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[FR Doc. 2019–00798 Filed 3–5–19; 8:45 am] BILLING CODE 6325–39–P

FEDERAL TRADE COMMISSION

16 CFR Part 24

Guides for Select Leather and Imitation Leather Products

AGENCY: Federal Trade Commission. **ACTION:** Regulatory review; request for public comment.

SUMMARY: The Federal Trade Commission ("FTC" or "Commission") requests public comments on its Guides for Select Leather and Imitation Leather Products ("Leather Guides" or "Guides"). The Commission is soliciting the comments as part of the Commission's systematic review of all current Commission regulations and guides.

DATES: Comments must be received by April 22, 2019.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comment part of the SUPPLEMENTARY INFORMATION section below. Write "Leather Guides Review, P188014" on your comment, and file your comment online at https://www.regulations.gov by following the instructions of that website. 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 610, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT:

James R. Golder (214–979–9376), jgolder@ftc.gov, Attorney, Southwest Region, Federal Trade Commission, 1999 Bryan Street, Suite 2150, Dallas, Texas 75201.

SUPPLEMENTARY INFORMATION:

I. Background

The Commission's Leather Guides address misrepresentations about the composition and characteristics of specific leather and imitation leather products.¹ The Guides apply to the manufacture, sale, distribution, marketing, or advertising of all kinds of leather or simulated leather purses, luggage, wallets, footwear, and other similar products. Importantly, the Leather Guides state that disclosure of non-leather content should be made for material that has the appearance of leather but is not leather.

The Commission adopted the Leather Guides in 1996, as part of its periodic review of its rules and guides.² On May 23, 2007, the Commission published a **Federal Register** notice seeking public comment on the Guides.³ On June 18, 2008, the Commission published its conclusion that there was a continuing need for the Guides, and it approved retention of the Guides in their current form ⁴

II. Regulatory Review Program

The Commission periodically reviews all Commission rules and guides. These reviews seek information about the costs and benefits of the Commission's rules and guides and their economic impact. The information obtained assists the Commission in identifying rules and guides that warrant modification or rescission. Therefore, the Commission solicits comment on, among other things, the economic impact of and the continuing need for its Leather Guides; possible conflict between the Guides and state, local, federal, or international laws: and the effect of any technological, economic, environmental, or other industry changes on the Guides.

III. Request for Comment

The Commission is particularly interested in comments and supporting

data on the following questions. These questions are designed to assist the public and should not be construed as a limitation on the issues on which public comment may be submitted. In their replies to each of these questions, commenters should provide any available evidence and data, such as empirical data, consumer perception studies, or consumer complaints, that support the commenter's asserted position.

(1) Is there a continuing need for the Leather Guides as currently promulgated?

(2) Are any specific provisions of the Leather Guides no longer necessary?

(3) Are the deceptive or unfair practices addressed by the Leather Guides prevalent in the marketplace? Are the Guides effective in addressing those practices?

(4) Åre there deceptive or unfair practices in the selling of leather or imitation leather products in other industries that are not covered by the Leather Guides, such as automotive and furniture upholstery products? If so, what is the extent of misrepresentations in those industries? How do consumers interpret or perceive the appearance of leather or simulated leather in those industries? Should the Commission expand the Guides to cover these or other products? What compliance costs would be imposed on these industries if the Commission were to expand the Guides? Are there any special considerations for those industries? Are there alternatives, such as individual enforcement actions under the FTC Act, that would be more effective or equally effective in addressing those practices?

(5) Have covered businesses adopted the Leather Guides as part of their routine business practice? Have uncovered businesses adopted the Leather Guides as part of their routine business practice? What is the degree of compliance with the Guides? How, and what effect, if any, does this have on the continuing need for the Guides? Do covered or uncovered businesses self-regulate or have voluntary standards or guidance, such as through trade associations, which overlap with the Guides?

(6) What benefits, if any, have the Leather Guides provided to consumers of the products affected by the Guides? Do the Guides impose any significant costs on consumers?

(7) What impact, if any, have the Leather Guides had on the flow of truthful or deceptive information to consumers?

(8) What changes, if any, should be made to the Leather Guides to increase their benefits to consumers? How would

these changes affect consumer benefits or business costs?

- (9) What burdens or costs, including costs of compliance, have the Leather Guides imposed on covered businesses? What burdens or costs have the Guides imposed on small businesses in particular? Have the Guides provided benefits to businesses? If so, what benefits?
- (10) What changes, if any, should be made to the Leather Guides to reduce the burdens or costs imposed on businesses? How would these changes affect consumer benefits or business costs?
- (11) Do the Leather Guides overlap or conflict with federal, state, or local laws or regulations? Do the Guides overlap or conflict with any international laws or regulations?

(12) Have consumer perceptions changed since the Leather Guides were issued and, if so, do these changes warrant revising the Guides?

(13) Since the Leather Guides were issued, what effects, if any, have changes in relevant technological, economic, or environmental conditions had on the need for or usefulness of the Guides?

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before April 22, 2019. Write "Leather Guides Review, P188014" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding at https://www.regulations.gov.

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. To ensure the Commission considers your online comment, you must file it at http://www.regulations.gov by following the instructions of that website.

If you file your comment on paper, write "Leather Guides Review, P188014" 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, please submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on a publicly accessible website at https://www.regulations.gov, you are

¹ The Leather Guides "are administrative interpretations of laws administered by the Commission for the guidance of the public in conducting its affairs in conformity with legal requirements. They provide the basis for voluntary and simultaneous abandonment of unlawful practices by members of industry." 16 CFR 1.5. Conduct inconsistent with the Guides may result in corrective action by the Commission under Section 5 of the FTC Act (15 U.S.C. 45).

² 61 FR 51577 (October 3, 1996). When adopted, the Leather Guides consolidated portions of the Guides for the Luggage and Related Products Industry, the Guides for Shoe Content Labeling and Advertising, and the Guides for the Ladies' Handbag Industry. The Leather Guides also included provisions previously contained in the Commission's Trade Regulation Rule Concerning Misbranding and Deception as to Leather Content of Waist Belts. See 72 FR 28907 (May 23, 2007).

³ 72 FR 28906 (May 23, 2007).

⁴⁷³ FR 34630 (June 18, 2008).

solely responsible for making sure that your comment does not include any sensitive personal information, such as your or anyone'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 ensuring 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 "[t]rade secret or any commercial or financial information which . . . is privileged or confidential"—as provided in Section (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, 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 publicly—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the www.regulations.gov 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.

Visit the FTC website to read this Notice and the news release describing it. 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 April 22, 2019. 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.

By direction of the Commission.

April Tabor,

Acting Secretary.

[FR Doc. 2019-03970 Filed 3-5-19; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. FDA-2018-N-4394]

Medical Devices; Exemption From Premarket Notification: Class II Devices; Flow Cytometer Instruments; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing its intention to exempt certain flow cytometer instruments from premarket notification requirements, subject to conditions and limitations. The Agency has determined based on established factors that these devices, which are currently regulated by FDA under product code OYE, no longer require premarket notification to provide reasonable assurance of safety and effectiveness. All other class II devices classified under FDA's automated differential cell counter regulation would continue to be subject to premarket notification requirements. FDA is publishing this proposed order to obtain comments regarding this proposed exemption, in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the notice by May 6, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 6, 2019. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of May 6, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https:// www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA—2018—N—4394 for "Medical Devices; Exemptions from Premarket Notification: Class II Devices; Flow Cytometer Instruments; Request for Comments." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS"