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July 2020

# OVER-THE- COUNTER DRUGS

## Information on FDA's Regulation of Most OTC Drugs

Accessible Version

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### Information on FDA's Regulation of Most OTC Drugs

#### Why GAO Did This Study

OTC drugs prevent and treat a variety of conditions; for example, sunscreen is used to help prevent sunburn. FDA officials and stakeholders, such as industry representatives and patient and provider groups, have questioned whether the monograph process used to regulate most OTC drugs has been overly burdensome and has limited FDA's ability to quickly update and finalize monographs in response to potential safety issues for consumers. Enacted in March 2020, the CARES Act changed how FDA regulates OTC drugs.

The Sunscreen Innovation Act included a provision for GAO to review FDA's regulation of OTC drugs. This report describes, among other issues, (1) the factors that affected FDA's ability to regulate OTC drugs and (2) how FDA identified and responded to safety issues associated with these drugs.

GAO reviewed federal statutes and agency documents and interviewed FDA officials and stakeholders familiar with the monograph process. These stakeholders included representatives from the OTC drug industry, health care provider and consumer groups, and researchers.

The Department of Health and Human Services provided technical comments on this report, which GAO incorporated as appropriate.

View [GAO-20-572](#). For more information, contact John E. Dicken at (202) 512-7114 or [dickenj@gao.gov](mailto:dickenj@gao.gov).

#### What GAO Found

The Food and Drug Administration (FDA) has regulated most over-the-counter (OTC) drugs—that is, drugs available without a prescription—through the OTC monograph process. FDA has described an OTC monograph as a "rulebook" for marketing safe and effective OTC drugs, such as aspirin, cough and cold medicine, and hand sanitizer. OTC monographs established conditions—such as active ingredients, indications for use, dosage forms, and product labeling—under which an OTC drug was generally recognized as safe and effective.

According to FDA officials, before the CARES Act, which was enacted in March 2020, the agency's ability to update and finalize monographs in response to safety issues and to reflect new scientific information was limited by the rulemaking process the agency was required to follow, as well as insufficient resources. Agency officials estimated that it took at least 6 years to complete the required rulemaking process. Additionally, the agency reported it was critically under-resourced to regulate the estimated 100,000 OTC drugs marketed through the monograph process. However, the CARES Act provided for a new process to regulate these OTC drugs rather than the rulemaking process. FDA officials expect it will take less time to update and finalize requirements for OTC drugs using the new process. The CARES Act also authorized FDA to assess user fees to provide additional resources to regulate OTC drugs. Although FDA officials said this new process and user fees should improve its regulation of OTC drugs, the agency's analysis of the effect of the CARES Act is still ongoing.

FDA officials told GAO that prior to the CARES Act, they used various methods to identify and respond to safety issues related to OTC drugs. For example, to identify these issues, FDA officials said they read medical literature related to safety issues and reviewed reports submitted to the agency's adverse event reporting system. To respond to these issues, FDA took steps such as issuing drug safety communications to consumers and requesting that manufacturers make changes to a drug's labeling. For example, in 2015, two FDA advisory committees recommended that cough and cold drugs with codeine be removed from the relevant OTC monograph for use in drugs in children. In 2018, FDA also issued a drug safety communication stating the risks outweighed the benefits for the use of these drugs in children. However, FDA officials said these methods were not a substitute for rulemaking because manufacturers could legally market their OTC drugs without making requested safety changes until the rulemaking process was completed.

According to FDA officials, the new process for regulating OTC drugs included in the CARES Act could improve FDA's ability to address identified safety risks in a more timely and efficient manner in the future. The act established an expedited process to address safety issues that pose an imminent hazard to public health or to change a drug's labeling to mitigate a significant or unreasonable risk of a serious adverse event.

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### Abbreviations

FDA	Food Drug and Administration
GRASE	generally recognized as safe and effective
MUsT	maximal usage trial
OTC	over-the-counter
SPF	sun protection factor
UV	ultraviolet

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July 29, 2020

The Honorable Lamar Alexander  
Chairman  
The Honorable Patty Murray  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
United States Senate

The Honorable Frank Pallone, Jr.  
Chairman  
The Honorable Greg Walden  
Republican Leader  
Committee on Energy and Commerce  
House of Representatives

Over-the-counter (OTC) drugs play a vital role in the U.S. health care system. OTC drugs—those available to consumers without a prescription—have a variety of uses, such as sunscreen to help prevent sunburn, aspirin to relieve minor aches and pains, and hand sanitizers to help reduce bacteria when soap and water are not available. The Food and Drug Administration (FDA) has regulated most OTC drugs through the OTC monograph process, which was established in the 1970s.<sup>1</sup> FDA has described an OTC monograph as a “rulebook” for marketing safe and effective OTC drugs.<sup>2</sup> OTC monographs established conditions, such as active ingredients, indications for use, dosage forms, and product labeling, under which an OTC drug was generally recognized as safe and effective (GRASE) for use. OTC drugs that met a monograph’s requirements did not need individual preapproval from FDA to be marketed, assuming the drug complied with all other applicable

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<sup>1</sup>We use the term OTC drugs in this report to refer only to those OTC drugs marketed in the United States without an approved new drug application or abbreviated new drug application. FDA may approve an individual drug for OTC marketing through the approval of a new drug application or an abbreviated new drug application, which is used for generic drugs.

<sup>2</sup>Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, Food and Drug Administration, *Modernizing FDA’s Regulation of Over-the-Counter Drugs*, testimony before the Subcommittee on Health, House Energy and Commerce Committee, 115<sup>th</sup> Cong., 1<sup>st</sup> sess., Sept. 13, 2017.

regulations. The CARES Act, enacted in March 2020, made significant changes to the monograph process and the regulation of OTC drugs.<sup>3</sup>

FDA officials and stakeholders, such as industry representatives, researchers, and patient and provider groups, have questioned whether the monograph process has been overly burdensome and, therefore, has limited FDA's ability to quickly update and finalize OTC monographs in response to safety issues or to allow additional products to be marketed. In particular, stakeholders concerned about the risk of skin cancer expressed frustration that although applications had been filed with FDA for sunscreen active ingredients available in other countries, these active ingredients were not available in the United States through the monograph process. In response to concerns about the sunscreen monograph, the Sunscreen Innovation Act, enacted in 2014, changed FDA's process for reviewing applications for sunscreen active ingredients not yet on the U.S. market.<sup>4</sup> This act also required FDA to issue guidance documents related to sunscreen and to regularly report to Congress on the agency's implementation of these provisions, among other things. The CARES Act further changed the regulatory process for sunscreen.

The Sunscreen Innovation Act also included a provision for us to review FDA's regulation of sunscreen and other OTC drugs.<sup>5</sup> This report describes

1. the factors that affected FDA's ability to regulate OTC drugs,
2. how FDA identified and responded to safety issues associated with OTC drugs, and
3. the status of FDA's efforts to implement the activities required by the Sunscreen Innovation Act.

To describe the factors that affected FDA's ability to regulate OTC drugs, we reviewed FDA documents, such as congressional testimony, budget

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<sup>3</sup>Pub. L. No. 116-136, tit. III, subtit. F, 134 Stat. 281, 435-69 (2020).

<sup>4</sup>Pub. L. No. 113-195, 128 Stat. 2035 (2014) (codified, as amended, at 21 U.S.C. § 360fff et seq.).

<sup>5</sup>Pub. L. No. 113-195, § 4(b), 128 Stat. 2035, 2049-50 (2014). The act included provisions for two GAO reports. Our first report examined FDA's review of applications for sunscreen active ingredients under the OTC monograph process. See GAO, *Sunscreen: FDA Reviewed Applications for Additional Active Ingredients and Determined More Data Needed*, [GAO-18-61](#) (Washington, D.C.: Nov. 15, 2017).

justifications, and reports to Congress. Our review focused on FDA regulation of OTC drugs marketed in the United States without an approved new drug application or abbreviated new drug application.<sup>6</sup> We also reviewed FDA information on the status of 26 original OTC monograph categories, as of December 2019. We reviewed provisions of the CARES Act affecting FDA's regulation of OTC drugs.<sup>7</sup> We interviewed FDA officials and eight stakeholders familiar with the monograph process about the main factors affecting the agency's ability to regulate OTC drugs, including updating and finalizing monographs. These stakeholders represented industry, health care provider and consumer groups, and researchers.<sup>8</sup>

To describe how FDA identified and responded to safety issues associated with OTC drugs, we reviewed FDA documentation of its response to specific safety issues. We also reviewed documentation associated with select OTC drug safety issues, including drug safety communications and information from drug advisory committee meetings from 2011 to 2018. We interviewed FDA officials responsible for the regulation of OTC drugs about their processes for identifying and

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<sup>6</sup>We use the term OTC drugs in this report to refer to OTC drugs marketed in the United States without an approved new drug application or an abbreviated new drug application. Our review did not include FDA regulation of OTC drugs marketed through FDA approval of a new drug application or an abbreviated new drug application, which is used for generic drugs. Under the new drug application process, FDA must determine that an individual drug is safe and effective for its intended use before that drug can be marketed in the United States. Under the abbreviated new drug application process, the applicant relies on FDA's previous finding of safety and effectiveness for an already approved drug, typically a brand name drug. In addition, some drugs initially approved for the U.S. market as prescription drugs through new drug applications were subsequently approved for OTC use (e.g., Voltaren for arthritis pain and Pataday to treat itchy eyes due to allergies); these OTC drugs are also outside the scope of our review.

<sup>7</sup>As FDA has not yet issued guidance or regulations pertaining to those provisions of the act that affect FDA's regulation of OTC drugs, our description of the act in this report does not necessarily reflect FDA's interpretation of the law. We did not evaluate FDA's implementation of the CARES Act. Section 3851(b) of the CARES Act includes a provision for us to report on the changes to regulation of OTC drugs within 4 years.

<sup>8</sup>Specifically, we interviewed representatives from the American Academy of Dermatology Association, the American Academy of Pediatrics, the Consumer Healthcare Products Association, the Environmental Working Group, the Personal Care Products Council, the Pew Charitable Trusts, the Public Access to SunScreens Coalition, and the Skin Cancer Foundation. We selected stakeholders that met at least two of the three following criteria: (1) they were interviewed as part of GAO's first report required under the Sunscreen Innovation Act, [GAO-18-61](#); (2) they submitted comments on FDA's February 2019 proposed rule for the sunscreen monograph; and (3) they submitted comments on potential user fees for OTC drugs.

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responding to safety issues and about which safety issues related to OTC drugs they considered their highest priorities.

To describe the status of FDA's efforts to implement the activities required by the Sunscreen Innovation Act, we reviewed the Sunscreen Innovation Act and relevant provisions in the CARES Act. We reviewed FDA's documentation of its actions related to the Sunscreen Innovation Act, including those taken since our 2017 GAO report on this topic, and interviewed FDA officials.<sup>9</sup>

We conducted this performance audit from July 2019 to July 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

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### FDA Regulation of OTC Drugs

Under the Federal Food, Drug, and Cosmetic Act, FDA—an agency within the Department of Health and Human Services—is responsible for ensuring that drugs marketed in the United States are safe and effective, including OTC drugs.<sup>10</sup> Most OTC drugs have been marketed by following the OTC monograph process. Under this process, FDA determined the conditions under which OTC drugs were generally recognized as safe and effective (GRASE). Until March 2020, the specific conditions under which OTC drugs could be marketed in the United States, such as the active ingredients used, the dosage forms (e.g., tablet or cream), and the product labeling, were published in an FDA regulation, known as an OTC monograph. OTC drugs that met a monograph's requirements did not need individual preapproval from FDA to be marketed, assuming compliance with applicable regulations. In 2019, there were an estimated

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<sup>9</sup>[GAO-18-61](#).

<sup>10</sup>See 21 U.S.C. §§ 321(p)(1) and 393.



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100,000 drugs marketed under the OTC monograph process, according to FDA.<sup>11</sup>

FDA created the OTC monograph process in 1972 and organized the thousands of different OTC drugs marketed at the time into 26 OTC monograph categories (see text box).<sup>12</sup> Under this process, FDA updated and finalized monographs through rulemaking, which involved multiple steps. In general, after review by federal officials at the Department of Health and Human Services and the Office of Management and Budget, FDA would publish a proposed monograph and a tentative final monograph in the Federal Register, both of which were available for public comment. After reviewing these public comments, FDA would publish a final monograph that included the conditions under which OTC drugs were considered GRASE. The final monographs were published in the Code of Federal Regulations.<sup>13</sup>

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<sup>11</sup>FDA also estimated that collectively, the OTC monographs included 800 active ingredients for over 1,400 different uses, as of December 2019.

<sup>12</sup>According to FDA, the agency has not published any updates to the list of 26 original monograph categories established in 1972. However, the agency noted these categories have changed to reflect new scientific information and may have split into separate categories or been combined as needed to best reflect current use. For example, analgesics split into internal analgesics and external analgesics, and sedatives and sleep aids split into daytime sedatives and sleep aids.

Of the 26 original OTC monograph categories, two categories—hematinics (e.g., iron supplements) and vitamin-mineral products—were subsequently removed from the OTC monograph system. Despite these removals, we refer to these 26 original OTC monograph categories because this was the only published list available at the time of our review.

<sup>13</sup>See 21 C.F.R. Parts 328-358 (2019). At the time of our review, some monographs were not yet finalized or had not yet gone into effect. FDA generally did not object to the marketing of OTC drugs that followed the conditions proposed in tentative final monographs unless failure to take action against marketing of the drugs posed a potential hazard to the consumer.

**Original 26 Over-the-Counter Monograph Categories**

- Antacids
- Laxatives
- Antidiarrheal products
- Emetics (e.g., activated charcoal)
- Antiemetics (e.g., antinausea medicine)
- Antiperspirants
- Sunburn prevention/treatment products
- Vitamin-mineral products
- Antimicrobial products
- Dandruff products
- Oral hygiene aids
- Hemorrhoidal products
- Hematinics (e.g., iron supplements)
- Bronchodilator and antiasthmatic products
- Analgesics (e.g., pain medicine)
- Sedatives and sleep aids
- Stimulants
- Antitussives (e.g., cough suppressants)
- Allergy treatment products
- Cold remedies
- Antirheumatic products
- Ophthalmic products (e.g., eye drops)
- Contraceptive products
- Miscellaneous dermatologic products
- Dentifrices and dental products
- Miscellaneous (all other OTC drugs not falling within one of the above categories)

Source: 37 Fed. Reg. 9,464, 9,475 (May 11, 1972) (codified at 21 C.F.R. § 330.5 (2019)) | GAO 20 572

The CARES Act, enacted in March 2020, changed the process for regulating OTC drugs. For example, the act established procedures for FDA to issue administrative orders that describe the conditions under

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which OTC drugs are GRASE, rather than rulemaking.<sup>14</sup> In addition, the act authorized FDA to assess user fees to provide the agency with additional resources to regulate OTC drugs.<sup>15</sup>

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## FDA Regulation of OTC Sunscreens

Sunscreens are intended to help prevent sunburn and, in some cases, decrease the risk of skin cancer and early skin aging caused by the sun. As a result, sunscreens are considered drugs under the Federal Food, Drug, and Cosmetic Act, and in the United States, most sunscreens have been marketed under the OTC monograph process.<sup>16</sup>

FDA issued a final sunscreen monograph in 1999, but in 2001, before it went into effect, FDA imposed a stay on the monograph. FDA imposed the stay because the agency intended to propose requirements related to formulation, labeling, and testing for ultraviolet A (UVA) and ultraviolet B (UVB) radiation protection.<sup>17</sup> In May 2018, FDA issued guidance stating that while the sunscreen monograph was stayed, FDA did not object to

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<sup>14</sup>CARES Act, § 3851, 134 Stat. at 437-47 (codified at 21 U.S.C. § 355h(b)). Administrative orders are not subject to the same process as rulemaking, which involves review by the Office of Management and Budget. According to FDA, the time frames for administrative orders are substantially shorter than those for rulemaking, in part, because with administrative orders, industry stakeholders can submit information directly to FDA through the agency's website, which FDA can immediately access. The act also requires electronic submission of documentation related to FDA's regulation of OTC drugs. CARES Act, § 3851, 134 Stat. at 450 (codified at 21 U.S.C. § 355h(j)). Prior to the act, stakeholders often provided such documentation in paper form, according to FDA.

<sup>15</sup>CARES Act, §§ 3861-62, 134 Stat. at 458-69 (codified at 21 U.S.C. §§ 379j-71 to 379j-73). FDA also collects user fees from sponsors with respect to prescription drugs, medical devices, generic drugs, tobacco products, and biosimilar biologics, which are used to support the agency's review of applications for these types of products and for other related activities.

<sup>16</sup>The Federal Food, Drug, and Cosmetic Act defines a drug to include, among other things, "articles intended for use in the diagnosis, cure, mitigation, or prevention of disease in man or other animals." 21 U.S.C. § 321(g)(1).

<sup>17</sup>Sunscreens labeled as "broad spectrum" have been tested for both UVA and UVB protection. UVA radiation penetrates the skin more deeply and can cause skin cancer and other skin damage. UVB radiation can cause sunburn and result in skin damage. See app. I for a timeline of selected actions related to the sunscreen monograph.

the marketing of sunscreens without an approved application, as long as these sunscreens met certain standards outlined in guidance.<sup>18</sup>

The Sunscreen Innovation Act, enacted in 2014, required FDA to finalize and put into effect a sunscreen monograph by November 26, 2019, and established time frames for FDA's review of sunscreen active ingredients not listed in the stayed 1999 final monograph, among other things.<sup>19</sup> The Sunscreen Innovation Act also changed the process FDA uses to issue a GRASE determination for additional active ingredients and other conditions, from rulemaking to administrative orders. In February 2019, FDA published a proposed rule that, if finalized, would have put into effect a final sunscreen monograph.<sup>20</sup>

The CARES Act eliminated the requirement for FDA to finalize the sunscreen monograph by November 26, 2019, which FDA had not done when the act was enacted in March 2020. The act also provided that sunscreens will be considered GRASE if they meet the conditions in the newly deemed administrative order for sunscreen established in the act. As of June 2020, FDA officials told us that the agency has not yet completed its review of those provisions in the CARES Act that affect FDA's regulation of OTC drugs, and therefore, officials could not comment on the specific requirements that will be included in the newly deemed administrative order.<sup>21</sup> The CARES Act also requires FDA to issue a proposal to revise the sunscreen order no later than 18 months after enactment (by September 27, 2021), with an effective date of at least 1 year after publication of the final order.<sup>22</sup>

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## FDA Officials Reported the Rulemaking Process and Resource Constraints Have

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<sup>18</sup>Food and Drug Administration, *Enforcement Policy—OTC Sunscreen Drug Products Marketed Without an Approved Application, Guidance for Industry*, (Silver Spring, Md.: May 2018), accessed Aug. 7, 2019, <https://www.fda.gov/media/80403/download>.

<sup>19</sup>See app. II for selected requirements in the Sunscreen Innovation Act and FDA's actions to implement these requirements.

<sup>20</sup>See 84 Fed. Reg. 6,204 (Feb. 26, 2019).

<sup>21</sup>FDA officials said the agency did not have a plan or time frame for publishing those specific requirements of the deemed administrative order for sunscreen as of June 2020.

