



CONSUMER
HEALTHCARE
PRODUCTS
ASSOCIATION

Taking healthcare personally.

Submitted electronically

December 4, 2020

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
AGENCY: Department of Health and Human Services (HHS).
ACTION: Notice of proposed rulemaking to set expiration dates for
regulations
85 Fed. Reg. 70096 (November 4, 2020)

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA) appreciates the opportunity to comment on the above captioned proposed rule to require assessments and reviews of certain regulations, including action or sunset dates. 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. As such, we have an interest in this proposed rule.

The proposed rule would set expiration or sunset dates for regulations and would require agencies within HHS to review regulations every ten years under criteria in the Regulatory Flexibility Act. Without such a review, a regulation would sunset. The exceptions to the proposed rule are very narrow, leaving nearly all FDA regulations, which are of critical importance to our members, to fall under the proposed rule's requirements. We understand that initial reviews of regulations older than ten years are proposed to be completed within two years or those regulations would likewise sunset.

These comments cover three areas:

1. We request an extension of the comment period;
2. The breadth of the proposed rule would create a heavy workload on agencies within HHS, diverting attention of more pressing, time-sensitive work; and
3. A preliminary review raises concerns with rulemaking broadly, which would be exacerbated if the rule were finalized as proposed.

1. We request an extension of the comment period.

As an initial matter, we request an extension of at least an additional 60 days to comment on the proposed rule.

You have invited specific comments and broad-ranging comments, including on:

- The number of exceptions;
- Regulations that should be prioritized to be sure they don't sunset;
- Whether there are other factors that should be included in reviews;
- The appropriate course of conduct between a review resulting in a decision to amend a regulation and a proposed amendment, and whether HHS should allow a period from a decision to amend to finalization to exceed two years; and
- The overall regulatory impact of the proposed rule.

Each of these areas touch broadly on regulations as they exist today and carry potentially strong impact on the regulated industries. This merits extensive and more careful, in-depth consideration that cannot be completed within the 30-day comment period, a period that included a major national holiday.

In the absence of an extension of the comment period, our preliminary comments on the proposed rule are outlined in the two sections that follow.

2. The breadth of the proposed rule would create a heavy workload on agencies within HHS, diverting attention of more pressing, time-sensitive work.

CHPA's member company products live in an FDA-regulated and approval-based world. At the time some of these regulations were issued or in their preparation, CHPA may well have had substantive policy disagreements with a regulation's or proposed regulation's approach, but only rarely would those policy views impact a Regulatory Flexibility Act issue. In those cases, we would make our arguments before a regulation is finalized or ahead of the compliance date, not retrospectively. In the case of OTC medicines and some

consumer medical devices, CHPA member company products are also under user fee acts, which have time-based goals and metrics supported by fees. We look at each of these areas – existing regulations and time-based goals – in turn:

Existing regulations. CHPA member products exist under an extensive system of FDA regulations, many of which remain current yet are decades old and would seldom merit revisitation. For instance, the statement of identity for an OTC medicine (the established name of a drug and the general pharmacological category(ies) or its principal intended actions [ie, aspirin pain reliever/fever reducer]) was last revisited in February 1976. Similarly, the statement of identity for dietary supplements dates from the mid-1970s. A third example is the pregnancy/breast-feeding warning on all OTC medicines intended for systemic absorption was issued in 1982. These three examples are simple cases where an agency could readily determine during the assessment stage that a full regulatory review was not merited, but there are hundreds if not thousands of regulations such as these in Title 21 of the Code of Federal Regulations. The number of required assessments will no doubt create a significant workload, particularly in instances where regulations predate 1980's Regulatory Flexibility Act and there is no pre-existing regulatory impact analysis. Presumably these pre-1980 regulations would trigger creation of a regulatory impact analysis even if not proposed for amendment, if for no other reason than to demonstrate the agency was not being arbitrary and capricious.

Finally, most OTC medicines today fall under OTC monographs, which themselves are regulations (or proposed regulations termed tentative final monographs). While provisions of the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020 will shift many of these regulations to administrative orders within FDA, there will be a lag during which time the labeling, dosages, and legal status – including the legal status of ingredients which may **not** legally be included in OTC medicines in the absence of a new drug application – will remain under regulations. Since the status of these OTC monograph regulations will shift over the next one to three years, they should be exempted from assessment and review. If not, they also face the same risks and bottlenecks while adding to challenges described in the preceding paragraph.

Time-based goals under user fee acts. Increasingly over the past 28 years, FDA workload has been driven by user fee acts and their reauthorizations. 1992 marked passage of the Prescription Drug User Fee Act and since that time we've seen user fee programs expanded to medical devices, generic drugs, biosimilars, animal drugs, and, most recently, OTC drugs under the FDA monograph system (itself a regulation-based system before now, with

continued reliance on regulations until the new system is set up). For each user fee act and its 5-year reauthorization, FDA sets out performance metrics and milestone in performance or goals letters to Congress. While user fees cover a significant majority of the program costs involved, the net result is there is a strain on clearance capacity as each new or amended regulation driven by a user fee reauthorization, each new guidance, and each new initiative is ultimately going through the same clearance processes that would have to be used to undertake assessments and, where indicated, full regulatory reviews of almost all existing FDA regulations. In this environment, either user fee goals will slip or regulations risk sunseting as regulatory review timelines are missed.

3. A preliminary review raises concerns with rulemaking broadly, which would be exacerbated if the rule were finalized as proposed.

For whatever reason, the process of rulemaking has slowed over the past few decades. Some of this, including the need for Office of Information and Regulatory Affairs review, is for beneficial reasons. But the fact that the process has slowed in the decades since initial passage of the Regulatory Flexibility Act points to another challenge: Adding more reviews and potential amendments to an already slow system threatens to undermine one of the goals of the proposed rule: having a regulatory system with appropriate impact. That includes lags in issuing rules the regulated community may want to advance public health.

For instance, the switch of medicines from prescription to OTC status through new drug applications (or supplemental new drug applications) has long been a mechanism to increase access to proven safe and effective medicines for Americans, with greater utilization and cost savings to the healthcare system and Americans' pocketbooks. To allow the next generation of more complex prescription-to-OTC switches, FDA has discussed allowing additional conditions of use beyond the existing Drug Facts label on an OTC package. Part of this would require a new regulation. The December 2017 unified agenda of regulatory actions targeted August 2018 for a proposed rule. Over two years later, the proposed rule has not been published for comment. (The most recent unified agenda included a December 2020 target.) Industry comments on this proposed rule will no doubt be extensive, but delays in the rulemaking process today mean CHPA and its member companies haven't had an opportunity to see the proposed rule, let alone comment. Adding a re-review of existing regulations to an already stressed process can only add to delays.

Several examples of long delays in the OTC monograph system were among the reasons we advocated for the changes in that system enacted in the CARES Act referenced above.

Adding to the challenges of an already cumbersome rulemaking process that the proposed rule would create, new questions would arise. For instance:

- If a regulation is identified for amendment, does that take precedent over proposed regulations of finalization already drafted?
- Do regulations driven by user fee authorizations get delayed? Do they get preferential treatment and, if so, does that mean a greater than 2-year extension for amended regulations will be needed?
- If a regulation sunsets because a review was not completed by the set deadline, what is the process to reissue an otherwise unchanged regulation? Must it undergo notice and comment rulemaking? Where would such cases fall in the queue?

Heavily regulated entities benefit from certainty in appropriate regulation. Our member companies need and want to understand the rules of the road. Consumers can trust the products our members provide in part because they know they are appropriately regulated. If a regulation inadvertently sunsets, the opposite occurs: Disreputable companies will be tempted to cut corners, with uncertainty at best and an unlevel playing field at worst for responsible companies. Consumer trust risks erosion.

Conclusion.

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. As the preamble to the proposed rule notes, many states have had positive experiences in requiring periodic regulation or law reviews without which a regulation or law sunsets. Further, CHPA has and will advocate for changes in select regulations. But imposing such a system for HHS and the agencies within it in the manner proposed would risk misplaced prioritization of focus by agencies within HHS; would likely lead to significant workload challenges; would exacerbate problems and backlog that already exist in the rulemaking process; and raise significant questions that require further evaluation by the regulated community that are not amenable to a 30-day comment period.

We appreciate the opportunity to submit these preliminary comments on this sweeping proposal.

Respectfully submitted,

David Spangler

David C. Spangler
Senior Vice President,
Legal, Government Affairs
& Policy

HHS sunseting rule comments-Dec2020