure requirements or the filing of generic fiber name petitions would be minimal (less than 10,000 hours) and can be subsumed within the burden estimates set forth above.

Estimated annual cost burden: \$40,302,000, rounded to the nearest thousand (solely relating to labor costs.).

Task	Hourly rate	Burden hours	Labor cost
Determine label content	\$20.00	630,000	\$12,600,000
Draft and order labels	13.00	157,500	2,047,500
Attach labels	⁵ 3.00	6,222,222	18,666,666
Recordkeeping	13.00	537,500	6,987,500
Total			40,301,666

⁵ See note 3.

Staff believes that there are no current start-up costs or other capital costs associated with the regulations. Because the labeling of textile products has been an integral part of the manufacturing process for decades, manufacturers have in place the capital equipment necessary to comply with the regulations' labeling requirements. Industry sources indicate that much of the information required by the Textile Act and its implementing rules would be included on the product label even absent their requirements. Similarly, recordkeeping, invoicing, and advertising disclosures are tasks performed in the ordinary course of business so that covered firms would incur no additional capital or other non-labor costs as a result of the Regulations.

4. The Care Labeling Rule, 16 CFR Part 423 (Control Number: 3084-0103)

The Care Labeling Rule, 16 CFR part 423, requires manufacturers and

importers to attach permanent care label to all covered textile clothing in order to assist consumers in making purchase decisions and in determining what method to use to clean their apparel. Also, manufacturers and importers of piece goods used to make textile clothing must provide the same care information on the end of each bolt or roll of fabric.

Estimated annual hours burden: 6,054,000 hours, rounded to the nearest thousand (solely relating to disclosure⁶).

Staff estimates that approximately 16,500 manufacturers or importers of textile apparel, producing about 15.2 billion textile garments annually, are subject to the Rule's disclosure requirements. The burden of developing proper care instructions may vary greatly among firms, primarily based on the number of different lines of textile garments introduced per year that require new or revised care instructions.

Staff estimates the burden of determining care instructions to be 43 hours each year per respondent, for cumulative total of 709,500 hours. Staff further estimates that the burden of drafting and ordering labels is 2 hours each year per respondent, for a total of 33,000 hours. Staff believes that the process of attaching labels is fully automated and integrated into other production steps for about 35 percent of the approximately 14.7 billion garments that are required to have care instructions on permanent labels.⁷ For the remaining 9.56 billion items (65 percent of 14.7 billion), the process is semi-automated and requires an average of approximately two seconds per item, for a total of 5,311,100 hours per year. Thus, the total estimated annual burden for all respondents is 6,053,600 hours.

Estimated annual cost burden: \$30,552,000, rounded to the nearest thousand (solely relating to labor costs).

⁴ The apparent consumption of garments in the U.S. in 2001 was 15.2 billion. Staff estimates that .5 billion garments are exempt from the Textile Act (i.e., any kind of headwear and garments made from something other than a textile fiber product, such as leather) or are subject to a special exemption for hosiery products sold in packages where the label information is contained on the package. Based on available data, staff estimates that an additional 3 billion household textile products (non-garments, such as sheets, towels, blankets) were consumed.

However, approximately .5 billion of all of these combined products (garments and non-garments) are subject to the Wool Products Labeling Act, not the Textile Fiber Products Identification Act, because they contain some amount of wool. Thus, the estimated net total products subject to the Textile Fiber Products Identification Act is 17.2 billion.

⁶ The Care Labeling Rule imposes no specific recordkeeping requirements. Although the Rule requires manufacturers and importers to have

reliable evidence to support the recommended care instructions, companies may provide as support current technical literature or rely on past experience.

⁷ About .5 billion of the 15.2 billion garments produced annually are either not covered by the Care Labeling Rule (gloves, hats, caps, fur, plastic, or leather garments) or are subject to an exemption that allows care instructions to appear on packaging (hosiery).

Task	Hourly rate	Burden hours	Labor cost
Determine care instructions	\$20.00	709,500	\$14,190,000
Draft and order labels	13.00	33,000	429,000
Attach labels	*3.00	5,311,100	15,933,300
Total			30,552,300

Staff⁸ believes that there are no current start-up costs or other capital costs associated with the Rule. Because the labeling of textile products has been an integral part of the manufacturing process for decades, manufacturers have in place the capital equipment necessary to comply with the Rule's labeling requirements. Based on knowledge of the industry, staff believes that much of the information required by the Rule would be included on the product label even absent those requirements.

John D. Graubert,
Acting General Counsel.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1526]

Robert A. Fiddes; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) debaring Dr. Robert A. Fiddes for 20 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Fiddes was convicted of a felony under Federal law for conspiring to make false statements to a government agency, and was a material participant in offenses for which three other people are being debarred. Dr. Fiddes has failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

DATES: This order is effective November 6, 2002.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm., 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Mary Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

On September 30, 1997, the U.S. District Court for the Central District of California accepted Dr. Fiddes' plea and entered judgment against him for one count of conspiring to make false statements to a government agency, the FDA, in violation of 18 U.S.C. 371 and 1001. This conspiracy conviction was based on Dr. Fiddes participating in, directing, and encouraging the submission of false information to sponsors in required reports for clinical studies used by FDA to evaluate the safety and effectiveness of drug products.

As a result of this conviction, FDA served Dr. Fiddes by certified mail on June 6, 2002, a notice proposing to debar him for 20 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Dr. Fiddes an opportunity for a hearing on the proposal. The debarment proposal was based on findings: (1) Under section 306(b)(2)(B)(i)(II) of the act (21 U.S.C. 335a(b)(2)(B)(i)(II)) that Dr. Fiddes was convicted of a felony under Federal law for conspiracy to make false statements to a government agency and, (2) under section 306(b)(2)(B)(iii) of the act that Dr. Fiddes was a material participant in offenses leading to the conviction and debarment of three other individuals. Dr. Fiddes was provided 30 days to file objections and to request a hearing. Dr. Fiddes did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(b)(2)(B) of the act, and under authority delegated to her (21 CFR 5.99), finds that Dr. Robert A. Fiddes: (1) Has been convicted of a felony under Federal law for conspiring

to make false statements to a government agency, and (2) was a material participant in offenses leading to the conviction and debarment of three other individuals.

As a result of the foregoing findings, Dr. Robert A. Fiddes is debarred for 20 years (4 periods of 5 years, to run consecutively, based on his conviction of a Federal felony and his role as a material participant in the offenses leading to the conviction and debarment of three other individuals) from providing services in any capacity to a person that has an approved or pending drug product application under section 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262) (see sections 306(c)(1)(B) and (c)(2)(A)(iii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Dr. Fiddes, in any capacity, during his period of debarment, will be subject to civil money penalties. If Dr. Fiddes, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Fiddes during his period of debarment.

Any application by Dr. Fiddes for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 00N-1526 and sent to the Dockets Management Branch (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 15, 2002.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

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⁸ See note 3.