<sup>22</sup>CARES Act, § 3854(c), 134 Stat. at 456-57.

## Limited Their Ability to Regulate OTC Drugs, but New Law Could Help Address These Factors

Before the CARES Act was enacted, FDA officials reported that two main factors—the rulemaking process and resource constraints—limited the agency’s ability to regulate OTC drugs, including responding to safety issues in a timely manner.<sup>23</sup> FDA officials noted the following:

- **Burdensome rulemaking process to update and finalize OTC monographs.** FDA officials said the OTC monograph process was burdensome and limited the agency’s ability to update and finalize monographs based on, for example, new scientific information. Until March 2020, FDA was required to make all changes to OTC monographs, including those to address urgent safety issues, through rulemaking. FDA officials told us that the multiple steps required of rulemaking could take a minimum of 6 years to complete. According to information FDA provided us, seven of the 26 original OTC monograph categories had no final monograph in effect, including the monograph for sunscreen, as of December 2019. For 17 of the 26 original OTC monograph categories that had a final monograph in effect, FDA told us that 12 categories had proposed changes associated with them.<sup>24</sup>
- **Resource constraints.** According to FDA officials, the agency has not had sufficient resources to adequately regulate OTC drugs. In 2020, FDA reported that FDA received very few resources that it

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<sup>23</sup>Food and Drug Administration, *Modernizing FDA’s Regulation of Over-the-Counter Drugs*, testimony.

<sup>24</sup>These proposed changes included, for example, updating the OTC monographs to add new active ingredients (e.g., for nighttime sleep aids in the final monograph for sedatives and sleep aids) or updating the labeling to add a new indication for use (e.g., proposed changes related to hangover symptom relief in the final monograph for stimulants).

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could allocate to reviewing monographs; further, the agency reported it was critically understaffed in this area.<sup>25</sup>

The CARES Act included provisions that could help address these two factors.

- **Established an administrative order process.** The CARES Act established a process for FDA to regulate OTC drugs with administrative orders rather than through rulemaking, a change supported by five of the eight stakeholders we interviewed.<sup>26</sup> According to FDA officials, administrative orders could improve FDA's efficiency and timeliness in addressing safety issues and in updating and finalizing requirements for OTC drugs. The officials explained that while rulemaking can take a minimum of 6 years to complete, using administrative orders could take less than 2 years. FDA reported the new administrative order process is intended to reduce the time needed for action related to OTC drugs while still maintaining public comment as well as FDA's standards for safety and efficacy.
- **Provided additional resources to FDA by authorizing user fees for OTC drugs.** The CARES Act authorized FDA to assess user fees from OTC drug manufacturers to provide resources for regulating OTC drugs, beginning in fiscal year 2021.<sup>27</sup> Seven of the eight

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<sup>25</sup>FDA reported that when the Sunscreen Innovation Act was enacted in 2014, appropriations funded 18 full-time-equivalent employees for all review work for OTC monographs. Food and Drug Administration, *Report to the U.S. Senate Committee on Health, Education, Labor, and Pensions and the U.S. House of Representatives Committee on Energy and Commerce, Report in Response to Section 586G of the Federal Food, Drug, and Cosmetic Act (as Added by the Sunscreen Innovation Act (P.L. 113-195))* (Silver Spring, Md.: May 2020).

<sup>26</sup>CARES Act, § 3851, 134 Stat. at 437-47 (codified at 21 U.S.C. § 355h(b)). Of the remaining three stakeholders, two did not comment on the role of rulemaking, and one stakeholder did not have concerns about the rulemaking process.

<sup>27</sup>Section 3862 of the CARES Act established two types of OTC user fees effective beginning in fiscal year 2021: (1) annual facility fees and (2) fees for administrative order requests. The CARES Act authorizes FDA to collect approximately \$22 million in facility fees for fiscal year 2021, and either \$100,000 or \$500,000 administrative order request fees, depending on the type of order request. See 21 U.S.C. § 379j-72. FDA may only collect and obligate such fees in the amount provided in advance in appropriations acts. As of May 2020, legislation providing for an appropriation for these fees had not yet been enacted.

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stakeholders we interviewed cited the need for additional FDA resources for the agency to regulate OTC drugs.<sup>28</sup>

FDA officials said it will take time before FDA is able to fully realize any benefits that might result from changes in the CARES Act.<sup>29</sup> For example, according to FDA, it generally takes 2 years for any newly hired FDA staff to complete training and to acquire the knowledge and experience needed to be fully effective in reviewing scientific information related to the regulation of OTC drugs.<sup>30</sup> FDA officials and stakeholders said these changes should improve FDA's ability to regulate OTC drugs, though the agency is still analyzing the CARES Act.

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## FDA Has Used Various Methods to Identify and Respond to Safety Issues

FDA has identified potential safety issues related to OTC drugs in various ways, including by reading reports in published journals and through submissions to FDA's adverse event reporting system, according to

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<sup>28</sup>The remaining stakeholder did not have comments on user fees for OTC drugs.

In addition to the two main factors of the rulemaking process and resource constraints, FDA officials noted the lack of an electronic system to receive information related to OTC drugs had affected their ability to efficiently review the information submitted to the agency. Two of the eight stakeholders we interviewed specifically noted the need for FDA to require standardized submissions to facilitate its review. Section 3851 of the CARES Act required electronic submission of documentation related to FDA's regulation of OTC drugs. See 21 U.S.C. § 355h(j). FDA officials said they expect it will take several years to create the infrastructure needed to be able to receive electronic submissions.

<sup>29</sup>The agency anticipates that certain timelines and performance goals for reviewing requests for administrative orders will not apply during the first 3 years of FDA's implementation of its user fee program for OTC drugs. See Food and Drug Administration, *Potential Over-the-Counter Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2018-2022*, accessed Sept. 17, 2019, <https://www.fda.gov/media/106407/download>. The goals proposed in this document are the product of FDA's discussions with regulated industry on potential user fees for OTC drugs and input from public stakeholders.

<sup>30</sup>FDA's document on a user-fee program for OTC drugs includes targets for when employees are hired and begin working at FDA; these targets are 30, 24, and 23 full-time equivalent staff in each of the first 3 fiscal years, respectively. Food and Drug Administration, *Over-the-Counter Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2018-2022*.

agency officials.<sup>31</sup> FDA officials said that because of the differences in information and regulatory actions available to them, the agency's methods for identifying and responding to safety issues have varied depending on the drug and potential issue. In some cases, FDA officials stated they have identified safety issues through required reporting for a prescription drug that may also indicate an issue for an OTC drug that includes the same active ingredient.

FDA's system for tracking safety issues categorizes potential safety issues based on severity.<sup>32</sup> Specifically, the agency's current system, effective April 30, 2020, classifies potential safety issues as either a potential risk or an important potential risk, which includes a 12-month time frame for the evaluation of a potential risk and a 6-month time frame for the evaluation of an important potential risk.

FDA has used various methods to respond to identified safety issues related to OTC drugs in lieu of updating or finalizing a monograph. These methods included consulting with the agency's drug advisory committees and issuing drug safety communications. FDA has also requested that manufacturers voluntarily change their marketing of an OTC drug, such as updating the product labeling or halting the sale of certain OTC drugs that may pose a safety issue. Prior to the CARES Act, FDA officials told us they used these other methods to more quickly respond to safety issues because updating and finalizing a monograph could take years. According to FDA, these methods did not serve as a substitute for finalizing a monograph. FDA noted that it could not require safety changes without updating and finalizing the relevant monograph, so any actions taken by manufacturers to address safety issues for OTC drugs were voluntary. Examples of FDA's use of these methods are described below:

- **Consulting FDA drug advisory committees.** In 2015, FDA consulted two of its drug advisory committees—the Pulmonary-Allergy Drugs Advisory Committee and the Drug Safety and Risk

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<sup>31</sup>FDA officials stated that they may learn of adverse events through voluntary or mandatory reporting of adverse drug events in the FDA Adverse Events Reporting System, for example. The FDA Adverse Events Reporting System is a publicly available database featuring reports of adverse events from health care providers, consumers, and drug manufacturers.

<sup>32</sup>Food and Drug Administration, Office of the Center Director, *Manual of Policies and Procedures 4121.3: Collaborative Identification, Evaluation, and Resolution of a Newly Identified Safety Signal (NISS)* (Silver Spring, Md.: 2020), accessed May 12, 2020, <https://www.fda.gov/media/137475/download>.



Management Advisory Committee—for recommendations on actions to take in response to identified safety issues associated with codeine in cough medicine for children. The committees recommended cough medicine with codeine be removed from the antitussive (cough relief) section of the relevant OTC monograph for use in consumers younger than 18 years of age.

- **Issuing drug safety communications.** FDA has issued drug safety communications, which are posted publicly to FDA’s website, to consumers.<sup>33</sup> Drug safety communications can include a description of the safety issue identified, a summary of data related to the risk, and recommended actions for consumers to take. For example, in June 2016, FDA issued a drug safety communication warning consumers of the risk of serious bleeding when taking OTC drugs containing aspirin to treat conditions such as heartburn and indigestion.<sup>34</sup> The drug safety communication noted certain consumer groups, such as those aged 60 years or older and consumers with a history of stomach ulcers or bleeding problems may be at increased risk of serious bleeding. The drug safety communication also recommended consumers carefully read the Drug Facts labeling and consider whether to choose a product without aspirin to treat their symptoms.
- **Requesting that manufacturers make voluntary changes to the OTC drug’s labeling.** In some cases, FDA has requested that manufacturers make voluntary changes to an OTC drug’s labeling, even though the changes are not yet reflected in a final monograph. For example, upon learning of skin reactions in people with an acetaminophen allergy, FDA determined that OTC drugs with acetaminophen as an active ingredient should include a warning about this risk on the labeling. However, officials said that because this new labeling provision was not reflected in a final monograph, adding this warning to an OTC drug with acetaminophen would be considered misbranding. To encourage manufacturers to add the warning, FDA published guidance to industry noting that it would

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<sup>33</sup>Food and Drug Administration, *Drug Safety Communications*, accessed November 6, 2019, <https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications>.

<sup>34</sup>Food and Drug Administration, *FDA Drug Safety Communication: FDA warns about serious bleeding risk with over-the-counter antacid products containing aspirin*, (Silver Spring, Md.: June 2016), accessed April 8, 2020, <https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-warns-about-serious-bleeding-risk-over-counter-antacid-products>.

exercise its enforcement discretion and would not take action against manufacturers for misbranding if they added the warning.<sup>35</sup>

- **Requesting that manufacturers remove an OTC drug from the market.** In other cases, FDA has requested that manufacturers voluntarily remove an OTC drug from the market. For example, in May 2018, FDA asked manufacturers to remove from the market OTC oral health care drugs containing benzocaine intended for the temporary relief of sore gums due to teething or for use by children under age 2.<sup>36</sup> FDA officials said that as a result of the agency's actions, certain OTC drugs, such as those containing benzocaine to treat teething pain in infants, are no longer available.

In some cases, FDA has used multiple methods to address an identified safety issue. For example, to address concerns with codeine in cough medicine for children, FDA consulted two of its advisory committees and published drug safety communications about the issue (see text box).

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<sup>35</sup>Food and Drug Administration, *Recommended Warning for Over-the-Counter Acetaminophen-Containing Drug Products and Labeling Statements Regarding Serious Skin Reactions, Guidance for Industry* (Silver Spring, Md.: Jan. 2017), accessed on May 12, 2020 at <https://www.fda.gov/files/drugs/published/Recommended-Warning-for-Over-the-Counter-Acetaminophen-Containing-Drug-Products-and-Labeling-Statements-Regarding-Serious-Skin-Reactions.pdf>.

<sup>36</sup>According to FDA officials, drugs containing benzocaine may cause methemoglobinemia, a condition that reduces the amount of oxygen carried in the blood. Symptoms of the condition include gray or blue colored skin, lips, and nail beds; shortness of breath; fatigue; lightheadedness; and rapid heart rate, and in some cases, especially in children under the age of 2, it can result in adverse events, including death.

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**Example of FDA Response to an OTC Safety Issue: FDA Actions Taken Related to Cough Medicine with Codeine for Children**

**Safety Issue:** According to Food and Drug Administration (FDA) officials, codeine works by suppressing the brain's functions related to pain and breathing, and in some people, codeine is metabolized in a way that results in additional brain suppression. The officials said this risk is greater in children.

**Actions taken:** On December 10, 2015, two of FDA's advisory committees met to discuss the safety issues related to codeine, and the majority of members recommended that codeine be removed from the antitussive section of the relevant over-the-counter (OTC) monograph for children younger than 18 years of age. FDA published drug safety communications related to this issue, including in January 2018, a drug safety communication noting that, for cough and cold medicine with codeine, "the risks of these medicines outweigh their benefits in children younger than 18." FDA testified in 2017 that although these non-rulemaking approaches have been helpful as alternative ways to effect safety labeling changes and to notify consumers of safety risks, these approaches were far from optimal because they did not result in changing the relevant OTC monograph to reflect the new safety labeling. The CARES Act enacted in March 2020, requires FDA to annually report on the agency's progress in evaluating and revising the cough and cold monograph with respect to children under the age of 6.

Source: GAO summary of FDA information and the CARES Act, Pub. L. No. 116-136, § 3855, 134 Stat. 281, 457-58 (2020) | GAO-20-572

FDA officials expect the changes to the OTC monograph process enacted in the CARES Act will mitigate some of the issues the agency identified related to updating and finalizing monographs to address safety issues. The agency's plan for implementing the new user fee program for OTC drugs includes time frames and performance goals for issuing administrative orders—either at a manufacturer's request or through FDA's own initiative.<sup>37</sup> In addition, the CARES Act established an expedited process to address safety issues that pose an imminent hazard to public health or to change a drug's labeling to mitigate the risk of a serious adverse event.<sup>38</sup>

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<sup>37</sup>Food and Drug Administration, *Over-the-Counter Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2018-2022*.

<sup>38</sup>If the Secretary of Health and Human Services determines that an OTC drug poses an imminent hazard to public health, the Secretary may issue an interim final administrative order with a detailed statement of the reasons for the order. With respect to safety labeling changes, if the agency determines that a change in the labeling of an OTC drug is reasonably expected to mitigate a significant or unreasonable risk of a serious adverse event, FDA may issue an interim final administrative order to require such change. In both cases, the agency must make reasonable efforts to notify affected sponsors not later than 48 hours before issuance of the order and must provide for a 45-day public comment period. See 21 U.S.C. § 355h(b)(4).

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## FDA Implemented Requirements of the Sunscreen Innovation Act

FDA implemented requirements of the Sunscreen Innovation Act, including issuing reports to Congress on various performance metrics.<sup>39</sup> In 2017, we reported that FDA implemented nearly all of the activities required by the Sunscreen Innovation Act, including reviewing applications for new sunscreen active ingredients (not currently marketed in the United States) within mandated time frames.<sup>40</sup> Since then, FDA implemented the act's requirement that it issue additional reports to Congress in 2018 and 2020.<sup>41</sup> The agency did not finalize and put into effect a sunscreen monograph by November 26, 2019, as required by the

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<sup>39</sup>These reports included information on performance metrics such as the total number of requests for new active ingredients submitted, pending, or completed under the provisions of the Sunscreen Innovation Act. See appendix II for information on selected Sunscreen Innovation Act requirements and the status of FDA's completion of these requirements.

<sup>40</sup>GAO-18-61. As of March 2020, the eight applications for sunscreen active ingredients that were pending at the time of our 2017 report remained pending after FDA requested safety and effectiveness data to support a GRASE determination, according to FDA officials. Section 3854(d) of the CARES Act allows manufacturers with applications for sunscreen active ingredients that were pending at the time of enactment to continue through the review process established under the Sunscreen Innovation Act or to opt for a new review process established in the CARES Act.

In 2017, we reported that the process for sponsors of applications for new sunscreen active ingredients to request the Office of the Commissioner to issue GRASE determinations had not been used because FDA had met its required time frames for reviewing and initially responding to these applications. As of May 2020, FDA had met all its required time frames for responding to applications, so this process had still not been used. Similarly, while the Sunscreen Innovation Act included provisions for optional advisory committee meetings, as of May 2020, FDA officials reported it had not been necessary to convene a Nonprescription Drugs Advisory Committee meeting to discuss a sunscreen active ingredient.

<sup>41</sup>Food and Drug Administration, *Report to the Committee on Health, Education, Labor, and Pensions, U.S. Senate, and the Committee on Energy and Commerce, U.S. House of Representatives, Report in Response to the Sunscreen Innovation Act (P.L. 113-195) Section 586G*, accessed July 11, 2019 at <https://www.fda.gov/media/113316/download> and Food and Drug Administration, *Report to the Committee on Health, Education, Labor, and Pensions, U.S. Senate, and the Committee on Energy and Commerce, U.S. House of Representatives, Report in Response to the Sunscreen Innovation Act (P.L. 113-195) Section 586G*, accessed July 1, 2020 at <https://www.fda.gov/media/138616/download>.

Sunscreen Innovation Act; however, the CARES Act eliminated this requirement in March 2020.<sup>42</sup>

According to FDA officials, the agency did not issue and put into effect a final sunscreen monograph by the November 2019 date required in the Sunscreen Innovation Act because the agency needed to review the nearly 15,000 comments it received on the proposed sunscreen monograph it issued in February 2019.<sup>43</sup> FDA officials said while some comments were similar in nature—such as those expressing concerns about requirements to conduct animal testing or potential damage to coral reefs from sunscreen active ingredients—about 1,100 comments were unique. The officials said more than 100 comments included extensive attachments, such as studies or technical comments.

Among the comments FDA received, many were in response to the types of data and testing the agency believes it needs to review in order to determine whether a sunscreen active ingredient was GRASE.<sup>44</sup> For example, FDA generally requested data from maximal usage trials (MUsT) on the effect of maximal use on absorption into the body and

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<sup>42</sup>CARES Act § 3854(b)(5), 134 Stat. at 456. The CARES Act provided that sunscreens will be considered GRASE if they meet the conditions in the newly deemed administrative order for sunscreen established by the act. As of June 2020, FDA officials told us that the agency has not yet completed its review of those provisions in the CARES Act that affect FDA's regulation of OTC drugs, and, therefore, officials could not comment on the specific requirements that will be included in the newly deemed administrative order. FDA officials said the agency did not have a plan or time frame for publishing those specific requirements of the deemed administrative order for sunscreen as of June 2020.

<sup>43</sup>FDA published a proposed monograph in the Federal Register describing the conditions under which sunscreens would be recognized as GRASE, among other things. See 84 Fed. Reg. 6,204 (Feb. 26, 2019). The proposed monograph also addressed dosage forms, broad-spectrum requirements, labeling, and sun protection factor as well as sunscreen-insect repellent combination products.

<sup>44</sup>FDA proposed that, of the 16 active ingredients on the sunscreen monograph, two were GRASE, two were not GRASE, and 12 had insufficient data to determine that the active ingredients were GRASE.

studies on the potential for developing cancer.<sup>45</sup> Five of the eight stakeholders we interviewed expressed concerns about MUsTs as a possible testing requirement. For example, two stakeholders questioned FDA's emphasis on MUsTs as opposed to other types of absorption testing used in other countries.<sup>46</sup> Stakeholders we contacted also expressed concerns about the tests FDA had proposed for studying the development of cancer, which they said require animal testing. Two stakeholders said animal testing was a concern because some sunscreen manufacturers had made commitments that they would not conduct this type of testing. In addition, the two stakeholders noted that in some countries, sunscreen is marketed as a cosmetic instead of a drug, and certain countries have banned animal testing for cosmetics.

In contrast with the views of stakeholders, FDA has highlighted the importance of the information obtained from a MUsT. In the 2019 proposed monograph, FDA proposed that additional safety data are needed for 12 sunscreen active ingredients included in the stayed 1999 sunscreen monograph so the agency can evaluate them in light of changed conditions over the last two decades.<sup>47</sup> For example, FDA describes how the amount and frequency of sunscreen usage has increased over time and how scientific understanding and safety evaluation methods for these products have advanced since sunscreens were originally evaluated. FDA also notes that a growing body of data in

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<sup>45</sup>A MUsT is a type of human pharmacokinetic study that is designed to capture the effect of maximal use of the drug on absorption of an active ingredient into the body. According to FDA officials, this test helps to determine the potential effect of the long-term use of an active ingredient. The test measures the amount of the ingredient that is absorbed through the skin and into the bloodstream, when used in the highest concentration for which a generally recognized as safe and effective determination is sought and on the upper limit of skin surface area on which the ingredient would be applied. For a sunscreen active ingredient, FDA recommends that the MUsT be conducted with a minimum of four formulations using the active ingredient on at least 75 percent of the body surface area. See Food and Drug Administration, *Maximal Usage Trials for Topically Applied Active Ingredients Being Considered for Inclusion in an Over-The-Counter Monograph: Study Elements and Considerations, Guidance for Industry*, (Silver Spring, Md.: May 2019), accessed September 12, 2019, <https://www.fda.gov/media/125080/download>.

<sup>46</sup>Additionally, three stakeholders questioned FDA's proposed threshold for the level of absorption of an ingredient in a MUsT. According to FDA, this threshold would lead the agency to conclude additional toxicology studies—studies that assess potential adverse effects if the active ingredients are absorbed into the blood stream—would be needed to fully assess the safety of an active ingredient for use in sunscreens. Stakeholder comments about the MUsT and other tests were similar to comments we reported from stakeholders in our prior Sunscreen Innovation Act report, [GAO-18-61](#).

<sup>47</sup>84 Fed. Reg. 6,204, 6,205 (Feb. 26, 2019).

recent years has suggested the absorption of some sunscreen active ingredients through the skin is greater than previously thought.<sup>48</sup> According to FDA, these data on absorption may raise previously unevaluated safety concerns, including the potential for reproductive, developmental, or cancer-causing effects. For those reasons, in its proposed monograph, FDA states it expects data from a MUSt will be needed to support an adequate assessment of safety for most sunscreen active ingredients. FDA officials said they are still evaluating how the 2019 proposed monograph and the comments FDA received on it will inform the agency's efforts to implement the provisions of the CARES Act related to its regulation of OTC sunscreen.

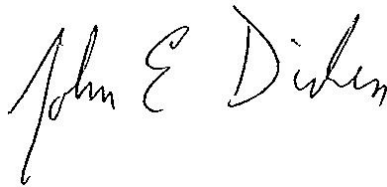
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## Agency Comments

We provide a draft of this product to the Department of Health and Human Services for its review and comment. The Department provided technical comments, which we incorporated as appropriated.

We are sending copies of this report to the appropriate congressional committees and the FDA Commissioner. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or [dickenj@gao.gov](mailto:dickenj@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.



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<sup>48</sup>M.K. Matta, R. Zusterzeel, N.R. Pilli, et al, "Effect of Sunscreen Application Under Maximal Use Conditions on Plasma Concentration of Sunscreen Active Ingredients: A Randomized Clinical Trial," *Journal of the American Medical Association*, vol. 321, no. 21 (2019): p. 2082-2091 and M.K. Matta, J. Florian, R. Zusterzeel, et al, "Effect of Sunscreen Application on Plasma Concentration of Sunscreen Active Ingredients: A Randomized Clinical Trial," *Journal of the American Medical Association*, vol. 323, no. 3 (2020): p. 256-267.

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Letter

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John E. Dicken  
Director, Health Care



# Appendix I: Timeline of Selected Actions Related to the Sunscreen Monograph

**Table 1: Timeline of Selected Actions Related to the Sunscreen Monograph, as of March 2020**

Date	Action
December 1972	The Food and Drug Administration (FDA) requested information, including safety and effectiveness data, on all active ingredients used in sunscreen products. (37 Fed. Reg. 26,456)
August 1978	FDA published a proposed monograph for sunscreen products containing the recommendations from an advisory panel that would classify 21 active ingredients as generally recognized as safe and effective (GRASE) for use in sunscreens, among other things. (43 Fed. Reg. 38,206)
May 1993	FDA published a tentative final monograph that proposed to classify 20 active ingredients as GRASE for use in sunscreens, among other things. (58 Fed. Reg. 28,194)
June 1994	FDA removed five active ingredients from the tentative final monograph for which relevant manufacturer associations did not express interest in developing specific drug standards. A sixth active ingredient was subsequently deferred from inclusion in the 1999 final monograph for the same reason. (59 Fed. Reg. 29,706)
September 1996	FDA added one active ingredient to the tentative final monograph. (61 Fed. Reg. 48,645 )
October 1998	FDA added one active ingredient to the tentative final monograph. (63 Fed. Reg. 56,584 )
May 1999	<p>FDA published a final monograph for sunscreen products, which included 16 active ingredients and the conditions (including maximum concentrations) under which they would be considered GRASE for use in sunscreens. The final monograph also established a minimum labeled sun protection factor (SPF) value of 2 and a maximum labeled SPF value of 30+, among other things. (64 Fed. Reg. 27,666)</p> <p>The initial effective date of the monograph was May 21, 2001, but it was later extended to December 31, 2002. (65 Fed. Reg. 36,319)</p>
December 2001	FDA published a notice to stay the final monograph until further notice to provide additional time to resolve various outstanding issues, such as the labeling and testing of over-the-counter (OTC) sunscreen products. (66 Fed. Reg. 67,485)
February 2007	FDA and the Environmental Protection Agency requested information on insect repellent and sunscreen combination products. (72 Fed. Reg. 7,941)
August 2007	FDA proposed to amend the stayed final monograph to address formulation, labeling, and testing requirements for both ultraviolet A (UVA) and ultraviolet B (UVB) radiation protection. (72 Fed. Reg. 49,070)
June 2011	FDA published draft guidance addressing the circumstances under which FDA intended to exercise its enforcement discretion with respect to certain marketed OTC sunscreen product until a final OTC sunscreen monograph becomes effective. (76 Fed. Reg. 35,665)
June 2011	<p>FDA published a final rule establishing labeling and effectiveness testing requirements for sunscreen products containing the ingredients specified in the stayed 1999 final rule.</p> <p>FDA also requested additional data on OTC sunscreen products in certain dosage forms (i.e., oils, lotions, creams, gels, butters, pastes, ointments, sticks, and sprays). (76 Fed. Reg. 35,619 and 35,669)</p>

**Appendix I: Timeline of Selected Actions  
Related to the Sunscreen Monograph**

<b>Date</b>	<b>Action</b>
November 2014	The Sunscreen Innovation Act changed FDA's process of determining whether a sunscreen active ingredient not listed in the stayed 1999 final monograph is GRASE and established time frames for the agency's review of these active ingredients, among other things. The law also required FDA to issue a final sunscreen monograph by November 26, 2019. (Pub. L. No. 113-195, 128 Stat. 2035 (2014))
May 2018	FDA finalized guidance related to its enforcement approach to OTC sunscreen products marketed without an approved drug application before a final sunscreen monograph becomes effective. The guidance indicated that FDA did not intend to take enforcement action against marketing of sunscreen products without a new drug application, as long as they met the requirements of applicable effective FDA regulations and conformed with specific conditions described in the guidance document, such as for SPF testing, dosage forms, and broad spectrum UV protection. (83 Fed. Reg. 23,917)
February 2019	FDA proposed to put into effect a final sunscreen monograph, proposing to categorize two ingredients as GRASE for use in sunscreens, two ingredients as not GRASE for use in sunscreens due to safety concerns, and 12 ingredients as requiring additional data to support their safety and effectiveness for use in sunscreens. The proposed rule also included provisions related to dosage forms, broad spectrum protection, and labeling, among other things. (84 Fed. Reg. 6,204)
November 26, 2019	Date by which the Sunscreen Innovation Act required FDA to issue and put into effect a final sunscreen monograph. FDA did not issue a final monograph by this date and this requirement was eliminated in March 2020 under the CARES Act.
March 2020	The CARES Act provided that sunscreens will be considered GRASE if they meet the conditions in the newly deemed administrative order for sunscreen established by the act and required FDA to issue a proposal to revise the sunscreen order no later than 18 months after enactment. This proposal must be issued at least 1 year prior to its effective date.  Under the CARES Act, provisions in the Sunscreen Innovation Act will sunset by the end of fiscal year 2022. (Pub. L. No. 116-136, tit. III, subtit. F, 134 Stat. 281, 435-69 (2020))

Source: GAO analysis of relevant laws, regulations, and Federal Register notices. | GAO-20-572

## Appendix II: Status of FDA Implementation of Selected Sunscreen Innovation Act Requirements as of May 2020

**Table 2: Status of FDA Implementation of Selected Sunscreen Innovation Act Requirements as of May 2020**

Requirement	Statutory deadline	Implementation date
Issue notice that feedback letters from FDA, sent to sponsors of some applications for additional sunscreen active ingredients (sunscreen applications) prior to the enactment of the Sunscreen Innovation Act, are considered proposed orders <sup>a</sup> (21 U.S.C. § 360fff-3(b)(3))	1/10/2015	1/7/2015
Issue proposed orders for pending sunscreen applications submitted prior to the Sunscreen Innovation Act that did not receive feedback letters prior to the law's enactment (21 U.S.C. § 360fff-3(b)(4))	2/24/2015	2/24/2015
Issue draft guidance for sunscreen applications on: <ul style="list-style-type: none"> <li>• format and content of data submissions</li> <li>• safety and efficacy data</li> <li>• withdrawal of applications</li> <li>• use of advisory committee (21 U.S.C. § 360fff-4(a)(1)(A))</li> </ul>	11/26/2015	11/20/2015
Issue first report to Congress on various performance metrics (21 U.S.C. § 360fff-7(a))	5/26/2016	5/25/2016
Issue final guidance for sunscreen applications on: <ul style="list-style-type: none"> <li>• format and content of data submissions</li> <li>• safety and efficacy data</li> <li>• withdrawal of applications</li> <li>• use of advisory committee (21 U.S.C. § 360fff-4(a)(1)(B))</li> </ul>	11/26/2016	10/7/2016–11/22/2016
Issue second report to Congress on various performance metrics (21 U.S.C. § 360fff-7(a))	5/26/2018	5/4/18
Finalize sunscreen monograph (21 U.S.C. § 360fff-5)	11/26/2019	Repealed prior to implementation <sup>b</sup>
Issue third report to Congress on various performance metrics (21 U.S.C. § 360fff-7(a))	5/26/2020	5/22/2020

Source: Food and Drug Administration (FDA), Sunscreen Innovation Act, and CARES Act. | GAO-20-572

Note: References are to provisions of law added to the Federal Food, Drug, and Cosmetic Act by the Sunscreen Innovation Act, as codified to the U.S. Code.

<sup>a</sup>The Sunscreen Innovation Act changed the process FDA uses to issue its initial and final determinations of whether sunscreen applications are generally recognized as safe and effective to administrative orders rather than through rulemaking.

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**Appendix II: Status of FDA Implementation of  
Selected Sunscreen Innovation Act  
Requirements as of May 2020**

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<sup>b</sup>FDA did not finalize and put into effect the sunscreen monograph by November 26, 2019, as required by the Sunscreen Innovation Act; however, the CARES Act, enacted on March 27, 2020, eliminated this requirement. Pub. L. No. 116-136, § 3854(b)(5), 134 Stat. 281, 456 (2020). The CARES Act provides that sunscreens will be considered generally recognized as safe and effective if they meet the conditions in the newly deemed administrative order for sunscreen established by the act and required FDA to issue a proposal to revise the sunscreen order no later than 18 months after enactment.

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## Appendix III: GAO Contact and Staff Acknowledgments

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### GAO Contact

John E. Dicken, (202) 512-7114 or [dickenj@gao.gov](mailto:dickenj@gao.gov)

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### Staff Acknowledgments

In addition to the contact named above, Kim Yamane (Assistant Director), Gay Hee Lee (Analyst-in-Charge), Sam Amrhein, Kaitlin Farquharson, and Caroline Hale made key contributions to this report. Rebecca Hendrickson also contributed to this report.

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