



## Week in Regulation

# Sunscreen Dominates Last Week of February

DAN GOLDBECK, DAN BOSCH | MARCH 4, 2019

The final week of February 2019 brought yet another regulatory week. A single proposed rule regarding over-the-counter (OTC) sunscreen standards out of the Food & Drug Administration (FDA) provided the bulk of new costs in what would have otherwise been a fairly mundane week. This proposal also provided an interesting example of how long and winding the regulatory road can get. Between both proposed and final rules last week, agencies published \$646.9 million in total net costs, as well as 905,994 hours of new paperwork.

## REGULATORY TOPLINES

- New Proposed Rules: 44
- New Final Rules: 51
- 2019 Total Pages: 7,238
- 2019 Final Rule Costs: \$8.9 Billion
- 2019 Proposed Rule Costs: \$3.5 Billion

## TRACKING THE REGULATORY BUDGET

The FDA sunscreen proposal was the clearly the preeminent rulemaking of the week. The [proposal](#) seeks to “update and make effective regulations to ensure the safety and effectiveness of sunscreen products marketed under the OTC drug monograph.” These amended standards could bring total, undiscounted costs of nearly \$620 million over 20 years. Since this is still only a proposed rule, it does not yet count as a regulatory action for

the purposes fiscal year (FY) 2019’s regulatory budget under Executive Order (EO) 13,771.

So far in FY 2019 (which began on October 1, 2018), there have been 31 deregulatory actions (per the rubric created by EO 13,771 and the administration’s subsequent [guidance document](#)) against 12 rules that increase costs and fall under the EO’s reach. Combined, these actions yield quantified net costs of roughly \$10.2 billion. This total, however, includes the caveat regarding the baseline in the Department of Agriculture’s “[National Bioengineered Food Disclosure Standard](#).” If one considers that rule to actually be deregulatory, the administration-wide net total is approximately \$3.5 billion in net costs. The administration’s cumulative savings goal for [FY 2019](#) is approximately \$18 billion.

## THIS WEEK’S REGULATORY PICTURE

One can describe “regulatory policy” in many ways: mundane, opaque, monotonous, complex, legalistic. The list goes on. In order to help provide a clearer and more straightforward view into this world, the American Action Forum will seek to provide a brief illustration of a notable regulatory trend we have identified in a given week. This week’s entry: Rulemaking is Hard – Sunscreen Edition.

**Unified Agenda And Regulatory Plan Search Results**

Unified Agenda and Regulatory Plan Search Criteria: Terms=0910-AF43;

Number Of Records Found: 23 [View by Page](#) [View All RIN Data \(Max 350\)](#) [Download All RIN Data in XML](#)

| Agency  | Agenda Stage of Rulemaking | Title   | Publication | RIN                       |
|---------|----------------------------|---|-------------|---------------------------|
| HHS/FDA | Prerule Stage              | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Spring 2004 | <a href="#">0910-AF43</a> |
| HHS/FDA | Prerule Stage              | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Fall 2004   | <a href="#">0910-AF43</a> |
| HHS/FDA | Prerule Stage              | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Spring 2005 | <a href="#">0910-AF43</a> |
| HHS/FDA | Proposed Rule Stage        | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Fall 2005   | <a href="#">0910-AF43</a> |
| HHS/FDA | Proposed Rule Stage        | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Spring 2006 | <a href="#">0910-AF43</a> |
| HHS/FDA | Prerule Stage              | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Fall 2006   | <a href="#">0910-AF43</a> |
| HHS/FDA | Proposed Rule Stage        | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Spring 2007 | <a href="#">0910-AF43</a> |
| HHS/FDA | Proposed Rule Stage        | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Fall 2007   | <a href="#">0910-AF43</a> |
| HHS/FDA | Long-Term Actions          | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Spring 2008 | <a href="#">0910-AF43</a> |
| HHS/FDA | Proposed Rule Stage        | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Fall 2008   | <a href="#">0910-AF43</a> |
| HHS/FDA | Proposed Rule Stage        | Over-The-Counter (OTC) Drug Review--Sunscreen Products                            | Spring 2009 | <a href="#">0910-AF43</a> |
| HHS/FDA | Proposed Rule Stage        | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Fall 2009   | <a href="#">0910-AF43</a> |
| HHS/FDA | Proposed Rule Stage        | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Spring 2010 | <a href="#">0910-AF43</a> |
| HHS/FDA | Proposed Rule Stage        | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Fall 2010   | <a href="#">0910-AF43</a> |
| HHS/FDA | Proposed Rule Stage        | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Spring 2011 | <a href="#">0910-AF43</a> |
| HHS/FDA | Prerule Stage              | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Fall 2011   | <a href="#">0910-AF43</a> |
| HHS/FDA | Prerule Stage              | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | 2012        | <a href="#">0910-AF43</a> |
| HHS/FDA | Prerule Stage              | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Spring 2013 | <a href="#">0910-AF43</a> |
| HHS/FDA | Prerule Stage              | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Fall 2013   | <a href="#">0910-AF43</a> |
| HHS/FDA | Proposed Rule Stage        | Over-the-Counter (OTC) Drug Review--Sunscreen Products                            | Spring 2014 | <a href="#">0910-AF43</a> |
| HHS/FDA | Proposed Rule Stage        | Sunscreen Drug Products For Over-The-Counter-Human Use; Tentative Final Monograph | Fall 2017   | <a href="#">0910-AF43</a> |
| HHS/FDA | Proposed Rule Stage        | Sunscreen Drug Products For Over-The-Counter-Human Use; Tentative Final Monograph | Spring 2018 | <a href="#">0910-AF43</a> |
| HHS/FDA | Proposed Rule Stage        | Sunscreen Drug Products For Over-The-Counter-Human Use; Tentative Final Monograph | Fall 2018   | <a href="#">0910-AF43</a> |

The image above illustrates the lengthy odyssey of the proposed sunscreen standards. The picture shows that this regulation (per the consistent “Regulation Identifier Number” or

RIN) has officially been under consideration for roughly 15 years. The full story of the rulemaking goes back even further. In 1999, the FDA published a final rule identifying 16 sunscreen ingredients with “general recognition of safety and effective” status for over-the-counter (OTC) use. Before the rule ever went into effect, however, the FDA stayed the rule indefinitely in 2001 to “provide additional time to resolve various outstanding issues, such as the labeling and testing of finished OTC sunscreen products.” This proposal is the latest effort to move the regulatory ball forward, but it is still not the end of the road. There is, however, light at the end of the tunnel as the Sunscreen Innovation Act of 2014 directs FDA to produce a final rule on the topic by November 26, 2019.

## TOTAL BURDENS

Since January 1, the federal government has published \$12.4 billion in net costs (with \$8.9 billion in finalized costs) and 19.3 million hours of net paperwork burden increases (including roughly 24.1 million hours from final rules). [Click here](#) for the latest Reg Rodeo findings.

