

# Food and Drug Administration

## Draft Report and Plan on Best Practices for Guidance

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## I. Executive Summary

Clear, concise, and timely communication through guidance documents is essential to the public health mission of the U.S. Food and Drug Administration (FDA, the Agency, or we). Since 2011, when FDA issued its “Food and Drug Administration Report on Good Guidance Practices Improving Efficiency and Transparency” (“2011 GGP Report”),<sup>1</sup> FDA has made significant strides to modernize and enhance our best practices for the efficient initiation, prioritization, development, review, clearance, and issuance of our guidance documents. As a result of these and other Agency improvement efforts, FDA has increased the number of guidance documents it publishes annually. The 2011 GGP report noted that FDA published 103 Level 1 guidance documents in 2010. Between 2005 and 2010, FDA annually published between 89 and 121 (average 101 per year) guidance documents with an accompanying Notice of Availability (NOA). However, FDA annually published between 112 and 231 (average 173 per year) guidance documents with an accompanying NOA between 2011 and 2019. In Fiscal Year (FY) 2022, FDA published 187 guidance documents with an accompanying NOA and in FY 2023, FDA issued more than 190 guidance documents, either as draft or final.<sup>2</sup>

In accordance with section 2505(a) of the Consolidated Appropriations Act, 2023,<sup>3</sup> FDA is issuing a “Draft Report and Plan on Best Practices for Guidance.” Specifically, FDA is identifying best practices for the efficient prioritization, development, review, clearance, issuance, and use of guidance documents. As a part of this draft report and plan, FDA is also considering opportunities to further improve our guidance development and review and clearance practices, streamline processes for regulatory submissions to FDA through issuance of guidance documents, and implement innovative guidance development processes. Pursuant to section 2505(c) of the Consolidated Appropriations Act, in a Federal Register Notice announcing the availability of this document, FDA is seeking public comment on this “Draft Report and Plan on Best Practices for Guidance.” We hope to receive feedback from a broad range of commenters, including regulated industry; researchers; academic organizations; pharmaceutical, biotechnology, and medical device developers; clinical research organizations; clinical laboratories; health care providers; food manufacturers; and consumer and patient groups on how we can best refine and enhance our current guidance practices.

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<sup>1</sup> FDA, “Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency”, available at <https://www.fda.gov/media/82644/download>.

<sup>2</sup> This is actually an underestimate of the annual number of guidance documents that FDA publishes, as it is based on a count of guidance documents issued with an accompanying NOA. FDA sometimes “bundles” multiple related guidance documents under a single NOA, as appropriate and also issues most “Level 2” guidance documents (described in section III.A., below) without an accompanying NOA, in accordance with our GGP regulation (21 CFR 10.115). FDA also notes additional limitations of a comparison of the total number of guidance documents issued year-to-year, including that these totals cannot account for factors such as the complexity of issues addressed in a guidance, the length of the document, and competing Agency priorities.

<sup>3</sup> Public Law 117-328. FDA plans to issue a separate draft report and plan addressing section 2505(b).

## II. Table of Acronyms/Abbreviations

<b>Abbreviation</b>	<b>What it Means</b>
CBER	FDA's Center for Biologics Evaluation and Research
CDER	FDA's Center for Drug Evaluation and Research
CDRH	FDA's Center for Devices and Radiological Health
CFR	Code of Federal Regulations
CFSAN	FDA's Center for Food Safety and Applied Nutrition
COVID-19	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
CPG	Compliance Policy Guide
CTP	FDA's Center for Tobacco Products
CVM	FDA's Center for Veterinary Medicine
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FR	Federal Register
FY	Fiscal Year
GGP	Good Guidance Practices
HHS	Department of Health and Human Services
ICR	Information Collection Request
NOA	Notice of Availability
OCE	FDA's Oncology Center of Excellence
OND	Office of New Drugs
OMB	Office of Management and Budget
ORA	Office of Regulatory Affairs
PHE	Public Health Emergency
PHS Act	Public Health Service Act
PRA	Paperwork Reduction Act
PSG	Product Specific Guidance
Secretary	Secretary of Health and Human Services
SOP	Standard Operating Procedure
U.S.C.	United States Code

### III. Background

#### A. FDA's Good Guidance Practices

FDA guidance documents are prepared for regulated industry, FDA staff, and the public to describe the Agency's interpretation of, or policy on, a regulatory issue.<sup>4</sup> Unlike statutes and regulations, guidance documents generally do not establish legally enforceable rights or responsibilities<sup>5</sup> and are thus exempt from notice and comment requirements applicable to most rulemaking under the Administrative Procedure Act.<sup>6</sup> However, the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA's GGP regulation<sup>7</sup> require FDA to provide an opportunity for public comment prior to implementation for all Level 1 guidance documents (i.e., guidance documents that include initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues), unless FDA determines that prior public participation is not feasible or appropriate.<sup>8</sup> If FDA determines that public participation is not feasible or appropriate prior to implementation of a guidance document, FDA must provide for public comment upon publication and take such comment into consideration.<sup>9</sup> For Level 2 guidance documents (i.e., guidance documents that set forth existing practices or minor changes in policy), the FD&C Act and FDA's GGP regulation require that FDA provide for public comment upon implementation.<sup>10</sup>

In addition to the GGP regulation, FDA guidance documents may contain collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA).<sup>11</sup> An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.<sup>12</sup> Therefore, when FDA issues a guidance document that contains a collection of information, FDA must either obtain an OMB approved information collection request (ICR) under the PRA for that guidance document or include in the NOA for the guidance document a list of the relevant ICRs previously approved by OMB along with the corresponding OMB control number(s). Development and approval of a collection of information under the PRA requires several steps. FDA develops the information request and publishes a 60-day notice in the Federal Register for comment. Following the public comment period, FDA reviews the public comments and makes changes, if applicable. FDA then publishes a 30-day notice in the Federal Register for public comment and concurrently submits an ICR package to OMB for

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<sup>4</sup> 21 CFR 10.115(b).

<sup>5</sup> 21 CFR 10.115(d).

<sup>6</sup> 5 U.S.C. 553(b)(A); (d)(2).

<sup>7</sup> 21 CFR 10.115.

<sup>8</sup> 21 U.S.C. 371(h)(1)(C)(i); 21 CFR 10.115(g).

<sup>9</sup> 21 U.S.C. 371(h)(1)(C)(i); 21 CFR 10.115(g)(3).

<sup>10</sup> 21 U.S.C. 371(h)(1)(D); 21 CFR 10.115(g)(4).

<sup>11</sup> 44 U.S.C. 3501-3521.

