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Submitted electronically

December 22, 2021

United States Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Docket No. HHS-OS- 2020-0012; RIN 0991-AC24
Securing Updated and Necessary Statutory Evaluations Timely; Proposal
to Withdraw or Repeal
AGENCY: Department of Health and Human Services (HHS).
ACTION: Proposed rule
86 Fed. Reg. 59906 (October 29, 2021)

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA) appreciates the opportunity to comment on the above captioned proposed rule to withdraw or repeal a rule that would require assessments and reviews of certain regulations, including action or sunset dates (the SUNSET final rule). CHPA, founded in 1881, is the national trade association representing leading manufacturers and marketers of over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices (Class I and certain Class II devices available directly to consumers without professional intervention). CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products. CHPA member company products are subject to a broad range of regulations issued by the Food and Drug Administration, among other agencies. As such, we have an interest in the proposed withdrawal or repeal of the rule.

A host of FDA regulations are of critical importance to our members, which is why the association submitted comments on December 4, 2020, when the rule was first proposed. At that time, we urged more time to consider the wide-ranging and disruptive impact of the SUNSET rule.

Then as now, we acknowledge revisiting regulations has merit to assure they are current with the demands of the time; to assure impacts are not disproportionate; to assure regulations efficiently achieve their intended public health impact; and as a hallmark of good government. Further, CHPA

has and will advocate for changes in select regulations. But the SUNSET final rule would impose a system for HHS and the agencies within it that would risk misplaced prioritization of focus by agencies within HHS; would likely lead to significant workload challenges; and would exacerbate problems and backlog that already exist in the rulemaking process.

CHPA supports withdrawal or repeal of the SUNSET final rule, as proposed by HHS.

We appreciate the opportunity to submit these comments to eliminate the SUNSET final rule.

Respectfully submitted,

David Spangler

David C. Spangler
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Proposed_withdrawal-HHS_sunset_rule-December2021