

11 October 2021

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Addendum

The following communication, dated 11 October 2021, is being circulated at the request of the delegation of the <u>United States of America</u>.

Title: Environmental Defense Fund, Earthjustice, Environmental Working Group, Center for Environmental Health, Healthy Homes Collaborative, Health Justice Project of Loyola University Chicago School of Law, Breast Cancer Fund, Improving Kids' Environment, Consumers Union, Natural Resources Defense Council, Consumer Federation of America, Learning Disabilities Association, Maricel Maffini, and Howard Mielke; Filing of Color Additive Petition

Reason for Addendum:	
[]	Comment period changed - date:
[]	Notified measure adopted - date:
[X]	Notified measure published - date: 8 October 2021
[X]	Notified measure enters into force - date: 6 January 2022
[X]	Text of final measure available from¹:
	https://www.govinfo.gov/content/pkg/FR-2021-10-08/html/2021-21892.htm https://www.govinfo.gov/content/pkg/FR-2021-10-08/pdf/2021-21892.pdf https://members.wto.org/crnattachments/2021/TBT/USA/final measure/21 6496 00 e.pdf Final rule; response to objections and denial of public hearing requests; removal of
	administrative stay
[]	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
[]	Content or scope of notified measure changed and text available from ¹ : New deadline for comments (if applicable):
[]	Interpretive guidance issued and text available from ¹ :
[]	Other:

Description: TITLE: Termination of Listing of Color Additives Exempt From Certification; Lead Acetate

AGENCY: Food and Drug Administration, HHS

 1 This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained.

ACTION: Final rule; response to objections and denial of public hearing requests; removal of administrative stay

SUMMARY: The Food and Drug Administration (FDA or we) is responding to objections and a public hearing request that we received from Combe Inc., on the final rule entitled "Termination of Listing of Color Additives Exempt From Certification; Lead Acetate," which published on 31 October 2018. The final rule amended the color additive regulations to no longer provide for the safe use of lead acetate in cosmetics intended for coloring hair on the scalp. After reviewing the objections, we have concluded that the objections do not raise issues of material fact that justify a hearing. Therefore, the stay of the effectiveness for the repeal and delisting of the color additive regulation is now lifted, and we are amending the color additive regulations to no longer provide for the safe use of lead acetate in cosmetics intended for coloring hair on the scalp.

This rule is effective 6 January 2022.

This final rule and previous actions notified under the symbol <u>G/TBT/N/USA/1287</u> are identified by Docket Number FDA-2017-C-1951. The Docket Folder is available on Regulations.gov at https://www.regulations.gov/docket/FDA-2017-C-1951/document and provides access to primary and supporting documents as well as comments received. Documents are also accessible from Regulations.gov by searching the Docket Number.