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David C. Shonka,

Acting General Counsel.

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## FEDERAL TRADE COMMISSION

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

**AGENCY:** Federal Trade Commission (FTC).

**ACTION:** Notice and request for comment.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) of 1995, the FTC is seeking public comments on its request to OMB to extend for three years the current PRA clearances for information collection requirements contained in the Commission's Rules and Regulations under the Textile Fiber Products Identification Act (Textile Rules). The clearance expires on April 30, 2018.

**DATES:** Comments must be received by May 9, 2018.

**ADDRESSES:** Interested parties may file a comment online or on paper by following the instructions in the Request for Comments part of the

**SUPPLEMENTARY INFORMATION** section below. Write "Textile Rules: FTC File No. P072108" on your comment, and file your comment online at <https://ftcpublic.commentworks.com/ftc/textile-rulespra2> by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the proposed information requirements should be addressed Jock K. Chung, Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Mail Code CC-9528, 600 Pennsylvania Ave. NW, Washington, DC 20580, (202) 326-2984.

#### SUPPLEMENTARY INFORMATION:

*Title:* Rules and Regulations under the Textile Fiber Products Identification Act, 16 CFR part 303.

*OMB Control Number:* 3084-0101.

*Type of Review:* Extension of a currently approved collection.

*Abstract:* The Textile Fiber Products Identification Act (Textile Act)<sup>1</sup> prohibits the misbranding and false advertising of textile fiber products. The Textile Rules establish disclosure requirements that assist consumers in making informed purchasing decisions, and recordkeeping requirements that assist the Commission in enforcing the Rules. The Rules also contain a petition procedure for requesting the establishment of generic names for textile fibers.

On January 22, 2018, the Commission sought comment on the information collection requirements in the Textile Rules. 83 FR 2992. No germane comments were received.<sup>2</sup> As required by OMB regulations, 5 CFR part 1320, the FTC is providing this second opportunity for public comment.

*Likely Respondents:* Manufacturers, importers, processors and marketers of textile fiber products.

*Frequency of Response:* Third party disclosure; recordkeeping requirement.

*Estimated annual hours burden:* 37,007,147 hours (782,600 recordkeeping hours + 36,224,547 disclosure hours).

*Recordkeeping:* 782,600 hours (approximately 12,040 textile firms incur average burden of 65 hours per firm).

*Disclosure:* 36,224,547 hours (698,360 hours to determine label content + 859,520 hours to draft and order labels + 34,666,667 hours to attach labels).

*Estimated annual cost burden:* 239,778,909 (solely relating to labor costs).

#### Request for Comment

You can file a comment online or on paper. For the FTC to consider your comment, we must receive it on or before May 9, 2018. Write "Textile Rules: FTC File No. P072108" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission website, at <http://www.ftc.gov/os/publiccomments.shtm>.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online, or to send them to the Commission by courier or overnight service. To make sure that the Commission considers your online

comment, you must file it at <https://ftcpublic.commentworks.com/ftc/textile-rulespra2> by following the instructions on the web-based form. When this Notice appears at <http://www.regulations.gov>, you also may file a comment through that website.

If you file your comment on paper, write "Textile Rules: FTC File No. P072108" on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610, Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service. Comments on the information collection requirements subject to review under the PRA should additionally be submitted to OMB. If sent by U.S. mail, they should be addressed to Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission, New Executive Office Building, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503. Comments sent to OMB by U.S. postal mail are subject to delays due to heightened security precautions. Thus, comments can also be sent via email to [Wendy.L.Liberante@omb.eop.gov](mailto:Wendy.L.Liberante@omb.eop.gov).

Because your comment will be placed on the publicly accessible FTC website at <https://www.ftc.gov>, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas,

<sup>1</sup> 15 U.S.C. 70 *et seq.*

<sup>2</sup> The Commission received three non-germane comments.

patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before May 9, 2018. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

David C. Shonka,

Acting General Counsel.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-1069]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Blood Establishment Registration and Product Listing, Form FDA 2830

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget

(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by May 9, 2018.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [aira\\_submission@omb.eop.gov](mailto:aira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0052. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Blood Establishment Registration and Product Listing, Form FDA 2830—21 CFR part 607 OMB Control Number 0910-0052—Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), any person owning or operating an establishment that manufactures, prepares, propagates, compounds, or processes a drug or device must register with the Secretary of Health and Human Services, on or before December 31 of each year, his or her name, places of business, and all such establishments, among other information, and must submit a list of all drug and all device products manufactured, prepared, propagated, compounded, or processed by him or her for commercial distribution, among other information. In part 607 (21 CFR part 607), FDA has issued regulations implementing these requirements for manufacturers of human blood and blood products.

Section 607.20(a), requires, in part, that owners or operators of certain establishments that engage in the manufacture of blood products register and submit a list of every blood product in commercial distribution.

Section 607.21 requires the owner or operator of an establishments entering into the manufacturing of blood products to register the establishment within 5 days after beginning such operation and to submit a list of every

blood product in commercial distribution at the time. If the owner or operator of the establishment has not previously entered into such operation for which a license is required, registration must follow within 5 days after the submission of a biologics license application. In addition, owners or operators of all establishments so engaged must register annually between October 1 and December 31 and update their blood product listing every June and December.

Section 607.22(a) requires, in part, that initial and subsequent registrations and product listings be submitted electronically through the Blood Establishment Registration and Product Listing system or any future superseding electronic system.

Section 607.22(b) requires, in part, that requests for a waiver of the requirements of § 607.22 be submitted in writing and include the specific reasons why electronic submission is not reasonable for the registrant.

Section 607.22(c) provides that if FDA grants the waiver request, FDA may limit its duration and will specify the terms of the waiver and provide information on how to submit establishment registration, drug listings, other information, and updates, as applicable (e.g., Form FDA 2830).

Section 607.25 sets forth the information required for establishment registration and blood product listing.

Section 607.26 requires, in part, that certain changes, such as ownership or location changes, be submitted to FDA electronically as an amendment to establishment registration within 5 calendar days of such changes using the FDA Blood Establishment Registration and Product Listing system, or any future superseding electronic system.

Section 607.30(a), in part, sets forth the information required from owners or operators of establishments when they update their blood product listing information in June and December of each year (at a minimum).

Section 607.31 requires that certain additional blood product listing information be provided upon request by FDA.

Section 607.40 requires, in part, that certain foreign blood product establishments comply with the establishment registration and blood product listing information requirements in part 607, subpart B (§§ 607.20 through 607.39, 607.40(a) and (b)), and provide the name and address of the establishment and the name of the individual responsible for submitting establishment registration and blood product listing information (§ 607.40(c))