Q: What is a Monograph?
A: A majority of OTC medicines include well-established active ingredients that meet the legal standard of general recognition of safety and effectiveness (GRAS/E). Rather than requiring individual applications for medicines with these ingredients, so long as the manufacturer follows formulation and labeling requirements spelled out by FDA, they may market a product without pre-approval. These requirements are called monographs, with over 50 monographs based on therapeutic categories (analgesics, antacids, first aid, cough/cold, etc.)

Q: Why was Monograph reform necessary?
A: In the nearly 50 years since the OTC Monograph system was first created, the process remains incomplete and movement on unfinished items has ground to a halt. Further, there is no system in place to innovate in a timely manner, which would benefit consumers and the marketplace. Modernization was necessary to ensure the Monograph system allows for government efficiency, faster action on new information concerning safety of an ingredient, and advances in science.

Q: What are the benefits of reform?
A: The legislation modernizes the OTC Monograph system by:
1. Creating more efficiency and placing scientific decisions with scientific personnel at FDA by using administrative orders, not rulemaking, which goes through multiple layers of clearance beyond FDA.
2. Providing an accelerated pathway for safety labeling changes, reducing risk.
3. Providing an innovation pathway, including a market incentive for essential human data, bringing more choice and benefit for consumers (and for store brands, building what then later becomes a pipeline, or even a realistic opportunity for store brands to innovate).
4. Giving the public a dashboard to preview upcoming monograph work: transparency and predictability on FDA’s monograph priorities.
5. Allowing closed meetings re: monograph issues, so potential innovations and research designs can remain confidential business information until a proposed administrative order is issued.
6. Deeming Category 1 Generally Recognized as Safe and Effective (GRAS/E) ingredients in tentative final monographs - the roughly 20% of monographs still unfinished nearly 50 years into the Monograph system - final.
7. Providing FDA resources and greater efficiency to address ingredients where FDA has not yet made a GRAS/E decision as priorities dictate, while products with these ingredients remain on the market.
8. Ensuring due process through a dispute resolution and hearing process to appeal decisions.
9. Providing FDA with new resources – over $130 million over 5 years – to effectively oversee and act on OTC monograph issues.

**Q: How does the modernized Monograph system differ from the new drug application system?**
**A:** The new drug application (NDA) system (including abbreviated new drug applications) is based on individual product review and prior approval. OTC medicines formerly available only by prescription over the past 30 years come through this system, as do OTC medicines which require special controls to assure quality, such as time release. In contrast, the Monograph system was developed for well-established ingredient uses found to be “generally recognized as safe and effective” (GRAS/E). Rather than requiring individual applications for well-established ingredients, as long as manufacturers follow the formulation and labeling conditions in the monograph, they may market a product without an application.

**Q: Do you prefer an administrative order process to rulemaking?**
**A:** Yes. When an agency is setting broad policy or process requirements that affect multiple treatment categories, notice and comment rulemaking makes sense. But when FDA is making scientific and medical determinations about a specific ingredient, such as a label warning or a new dosage form, rulemaking is slow and cumbersome. Rulemaking requires multiple levels of approval that slow the process down and that takes the decision-making out of the hands of the scientific and medical experts.

**Q: How does Monograph reform impact OTC products currently on the market?**
**A:** Reform has no effect on most products already on the market since these products have already had at least an initial review by the FDA. Reform primarily affects what future products are brought to the market. For a very small number of products, manufacturers either have to reformulate or work with FDA to continue marketing.

**Q: Shouldn’t parties other than drug companies be able to initiate an administrative order request?**
**A:** The administrative order request process, which usually includes a fee, is for manufacturers to request changes to monographs, such as new labeling or the addition of a new ingredient or dose form. Other parties can use processes, such as citizen petitions, to petition FDA for changes to OTC medicines.

**Q: How do well-established safe ingredients from outside the U.S. enter the Monograph system under reform?**
**A:** A manufacturer may submit a request to FDA to add ingredients, including those from outside the U.S., to a monograph. FDA will review the request on the merits of its data to ensure a drug can be used safely and effectively under monograph conditions.
Fees

Q: Why are user fees needed?
A: As user fees have been enacted in other areas within FDA, discretionary spending for non-user fee programs within the drug center has lagged and is prioritized for otherwise unfunded public health emergencies. Combined with a slowdown in rulemaking, this means resources for OTC monograph work had been de-prioritized and neglected. Creating an efficient, modernized system requires new resources. However, user fees should complement appropriations, not replace them, and funds (not exclusive to fees) should be balanced across innovation, completing monographs, and safety.

Q: How are user fees structured?
A: Fees are based on facilities manufacturing or processing OTC monograph medicines, with contract manufacturing facilities paying 2/3 the level of facility fees of other facilities. Fees are designed to be sufficiently low to as not cause an undue burden on any one manufacturer.

Before inflation or carry-over reserve adjustments, fees are designed to generate $22 million in year #1 rising to $34 million in year #5. In addition, a manufacturer requesting an administrative order will submit either a $500,000 or $100,000 fee (inflation adjusted), depending on the specific type of monograph change being requested.

An OTC monograph drug facility is a foreign or domestic entity engaged in manufacturing or processing an OTC monograph drug in finished dosage form. Separate buildings in one location under the same local management count as a single facility. Research suppliers or testing facilities are exempt.

FDA will verify the number of OTC monograph facilities through self-identification by the end of each year.

Q: How do fees in the OTC monograph program compare to other user fee programs?
A: OTC monograph fees will be $22 - $34 million (before operating reserve or inflation adjuster) plus FDA allocating $12 million from FDA appropriations (versus approximately $8 million on monograph activities in FY2016, and $10 million in FY2018).

Scale: That's less than one-fifteenth of GDUFA II’s $494 million in FY2018 or a thirtieth the size of PDUFA VI’s $899 million in FY2018.
Appropriations v. fees, in percentages –

PDUFA: 79% from fees in FY2018
GDUFA: 78% in FY2017
Projected OMUFA: 65% in FY2021 (and 74% in FY2025)

Q: What will FDA accomplish with user fees?
A: As with other FDA user fee programs, FDA provides a goals letter from FDA to Congress outlining what it intends to accomplish by when. This goals letter provides:
- Order request timelines in years 4 and 5 (generally 17.5 months, with variations based on the type of order)
- Meeting timelines
- Dashboard – 3-year projection of FDA’s anticipated work, updated annually
- Dispute resolution timelines
- IT goals
- Hiring goals
- Guidelines on meetings, content and format, consolidated proceedings, e-submissions, CDER dispute resolution, data to be held on file for solid oral dosage forms and a paired administrative order.

Q: Why weren’t small businesses exempt from fees in the bill?
A: Fees are designed to be sufficiently low to as not cause an undue burden on any one manufacturer. And larger companies will pay more when they have multiple facilities.

If the PDUFA definition of small business was used, over half of facilities would fall out, placing an unreasonable burden on those companies remaining.

Product differentiation/Exclusivity:

Q: Why is a market incentive or exclusivity period necessary?
A: Under reform, we anticipate innovations to established ingredients that bring benefits to consumers such as easier to take or apply dosage forms (a film you could swallow without water, for instance, or a spray that provides easier coverage or application compared to an existing gel); new combinations of existing ingredients to reduce the need to use multiple medicines at the same time; adding ingredients with an established track record of safety and effectiveness to a monograph (such as ingredients with documented experience in other parts of the world), or to add new indications when backed by science to existing ingredients to provide consumers with a wider range of choices and greater competition to assure value.
Innovations such as these require investments in data, including clinical efficacy trials, safety studies or special types of consumer behavior studies to show consumers understand how to follow labeled directions.

To provide an incentive for these products to come forward, the innovating firm should get a head-start to establish their brand and raise awareness in the marketplace before others follow. Since many products are seasonal and introducing a new product takes several months (for scale-up and labeling), a period of longer than a year is needed or else an innovating firm may miss out on the period altogether.

**Q: Will exclusivity lead to increased drug costs?**

**A:** The OTC marketplace is one of rigorous competition. Even with exclusivity, consumers would continue to have other options, since therapeutic categories almost universally have multiple ingredients. Consumers have complete price transparency with OTC medicines: An individual consumer can see the price of the product on the shelf and make a conscious decision of whether they believe the product provides sufficient value to them to complete the purchase. An exclusive period on the market also provides an innovator time to encourage trial and establish a brand before competitors enter.

There is no cost to the federal government for coverage of these medicines since, with very rare exceptions, OTC medicines are not reimbursed.

**Sunscreens:**

**Q: Will Monograph reform bring new sunscreens ingredients to the U.S.?**

**A:** FDA assesses new ingredients based on their scientific merits. Under the new law, a sponsor for a pending sunscreen ingredient may remain under the existing Sunscreen Innovation Act or may elect to move to the Monograph reform system.

**Q: What happens with the anticipated rule for sunscreens?**

**A:** Under the new law, the sunscreen monograph reverts back to a 1999 sunscreen monograph plus testing requirements in a different, existing rule. Those requirements would be final. It would be up to FDA to determine if they wanted to reissue the currently pending proposed rule as a proposed administrative order.