<sup>12</sup> 5 CFR 1320.8(b)(3)(vi).

review. Finally, OMB reviews the ICR package, raises any questions or comments with FDA, then issues a decision on the ICR. Most agencies estimate 6 to 9 months for PRA clearance from agency development to the Office of Information and Regulatory Affairs' decision.<sup>13</sup> PRA clearance may delay the issuance of final guidance, as changes relevant to information collections may occur between draft and final versions of a guidance document or during the development of the final guidance document.<sup>14</sup>

FDA posts draft Level 1 guidance documents on our website and publicizes them by publishing an NOA in the Federal Register. Generally, we have an initial public comment period (usually for 60 days) on draft Level 1 guidance documents. In some instances, FDA may also hold public meetings or workshops on published draft Level 1 guidance documents or present them to an advisory committee to solicit additional feedback.<sup>15</sup> In addition, for guidance documents that are cross-cutting (for example, guidance documents that address issues or policies of more than one Center or Office or products regulated by more than one Center or Office) or with potentially broad impact, FDA sometimes holds webinars during the public comment period to disseminate and describe the content of the guidance document, promote awareness, answer questions, and solicit public comments. Following the initial comment period, FDA reviews the comments and considers them as it prepares the final guidance document. Additionally, FDA routinely issues targeted outreach (including constituent or Center updates, email, webinars, podcasts, and social media posts), and, as appropriate, broader outreach such as press releases and press conferences for certain draft or final guidance documents.

FDA does not solicit public comment prior to implementation of Level 2 guidance documents or of Level 1 guidance documents for which “prior public participation is not feasible or appropriate.”<sup>16</sup> We publish an NOA in the Federal Register for Level 1 guidance documents, including Level 1 guidance documents that we will describe here as those issued “for immediate implementation” because prior public participation is not feasible or appropriate; we also post both types of guidance documents on our website.<sup>17</sup> FDA explains in the NOA and on our website that, in accordance with our procedures, interested persons may comment on any FDA guidance document at any time after they have been issued. FDA periodically reviews all comments and revises guidance documents based on comments when appropriate. Using our authority to issue some guidance documents for immediate implementation streamlines the guidance process and allows FDA to issue certain Level 1 guidance documents more expeditiously than standard Level 1 guidance documents, while still providing an opportunity for interested persons to provide input. Importantly, the additional administrative steps required for

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<sup>13</sup> U.S. General Services Administration, OMB, “PRA approval process”, available at <https://pra.digital.gov/clearance-process/>.

<sup>14</sup> As described below, during the COVID-19 Public Health Emergency (PHE), HHS issued several PRA waivers relevant to the development of FDA guidance.

<sup>15</sup> 21 CFR 10.115(g)(1)(iii).

<sup>16</sup> 21 CFR 10.115(g)(2).

<sup>17</sup> We may publish an NOA for certain Level 2 guidance documents, such as Small Entity Compliance Guides. The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA, Pub. L. 104-121, as amended by Pub. L. 110-28, May 25, 2007) contains specific requirements for issuance of “Small Entity Compliance Guides” to explain what actions affected entities must take to comply with agency rules.

standard Level 1 guidance documents (i.e., issuing a draft guidance document, providing a comment period, and issuing a final guidance document) generally make the issuance of standard Level 1 guidance documents a significantly longer process.

## B. FDA Guidance During the COVID-19 Public Health Emergency

### 1. Issuance of FDA Guidance Related to the COVID-19 PHE

On January 31, 2020, as a result of confirmed cases of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (COVID-19), and after consultation with public health officials, the Secretary of Health and Human Services (the Secretary), pursuant to section 319 of the Public Health Service Act (PHS Act),<sup>18</sup> determined that a Public Health Emergency (PHE) existed; this declaration was subsequently extended in 90-day increments until the PHE was allowed to expire on May 11, 2023.<sup>19</sup> On February 4, 2020, as amended on March 15, 2023, pursuant to section 564 of the FD&C Act,<sup>20</sup> the Secretary issued a determination that there is a PHE, or a significant potential for a PHE, that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a biological agent, namely a novel (new) coronavirus (COVID-19).<sup>21</sup> Based on this Section 564 determination, the U.S. Department of Health and Human Services (HHS) issued four emergency use declarations justifying the authorization of emergency use of in vitro diagnostics, personal respiratory protective devices, medical devices and alternative products used as medical devices, and drugs and biological products.<sup>22</sup> On March 13, 2020, the President declared that the COVID-19 outbreak in the United States constituted a national emergency beginning March 1, 2020.<sup>23</sup>

The facts and circumstances surrounding COVID-19 and the COVID-19 PHE enabled FDA to rapidly disseminate Agency recommendations and policies related to COVID-19. These flexibilities were critical to the significant work FDA accomplished during the COVID-19 pandemic. For example, on March 25, 2020, FDA issued a Federal Register Notice announcing that, in light of the need to act quickly and efficiently to respond to the COVID-19 PHE and pursuant to section 701(h)(1)(C) of the FD&C Act and 21 CFR 10.115(g)(2), FDA planned to

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<sup>18</sup> 42 U.S.C. 247d.

<sup>19</sup> U.S. Department of Health and Human Services (HHS), “Determination that a Public Health Emergency Exists”, available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>; HHS, “Declarations of a Public Health Emergency”, available at <https://aspr.hhs.gov/legal/PHE/Pages/default.aspx>; HHS, “Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap”, available at <https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html#:~:text=Based%20on%20current%20COVID%2D19,day%20on%20May%2011%2C%202023.>

<sup>20</sup> 21 U.S.C. 360bbb-3.

<sup>21</sup> 85 FR 7316 (Feb. 7, 2020); 88 FR 16644 (Mar. 20, 2023).

<sup>22</sup> 85 FR 17335 (Mar. 27, 2020); 85 FR 18250 (Apr. 1, 2020).

<sup>23</sup> See 85 FR 16949 (Mar. 25, 2020) (discussing the President’s declaration).

issue COVID-19-related guidance documents “for immediate implementation” without prior public comment because prior public participation on these guidance documents would not be feasible or appropriate.<sup>24</sup> In that Notice, FDA explained that we would solicit comment, review all comments received, and revise the guidance documents as appropriate. Rather than publishing a separate NOA for each COVID-19-related guidance document, FDA announced it would publish periodically a consolidated NOA announcing the availability of all COVID-19-related guidance documents issued during the relevant period and providing instructions to the public on how to provide comment on these guidance documents.

Additionally, on March 19, 2020, the Secretary invoked his authority to waive PRA requirements with respect to voluntary collection of information during a PHE, and determined, pursuant to section 319(f) of the PHS Act,<sup>25</sup> that the circumstances of the COVID-19 PHE necessitated a temporary waiver from PRA requirements for information to be collected by FDA pertaining to its guidance documents that relate to the COVID-19 pandemic response (PRA waiver).<sup>26</sup> Therefore, clearance by OMB under the PRA was not required for new voluntary collections of information in FDA’s COVID-19-related guidance documents; FDA relied upon this waiver for approximately 21 of our 84 COVID-19 guidance documents (not including revisions). Because the PRA waiver was only for new collections of information associated with the PHE, FDA still had to determine whether an existing ICR covered all or part of the information collection in each COVID-19-related guidance document. For guidance documents covered by existing ICRs, FDA listed the information collections covered by existing ICRs in the consolidated NOAs announcing the availability of the COVID-19 guidance documents. Subsequently, on April 9, 2020, the Secretary waived PRA requirements for information collected by FDA pertaining to voluntary surveys of non-manufacturing entities on medical product supplies, which were deemed necessary to support FDA’s investigation and response to the COVID-19 pandemic.<sup>27</sup> This waiver supported FDA’s medical product supply chain monitoring efforts during the PHE. The information collections facilitated by this PRA waiver also informed the development and revision of COVID-19 policies that provided temporary flexibilities to help mitigate product shortages, such as the guidance documents announcing temporary policies related to the preparation of certain alcohol-based hand sanitizer products. Finally, on April 29, 2020, the Secretary issued a PRA waiver that applied to information to be collected by FDA to evaluate various ways to maximize the number of healthy individuals who can donate blood in order to facilitate its response to the PHE.<sup>28</sup> The information collected pursuant to this PRA waiver supported the development of guidance documents intended to address blood shortages, such as the guidance on “Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency.”

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<sup>24</sup> 85 FR 16949 (Mar. 25, 2020).

<sup>25</sup> 42 U.S.C. 247d(f).

<sup>26</sup> [https://aspe.hhs.gov/sites/default/files/private/pdf/258866/FDA-PHE-PRA-Waiver-Notice\\_COVID-19\\_03.19.20.pdf](https://aspe.hhs.gov/sites/default/files/private/pdf/258866/FDA-PHE-PRA-Waiver-Notice_COVID-19_03.19.20.pdf). (See also HHS, Office of the Assistant Secretary for Planning and Evaluation, “HHS PRA Waiver Notices”, available at <https://aspe.hhs.gov/about/praw-waiver-irb-exemption/praw-waiver-notices>).

<sup>27</sup> [https://aspe.hhs.gov/sites/default/files/private/pdf/258866/FDA%2520PHE\\_PRA%2520Waiver%2520Notice\\_COVID-19%2520Surveys%2520-%252004-09-20.pdf](https://aspe.hhs.gov/sites/default/files/private/pdf/258866/FDA%2520PHE_PRA%2520Waiver%2520Notice_COVID-19%2520Surveys%2520-%252004-09-20.pdf).

<sup>28</sup> <https://aspe.hhs.gov/sites/default/files/documents/7361a78172a5bf6ac084b68b960b1008/FDA-PHE-PRA-Waiver-Notice-Blood-Donation-Survey-04-29-20.pdf>.

In addition to relying on the legal authorities and flexibilities described above, FDA took other procedural actions to speed the issuance of and ease access to COVID-19 guidance documents. For example, HHS and OMB worked closely with FDA to provide expedited external review and clearance to ensure timely publication of FDA’s COVID-19 guidance documents. In addition to posting COVID-19 guidance documents on the “Search for FDA Guidance Documents” web page,<sup>29</sup> FDA devoted a separate web page, entitled “COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders” to COVID-related guidance documents.<sup>30</sup> Additionally, FDA established one docket for each Center or Office that issued COVID-19-related guidance documents; comments on all COVID-19-related guidance documents issued by that Center or Office could be submitted to the docket associated with that Center or Office for review. Further, each Center or Office provided a single contact on the NOAs for all COVID-19-related guidance documents issued by that Center or Office.

From 2020 through 2022, FDA succeeded in issuing 84 new guidance documents (not including revisions) to provide policies and recommendations, transparency, and flexibility, as needed, to support the development and availability of vital medical products for COVID-19, to help ensure the continuity of the food supply, and to address myriad other public health issues the United States faced during the pandemic. This was achieved by prioritizing COVID-19-related issues above other work, devoting unprecedented resources to the COVID-19 response, implementing guidance documents without prior public participation, using PRA waivers, expediting external review and clearance, and taking the other actions described in this report.

## *2. Use of Templates to Accompany COVID-related Guidance*

As part of the guidance titled “Policy for Coronavirus Disease-2019 Tests,” the Center for Devices and Radiological Health (CDRH) made available a series of templates on its web page. The guidance document and web page noted that the templates reflect FDA’s current thinking on the data and information that developers should submit to facilitate the Emergency Use Authorization (EUA) process. The templates provided information and recommendations, and CDRH noted that it planned to update the templates as CDRH learned more about COVID-19 and gained experience with the EUA process for various COVID-19 tests.<sup>31</sup> Accordingly, CDRH has updated the templates, as appropriate, consistent with GGP procedures.

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<sup>29</sup> FDA, “Search for FDA Guidance Documents”, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

<sup>30</sup> FDA, “COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders.” An archive of this page is available at <https://public4.pagefreezer.com/browse/FDA/08-11-2023T13:22/https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>.

<sup>31</sup> FDA, “In Vitro Diagnostics EUAs”, available at <https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas#covid19ivdtemplates>.

### *3. Expiration of the COVID-19 PHE under the PHS Act*

On May 11, 2023, the PHE declared under section 319 of the PHS Act expired. In the Federal Register of March 13, 2023, FDA published a Notice addressing the Agency’s COVID-19-related guidance documents, including identification of which of these guidance documents would no longer be in effect after the expiration of the PHE, and which guidance documents FDA would be revising to continue in effect after the expiration of the PHE declaration.<sup>32</sup> For guidance documents that FDA did not withdraw at the end of the PHE, FDA began the work necessary to clear new ICRs as required by the PRA.

### **C. Section 2505(a) of the Consolidated Appropriations Act, 2023**

Section 2505(a) of the Consolidated Appropriations Act of 2023, Improving FDA Guidance and Communication, requires FDA to issue reports related to FDA’s guidance practices. Specifically, section 2505(a) requires FDA to issue a report “identifying best practices for the efficient prioritization, development, issuance, and use of guidance documents.” Additionally, this section requires FDA to issue a plan for implementation of such best practices, which will address: streamlining development and review of guidance documents within Centers and across FDA; streamlining processes for regulatory submissions to FDA, including through the revision or issuance of guidance documents; and implementing innovative guidance development processes and practices and transitioning or updating guidance issued during the COVID-19 PHE, as appropriate.

This draft report addresses section 2505(a) of the Consolidated Appropriations Act; FDA plans to issue a separate draft report and plan addressing section 2505(b).

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<sup>32</sup> 88 FR 15417 (Mar. 13, 2023).

### III. Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency

#### A. Introduction

As part of FDA’s Transparency Initiative, in 2011, FDA publicly released a comprehensive report titled “Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency” (2011 GGP Report).<sup>33</sup> The 2011 GGP Report identified “best practices” and made recommendations to streamline the development of guidance documents, reduce the time between issuing draft and final guidance documents, and improve access to guidance documents on FDA’s website. In identifying best practices and recommendations, the 2011 GGP Report recognized that each FDA Center and Office has different demands and resource constraints. The report also noted that certain factors, such as limited resources, competing priorities, and interagency review, directly affect the speed at which guidance is issued and that such factors must also be taken into consideration when issuing guidance.

Since publication of the 2011 GGP Report, FDA has made significant strides to modernize and improve our best practices for the efficient initiation, prioritization, development, review and clearance, and issuance of our guidance documents. Despite continued resource constraints, FDA has implemented a significant portion of the best practices and recommendations, within each Center and Office and Agency-wide.<sup>34</sup> FDA has also taken actions beyond those recommended in the 2011 GGP Report to regularly re-assess, modernize, and improve best practices to provide for the efficient prioritization, development, and issuance of FDA guidance documents. As a result of these efforts, FDA has increased the annual number of guidance documents it publishes. In the 2011 GGP Report, FDA stated that it published 103 Level 1 guidance documents in 2010. Between 2005 and 2010, FDA annually published between 89 and 121 guidance documents with an accompanying NOA (average 101 per year). However, between 2011 and 2019, FDA annually published between 112 and 231 guidance documents with an accompanying NOA (average 173 per year). In FY 2022, FDA published 187 guidance documents with an accompanying NOA and in FY 2023, FDA issued more than 190 guidance documents, either as draft or final<sup>35</sup>

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<sup>33</sup> FDA, “Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency”, available at <https://www.fda.gov/about-fda/transparency-initiative/background-report-good-guidance-practice>.

<sup>34</sup> FDA provided a partial update on its implementation of the 2011 Guidance Report and Plan in 2015 via correspondence to the U.S. Senate Committee on Health, Education, Labor and Pensions. This update is available at <https://www.help.senate.gov/imo/media/doc/3-9-2015%20FDA%20Guidance%20Letter%20Response.pdf>.

<sup>35</sup> As previously noted, this is actually an underestimate of the annual number of guidance documents that FDA publishes, as it is based on a count of guidance documents issued with an NOA. FDA sometimes “bundles” related guidance documents under a single NOA and also issues most Level 2 guidance documents without an accompanying NOA, in accordance with our GGP regulation (21 CFR 10.115). FDA also notes additional limitations of a comparison of the total number of guidance documents issued year-to-year, including that these totals cannot account for factors such as the complexity of issues addressed in a guidance, the length of the document, and competing Agency priorities.

## B. Best Practices for the Initiation, Prioritization, Development, Review, Clearance, and Issuance of Guidance Documents

The 2011 GGP Report and Plan recommended that FDA consider: (1) implementing strategies to improve the dialogue regarding the Guidance Agenda and potential topics for guidance development, including encouraging the submission of draft guidance documents to Centers and Offices for consideration, in addition to guidance topics, and standardizing the criteria for Guidance Agendas to the extent possible; (2) revising the GGP regulation to eliminate the requirement that FDA publish the Guidance Agenda in the Federal Register, allowing the Agency to publish the Guidance Agenda on the Internet only; and (3) developing Center-wide processes for the initiation, prioritization, development, review, clearance, and issuances of guidance documents.

### 1. Best Practices Regarding Guidance Initiation

#### a. Facilitating Input in Guidance Development

FDA gives interested persons a number of opportunities to provide input into topics for guidance document development, including topics for potential future guidance documents, via formal and informal channels. FDA has published annual Guidance Agendas in the *Federal Register*, which list possible topics for future guidance document development or revision during the upcoming year. Interested persons were invited to submit comments on the topics on the list and to suggest additional topics for guidance or ideas for revisions to existing guidance documents. However, the guidance development process is fluid and changes depending on public health needs and Agency resources. The Guidance Agendas do not bind FDA to a list of topics or obligate FDA to issue every guidance document on an agenda, especially given that competing priorities may arise during the year. These competing priorities may also result in FDA developing guidance documents on topics not on this list. As a result, by the time FDA completes clearance and publication of the Guidance Agenda for publication in the Federal Register, it might be outdated. For this reason among others, most FDA Centers also publish their proposed Guidance Agendas on their web pages.<sup>36</sup>

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<sup>36</sup> Current Guidance Agendas are available at the following websites: Center for Biologics Evaluation and Research (CBER) (<https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/guidance-agenda-guidance-documents-cber-planning-publish-during-calendar-year-2023>); Center for Drug Evaluation and Research (CDER) (<https://www.fda.gov/media/134778/download>); CDER, Office of Generic Drugs (OGD) (<https://www.fda.gov/drugs/guidances-drugs/upcoming-product-specific-guidances-generic-drug-product-development>); Center for Devices and Radiological Health (CDRH) (<https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2024fy2024>); FDA's Human Foods Program (<https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/foods-program-guidance-under-development>); Center for Veterinary Medicine (CVM) (<https://www.fda.gov/animal-veterinary/guidance-industry/guidances-under-development-2023>). FDA's Human Foods Program posted their inaugural Guidance Agenda in June 2021 and publishes the list annually, with updates mid-year. This list includes information about guidance under development by the Center for Food Safety and Applied Nutrition (CFSAN) and FDA's Office of Food Policy and Response (OFPR) within the Office of the Commissioner. The Center for Tobacco Products (CTP) recently issued a Regulation and Guidance Policy Agenda available at <https://www.fda.gov/tobacco-products/rules-regulations-and->

Under FDA’s GGP regulation interested persons may also suggest areas for guidance document development.<sup>37</sup> In addition, requests for guidance documents come to FDA informally; frequently, interested persons identify issues that would benefit from guidance at advisory committee meetings, industry meetings, roundtables, and listening sessions, or by contacting the appropriate FDA Center or Office. These requests are considered by the Center or Office.

Interested persons also may submit proposed draft guidance documents to FDA. Submitting proposed draft guidance documents, rather than guidance topics, may enable FDA to approach a guidance topic with a better understanding of the issues of interest. In March 2018, FDA issued a technical amendment to the GGP regulation to clarify how the public can electronically submit drafts of proposed guidance documents to FDA.<sup>38</sup> The amendment added an option in 21 CFR 10.115(f)(3) for submitting the draft of a proposed guidance to the Agency electronically through the regulations.gov website at Docket No. FDA-2013-S-0610. Submitted drafts of proposed guidances are routed to the appropriate Center or Office for consideration. FDA reviews all guidance topic suggestions and proposed draft guidance documents.

For medical product work that is funded by user fees, the user fee negotiation process provides an additional opportunity for input regarding topics for guidance development. For example, for human medical products and animal product user fees, the negotiation process includes opening a public docket and holding two public meetings (one at the opening of negotiations and one toward the end), providing additional opportunities for public input. The user fee agreement letters often include commitments to issue guidance on certain topics and/or within a certain timeframe. In addition, FDA publicly posts its user fee commitment agreements, providing additional visibility into topics and/or timelines for guidance development.

#### **b. Amendments to FDA’s GGP Regulation to Reflect Current Best Practices for Guidance Agendas**

FDA’s 2011 GGP Report recommended that the Agency consider revising its GGP regulation “to require the Agency to publish the annual Guidance Agenda on the Internet only. Eliminating the Federal Register publication requirement would reduce the Agency’s burden and increase efficiency. Moreover, it would prevent confusion that may arise by potentially outdated information, which would also advance transparency.”<sup>39</sup> As discussed above, FDA also publishes Guidance Agendas on the Internet, which allows for greater transparency, easier

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[guidance/center-tobacco-products-regulation-and-guidance-policy-agenda](https://www.fda.gov/oc/guidance/center-tobacco-products-regulation-and-guidance-policy-agenda) and the Office of the Chief Scientist recently posted a list of possible topics for future guidance document development or revision during the next year, available at <https://www.fda.gov/about-fda/guidance-documents-office-chief-scientist/office-chief-scientist-guidance-documents-under-development>.

<sup>37</sup> 21 CFR 10.115(f).

<sup>38</sup> 83 FR 13415 (Mar. 29, 2018).

<sup>39</sup> 2011 GGP Report at 7.

updates, better use of Agency resources,<sup>40</sup> and easier access to the Agency’s current guidance plans. Although FDA has made other updates to its GGP regulation since 2011, the Agency has not amended the GGP regulation to require that the Agency publish annual Guidance Agendas on the Internet only.

### c. Best Practices Regarding Guidance Initiation

As recommended in the 2011 GGP Report, FDA has developed and implemented written procedures addressing the guidance initiation process. The procedures reflect best practices to use guidance initiation forms or concept papers to determine guidance feasibility in light of other priorities, establish guidance objectives and scope, ensure inclusion of other affected FDA Centers and Offices as appropriate, identify lead writers and necessary subject matter experts, consider potential impacts and response, and ensure leadership support for developing guidance on a particular topic. For example, in 2018, FDA developed Staff Manual Guide 4103, “Expectations and Procedures for Engagement Among Medical Product Centers and Office of Combination Products on Regulations and Guidance Pertaining to Combination Products,”<sup>41</sup> to ensure engagement among the relevant Centers and the Office of Combination Products on the development and clearance of combination product guidance documents. Prior to guidance initiation, Centers and Offices also evaluate whether guidance is the appropriate mechanism to convey the information, as well as the appropriate guidance level (i.e., Level 1 or 2).

### 2. Best Practices Regarding Prioritizing/Work Planning/Tracking Guidance

The 2011 GGP Report recommended that FDA consider ways to make the guidance development and review and clearance processes more efficient, including: (1) use of a dynamic, systematic guidance prioritization process that permits adjustment of priorities as needed and (2) implementation of work planning and tracking strategies to ensure that staff are fully aware of established timeframes.

FDA has instituted processes and “best practices” to make the guidance development and review and clearance processes more efficient; these procedures have been developed at the Center or Office level. In recent years, FDA has worked diligently to improve the efficiency of its guidance development, review, and clearance processes. Since 2011, FDA, while considering demands and resource constraints, has implemented appropriate work planning and tracking mechanisms to establish milestones, track guidance development progress, and monitor timeframes to help ensure accountability and to provide for the efficient prioritization, development, and issuance of guidance documents. For example, the Center for Drug Evaluation and Research (CDER) enhanced its guidance development process by implementing a project

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<sup>40</sup> Publishing Guidance Agendas in the Federal Register requires time and monetary resources. FDA’s Regulatory and Editing staff must expend time to edit the Federal Register notice consistent with the Federal Register Document Drafting Handbook, and Federal Register staff must prepare the document for display and publication. FDA also must pay for publication in the Federal Register. U.S. Government Printing Office, “OFR Publishing Services”, available at <https://www.gpo.gov/how-to-work-with-us/agency/services-for-agencies/ofr-publishing-services>.

<sup>41</sup> FDA Staff Manual Guide 4103, “Expectations and Procedures for Engagement Among Medical Product Centers and Office of Combination Products on Regulations and Guidance Pertaining to Combination Products”, available at <https://www.fda.gov/media/112448/download>.

management software that tracks the specific tasks required for guidance development. This allows CDER to identify the areas where guidance development takes the longest, so that CDER can determine corrective measures for improvement. Similarly, CDRH recently developed a project management software to initiate and track guidances through their lifecycle, which provides guidance leads with a customizable timeline to facilitate meeting guidance publication goals. The Center for Food Safety and Applied Nutrition (CFSAN) uses project management software that tracks regulatory projects, communications, PRA, etc. throughout their life cycle. Additionally, the Center for Veterinary Medicine (CVM) has an internal guidance tracking system that is reviewed on a regular basis. The Center for Biologics Evaluation and Research (CBER) instituted biweekly priority report meetings to facilitate timely guidance document development and to adjust priorities as needed. Finally, the Center for Tobacco Products (CTP) tracks its guidance documents on an inventory chart which is updated and adjusted bi-weekly, and the Oncology Center of Excellence (OCE) Policy Team manages and tracks all oncology guidances via an internal database platform.

### *3. Best Practices for Working Groups and Developing Guidance*

The 2011 GGP Report recommended that FDA Centers and Offices: (1) develop best practices for working groups to ensure that they operate efficiently and (2) implement additional strategies, such as careful choice of authors and use of templates, to expedite the guidance drafting process as appropriate.

As recommended in 2011, FDA now has “best practices” for working groups and has implemented strategies to advance guidance development. These strategies include: determining when working groups are needed; delineating tasks among working group members; strategically selecting guidance leads and authors with the requisite scientific and drafting expertise; providing appropriate support (e.g., technical writers or professional editors) to draft quality guidance documents expeditiously; elevating issues to management to timely resolve differing views; and using guidance templates to ensure quality and consistency in drafting.

In October 2019, CDRH undertook a business process improvement initiative to apply “lean six sigma” methodologies<sup>42</sup> to simplify, standardize, and harmonize internal processes for guidances, regulations, and orders. This led to the development and revision of internal Standard Operating Procedures (SOPs) and work instructions to improve consistency and predictability of the overall guidance process. It also led to the development of the new project management software described above. The effort was part of the 2018-2020 CDRH Strategic Priorities<sup>43</sup> and continues to be an area of focus as part of the 2022-2025 CDRH Strategic Priorities.<sup>44</sup>

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<sup>42</sup> Lean Six Sigma is a process improvement method that increases performance and decreases process variation while eliminating waste and promoting work standardization and flow. See American Society for Quality, “What Is Lean Six Sigma?”, available at <https://asq.org/quality-resources/six-sigma>.

<sup>43</sup> FDA CDRH, “2018-2020 CDRH Strategic Priorities” at 12, available at <https://www.fda.gov/files/about%20fda/published/2018-2020-Strategic-Priorities.pdf>.

<sup>44</sup> FDA CDRH, “2022-2025 CDRH Strategic Priorities”, available at <https://www.fda.gov/media/155888/download?attachment>.

Similarly, in January 2021 after reviewing their guidance development processes and updating internal procedures, CDER implemented its guidance modernization initiative to reduce development time for guidances, reduce iterations and clearance times, and provide more consistent outputs for guidances. CDER's guidance modernization improvements incorporated best practices from CDER Super Offices to create consistency across offices and to streamline the initiation, development, clearance, and publication of the NOA in the Federal Register and posting guidance documents on the FDA guidance web page.

In 2022, the Office of Regulatory Affairs (ORA) also undertook a revision of its processes for management of guidance documents. Specifically, ORA included a guidance communications plan within the guidance SOP to delineate the process for collaboration with the Office of Communications on publication and promotion of guidance.

Additionally, as described in the 2011 GGP Report, FDA continues to use templates for guidance documents and their accompanying NOAs, which provide for the organization of guidance content and presentation of information in a logical sequence and ensures inclusion of standard elements required by FDA's GGP regulation<sup>45</sup> and relevant PRA information. These templates provide a consistent visual format for FDA guidances.

#### *4. Best Practices on Reviewing and Clearing Guidance*

The 2011 GGP Report recommended that each FDA Center and Office should consider implementing strategies to encourage compliance with review and clearance timeframes, and prevent multiple review and clearance cycles, within their own organizations and when reviewing documents from other parts of FDA. The 2011 GGP Report also recognized that other factors, such as limited resources, competing priorities, and interagency review, directly affect the speed at which guidance is issued.

Beginning in early 2011, FDA invested significant resources to design an Agency-wide tracking system for documents published in the Federal Register, including NOAs for FDA guidance documents and the guidance document itself. After a testing phase, the new tracking system was formally rolled out on August 25, 2014.<sup>46</sup>

In 2017, CDER launched a pilot program in the Office of New Drugs (OND) to provide a streamlined clearance process for a subset of CDER guidance documents that include recommendations on developing drugs intended to treat a specific disease or for a specific indication (disease or indication specific guidances). Guidance documents cleared under this streamlined process are conducive to being drafted in a bulleted format to present information in a succinct manner, are under 10 pages in length, and cover a limited scope of information. Under the pilot, multiple CDER Offices provided concurrent, as opposed to sequential, review and clearance. In 2018 and 2019, OND published over 100 guidance documents, an increase of more than 200%, with 50% of those guidance documents cleared under the pilot, including all the disease and indication specific guidance documents in that timeframe. In light of the notable

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<sup>45</sup> 21 CFR 10.115(i).

<sup>46</sup> <https://www.help.senate.gov/imo/media/doc/3-9-2015%20FDA%20Guidance%20Letter%20Response.pdf>.

increase in the number of disease or indication specific guidances<sup>47</sup> and the efficiency attributed to the bulleted format and streamlined clearance process, the pilot was permanently implemented and expanded to all CDER offices. In 2021, CDER incorporated the bulleted guidance format and the concurrent clearance pathway as part of its Guidance Modernization initiative. As noted above, this format is appropriate for a limited subset of guidance documents and is generally inappropriate for guidance documents that address more complex issues.

In addition, FDA has implemented agency-wide strategies to encourage compliance with review and clearance timeframes and reduce the number of review cycles through: (1) early identification of cross-cutting and/or contentious issues, and resolution of policy issues and differing Center and Office perspectives prior to clearance; (2) improved communication between staff and management during drafting and review and clearance; (3) establishing clear expectations and timeframe milestones for review and clearance; (4) identification of appropriate decision-makers and scope of review prior to clearance; (5) limiting multi-level reviews within single offices; and (6) delegating clearance functions to expedite clearance, where appropriate.

While FDA has implemented these process improvements to streamline guidance review, we have also experienced increased interest by other federal agencies in pre-publication review of some guidance documents. Such interagency review—by other components of HHS, other Federal agencies, and components of the Executive Office of the President—can support consistency with other policy actions taken or planned by other Federal agencies, but by necessity involves additional investment of time by FDA staff to complete guidance clearance and extension of the overall timeline for publication of guidance documents. FDA has implemented procedures to allow for earlier identification of guidance documents that will involve interagency review and clearance to better plan for when additional time and resources will be needed and to better manage expectations of when the guidance document will publish.

##### *5. Best Practices Regarding Timely Publication of Final Guidance, Periodic Guidance Review, Guidance Access, and Guidance Outreach*

The 2011 GGP Report recommended that each Center and Office facilitate timely publication of final guidance by: (1) establishing milestones for finalization of guidance in work planning documents; (2) using innovative forms of guidance that comply with GGP requirements, such as issuing Notice to Industry letters as Level 1 guidance “for immediate implementation,” to communicate more quickly with industry; (3) establishing expectations that working groups resolve issues raised by comments received on a draft guidance within a certain time-frame after the comment period closes; (4) establishing goals to finalize draft guidance that receives no comments, expeditiously, after the comment period closes; and (5) periodically evaluating draft guidance to determine whether any guidance that has been in draft for more than 3 years should be withdrawn, finalized, or issued as a revised draft. The 2011 GGP Report also recommended that FDA: (6) consider using social media tools to increase transparency, or awareness, of recently issued and withdrawn guidance; and (7) continue to provide centralized access to FDA guidance documents, as well as a list of withdrawn guidance documents.

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<sup>47</sup> FDA notes that the number of published disease or indication specific guidance documents dipped during the pandemic as FDA prioritized COVID-19-related guidance and pandemic duties.

#### a. Timely Publication of Final Guidance Documents

The 2011 GGP Report made several recommendations to support the timely publication of final guidances. Since publication of the 2011 GGP Report, CDRH undertook a significant initiative to expedite finalization of its draft guidance documents. On June 5, 2014, CDRH held a Public Workshop on Guidance Development and Prioritization at which interested parties and CDRH staff explored ideas to improve CDRH guidance development, and public feedback included the importance of timely finalization of draft guidance documents. As a result, CDRH announced in the Federal Register the Center’s commitment to performance goals for current and future draft guidances: For draft guidance documents, as resources permit, CDRH strives to finalize, withdraw, reopen the comment period, or issue another draft guidance on the topic for 80 percent of its guidance documents within 3 years of the close of the comment periods and for 100 percent of its draft guidance documents within 5 years of the close of the comment period.<sup>48</sup> CDRH has reaffirmed these commitments in the Medical Device User Fee Amendments of 2017 and 2022 (Medical Device User Fee Amendments IV and V).

Other FDA Centers and Offices have implemented strategies to support the finalization of draft guidances. For example, CBER establishes milestones for guidance document finalization and provides updates at bi-weekly meetings. CTP likewise discusses its inventory of guidances under development at bi-weekly meetings with Center leadership. CVM has established a goal to finalize its guidance documents within 1 year of issuing the draft guidance document. CFSAN, among other things, may consider the number of comments received on a guidance document in deciding how to prioritize finalization; a draft guidance document that received few comments may require less time and resources to finalize and therefore be elevated in priority. OCE does not have any published draft guidance documents that have remained in draft for more than 3 years.

Recognizing the varied demands on its resources, FDA continues to seek the right balance between finalizing its draft guidance documents and other critical Agency work, such as drafting new guidance to address diseases, novel technologies, and other issues for which FDA guidance is lacking, addressing urgent public health issues, and completing review of medical product applications, which are subject to user fee performance goals and which may make new treatments available to patients.

#### b. Use of Level 1 Guidance for Immediate Implementation

The 2011 GGP Report recommended that FDA use innovative forms of guidance that comply with GGP requirements, such as issuing Notice to Industry letters as Level 1 guidance “for immediate implementation,” to communicate more quickly with industry. FDA discussed its authorities to issue Level 1 guidance “for immediate implementation” in the preamble to our GGP regulation. There, we explained that under section 701(h)(1)(C) of the FD&C Act, FDA must ensure public participation prior to the implementation of guidance unless FDA determines that such prior public participation is not feasible or appropriate. FDA stated that we anticipate that this exception will generally be used when: (1) There are public health reasons for the

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<sup>48</sup> 80 FR 1424 (Jan. 9, 2015).

immediate implementation of the guidance document; (2) there is a statutory requirement, executive order, or court order that requires immediate implementation; or (3) the guidance document presents a less burdensome policy that is consistent with public health.<sup>49</sup>

Although the 2011 GGP Report recommended that FDA make more use of its authority to issue Level 1 guidance documents “for immediate implementation,” to date, with the exception of guidances issued in response to the COVID-19 PHE, FDA has issued only a small portion of Level 1 guidance documents “for immediate implementation.” Moreover, while the 2011 GGP Report did not address whether FDA should also increase use of its authority to issue Level 2 guidance documents without prior public comment, to date, most FDA Level 2 guidance documents are updates to existing guidance documents rather than new guidance documents.

### c. Periodic Guidance Review

The 2011 GGP report recommended that FDA periodically evaluate its draft guidance documents to determine whether any guidance that has been in draft for more than 3 years should be withdrawn, finalized, or issued as a revised draft. The 2011 Report also recommended that FDA build and update as needed a centralized web page that links to a list of withdrawn guidances. Since 2011, FDA Centers and Offices have periodically reviewed both draft and final guidance documents, with the aim of determining whether each guidance should be withdrawn because it is obsolete (in conflict with, or no longer reflective of FDA’s current thinking) or it has been replaced by another guidance document that better reflects the Agency’s current policies or recommendations on an issue or whether it should be revised and reissued to ensure that it reflects the Agency’s current thinking. For example:

- Since 2015, CDRH has conducted an annual retrospective review of a subset of its final guidance documents. In announcing its plans to conduct this retrospective review, CDRH noted that its guidance program has issued guidance over a period greater than 20 years, raising questions of whether previously issued guidance documents remain current.<sup>50</sup> CDRH started this review with its guidance documents issued in 2005, 1995, and 1985. CDRH committed to provide such lists annually through FY 2025 so that by FY 2025, CDRH and the public will have assessed the applicability of all CDRH guidance documents older than 10 years. As part of this retrospective review, CDRH has withdrawn over 200 guidance documents given that they were either obsolete or replaced by more recent policies and recommendations.
- In February 2020, as part of its continued commitment to clarify and streamline regulatory policy, CVM withdrew 27 guidance documents in the form of Compliance Policy Guides (CPGs) that were either obsolete or replaced by more recent Agency policies and recommendations. For example, several of the withdrawn CPGs were no longer needed because they had been superseded by the FDA Food Safety Modernization Act requirements for current good manufacturing practices and risk-based preventive controls for animal food. CVM had also determined that the topics

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<sup>49</sup> 65 FR 56468, 56472 (Sept. 19, 2000).

<sup>50</sup> 80 FR 1424, 1426-27 (Jan. 9, 2015).

of many of the withdrawn CPGs are already addressed by relevant sections of the FD&C Act.

- In July 2020, CBER withdrew 21 draft and final guidance documents. CBER also withdrew 48 blood memoranda, many of which dated to the 1980s and 1990s and addressed issues including blood and blood products, donor screening and HIV. Among the withdrawn guidance documents were a “Y2K-era” guidance document on handling the year 2000 date change for computer systems and software applications used to manufacture blood products and a 2003 guidance document on screening donors for SARS.
- In 2023, ORA evaluated Chapter 1 (Subchapters 100-160) the Manual of Compliance Policy Guides to ensure the accuracy and accessibility of the operational CPGs and to identify any CPGs that may need to be withdrawn or revised.
- In 2023, FDA’s Office of Clinical Policy withdrew four guidance documents as the policies and recommendations in those guidances were reflected in more recently-issued guidance.

Although the 2011 report recommended that FDA build a centralized web page that links to a list of withdrawn guidance documents, FDA believes that the public can better locate these withdrawn guidance documents by product area and therefore, currently, FDA has Center or Office-specific web pages that list their withdrawn guidance documents.<sup>51</sup>

#### d. Best Practices for Guidance Access

The 2011 Report recommended that FDA provide a centralized web page that links to each Center and Office’s guidance list on the FDA Basics for Industry web page, and update it as needed. In 2014, FDA launched an Agency-wide, user-friendly guidance web page that provides centralized access to all FDA guidance documents, titled “Search for FDA Guidance Documents.”<sup>52</sup> This web page links to over 2,700 draft and final FDA guidance documents. The “Search for FDA Guidance Documents” web page allows users to filter their search by a number of parameters, including product, FDA organization, topic, the document type (for example, Guidance, CPG, Small Entity Compliance Guide), issue date, and comment closing date. Searchers may sort the table of guidance documents by issuing Center or Office, issue date,

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<sup>51</sup> CBER (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/withdrawn-guidances-biologics>); CDER (<https://www.fda.gov/drugs/guidances-drugs/withdrawnexpired-guidances-drugs>); CDRH (<https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/withdrawn-or-expired-guidance>); CFSAN (<https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/guidance-documents-regulatory-information-topic-food-and-dietary-supplements#y2005>); CTP (<https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/withdrawnreplaced-guidances>); CVM (<https://www.fda.gov/animal-veterinary/guidance-industry/withdrawnreplaced-guidances>); Office of Clinical Policy (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/withdrawn-or-expired-clinical-trial-guidance-documents>).

<sup>52</sup> FDA, “Search for FDA Guidance Documents”, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

topic, whether the guidance document is draft or final, whether the comment period on a draft guidance document is still open, and comment closing date. The “Search for FDA Guidance Documents” web page is updated as new guidance documents are issued and is accessible via a link from the FDA Basics for Industry web page.

In addition to the “Search for FDA Guidance Documents” web page, CDER’s Office of Generic Drugs (OGD) manages a devoted database for the more than 2,100 Product Specific Guidances (PSGs) which support the development of generic drugs and the submission of Abbreviated New Drug Applications.<sup>53</sup> The features of this database include text search by active ingredient or by the Reference Listed Drug or Reference Standard application number, the option to export search results in Excel, CSV, or PDF format, and paginated search results.

In 2019-2020, FDA undertook a review of the “Search for FDA Guidance Documents” web page to ensure the completeness and accuracy of posted guidance documents and the metadata that support the functionality of the web page. FDA conducted an inventory of posted guidance documents to ensure that all effective FDA guidances were posted and that guidance documents that should no longer be posted had been removed. FDA also reviewed the metadata that supports the functionality of the “Search for FDA Guidance Documents” web page to ensure that the metadata were accurate. This review supported the accuracy and utility of the search functions.

#### e. Best Practices for Guidance Outreach

The 2011 GGP Report also recommended that, to increase transparency or awareness of recently issued guidance, Centers and Offices should consider using social media tools to increase outreach for recently issued significant guidance, including webinars and automatic e-mail alerts.

Once a guidance document is published, in addition to posting the guidance document on the “Search for FDA Guidance Documents” page, the Agency may link to that guidance document from a subject matter-specific web page. In addition, FDA Centers and Offices may use the following tools to increase awareness of recently issued guidance: email announcements using listservs, constituent or Center updates, email, webinars, podcasts, social media posts, and (when appropriate) press releases or press conferences. Other communication methods to help ensure the ability to understand and apply the recommendations may include webinars on one or more FDA guidance documents, website Questions & Answers (highlighting key points of the guidance in a more user-friendly and plain language manner), and podcasts. CDER’s Guidance Snapshot Pilot Program, launched in February 2020, communicates guidance recommendations to multiple audiences using visuals, plain language, and other innovative technologies to increase

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<sup>53</sup> FDA, CDER, Office of Generic Drugs, “Product-Specific Guidances for Generic Drug Development”, available at <https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development>.

awareness and understanding of cross-cutting guidance documents on topics related to modernizing drug clinical trials and accelerating drug development.<sup>54</sup>

### C. Streamlining Processes for Regulatory Submissions to FDA through the Issuance of Guidance Documents

FDA guidance documents address a variety of issues, including some that may not be directly related to making regulatory submissions to the Agency, such as those addressing enforcement policies, human subject protection, good manufacturing practices, user fees, and procedures for meetings with FDA. FDA has also issued hundreds of guidance documents that directly and indirectly assist industry in making regulatory submissions to the FDA, including those that support the submission of medical product applications for human and animal drugs, devices, and biological products; the submission of tobacco product applications; adverse event reporting; and registration and listing for FDA-regulated products. FDA's Guidance Agendas give insight into FDA's plans for issuing specific draft and final guidance documents, including guidance documents that may assist industry in making regulatory submissions to the agency.

Further, FDA has developed guidance to assist industry in completing forms that may accompany regulatory submissions, such as guidance to accompany FDA Form 356h Application to Market a New or Abbreviated New Drug or Biologic for Human Use.<sup>55</sup> Additionally, FDA has developed Technical Conformance Guides for certain submissions to the Agency. These Technical Conformance Guides may accompany a guidance document and provide more detail about what information should be included in a submission. For example, the FDA Guidance for Industry: Format and Content of a REMS Document (Jan. 2023) provides additional guidance on the type of information that should be included in a REMS document and is accompanied by a Technical Conformance Guide.<sup>56</sup> Another example is the guidance titled Providing Regulatory Submissions in Electronic Format — Standardized Study Data (eStudy Data), which is supplemented by the Study Data Technical Performance Guide.<sup>57</sup>

CDER continually develops disease or indication specific guidance documents that include recommendations on developing drugs intended to treat a specific disease or for a specific indication. Recent examples include Diabetic Foot Infections: Developing Drugs for

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<sup>54</sup> FDA, CDER, "Guidance Snapshot Pilot", available at <https://www.fda.gov/drugs/guidances-drugs/guidance-snapshot-pilot>.

<sup>55</sup> Identification of Manufacturing Establishments in Applications Submitted to CBER and CDER Questions and Answers Guidance for Industry (Oct. 2019), available at <https://www.fda.gov/media/131911/download>.

<sup>56</sup> See, e.g., the technical conformance guide developed to accompany the FDA Guidance for Industry: Format and Content of a REMS Document (Jan. 2023), available at <https://www.fda.gov/media/164344/download>.

<sup>57</sup> FDA, CBER, CDER "Providing Regulatory Submissions in Electronic Format -- Standardized Study Data", available at [www.fda.gov/media/82716/download](http://www.fda.gov/media/82716/download); FDA, CBER, CDER "Study Data Technical Conformance Guide Technical Specifications Document", available at <https://www.fda.gov/media/88173/download>.

Treatment<sup>58</sup> and Endogenous Cushing’s Syndrome: Developing Drugs for Treatment<sup>59</sup> while CDER’s OGD has published over 2,100 PSGs to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support generic drug approval.<sup>60</sup> CVM issued a series of nine guidances addressing the effectiveness of anthelmintics, which were developed to provide study design recommendations that will facilitate universal acceptance of the generated effectiveness data to fulfill the national/regional requirements for anthelmintic drugs in veterinary species in the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products regions.<sup>61</sup> CFSAN has prepared guidance to assist with food facility registration,<sup>62</sup> and CTP has published guidance on registration and listing for owners and operators of domestic tobacco product establishments.<sup>63</sup>

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<sup>58</sup> FDA, CDER “Diabetic Foot Infections: Developing Drugs for Treatment”, available at <https://www.fda.gov/media/173006/download>.

<sup>59</sup> FDA, CDER “Endogenous Cushing’s Syndrome: Developing Drugs for Treatment”, available at <https://www.fda.gov/media/171900/download>.

<sup>60</sup> FDA, CDER, Office of Generic Drugs, “Product-Specific Guidances for Generic Drug Development”, available at <https://www.accessdata.fda.gov/scripts/cder/psg/index.cfm>.

<sup>61</sup> FDA, CVM, “Anthelmintics Guidances”, available at <https://www.fda.gov/animal-veterinary/guidance-industry/anthelmintics-guidances>.

<sup>62</sup> FDA, CVM, “Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition)”, available at <https://www.fda.gov/media/85043/download>.

<sup>63</sup> FDA, CTP, “Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments”, available at <https://www.fda.gov/media/78165/download>.

## V. Draft Section 2505 Guidance Plan

### A. Plan for Updating Guidance Issued during the COVID-19 PHE

Section 2505 of the Consolidated Appropriations Act of 2023 directed that this plan address “transitioning or updating guidance issued during the COVID–19 public health emergency, as appropriate.” The PHE ended in May 2023, over 6 months in advance of the deadline for this report. In March 2023, FDA published a notice in the Federal Register that provided the Agency’s transition plan for guidance documents issued during the COVID-19 PHE.<sup>64</sup> In the March 2023 notice, FDA explained that as the COVID-19 pandemic evolves, FDA would continue “to assess the needs and circumstances related to the policies in our COVID-19-related guidances, and we may alter our approach for individual guidances listed in this notice.”<sup>65</sup> Since FDA already announced its transition plan for COVID-19-related guidance documents, FDA does not have any additional information on this subject to include in this report. If FDA alters its approach to any guidances listed in the March 2023 transition plan, we will continue to announce these changes in the Federal Register.

### B. Plan for Best Practices for the Efficient Prioritization, Development, Issuance, and Use of Guidance Documents

While FDA has significantly improved its best practices for the efficient prioritization, development, issuance, and use of guidance documents over the years, FDA continues to explore areas for enhancement. FDA proposes the following plan to refine its current best practices for the efficient prioritization, development, issuance, and use of guidance documents:

#### 1. *Revisions to FDA’s GGP Regulation*

The 2011 GGP Report recommended that the Agency consider revising its GGP regulation to require the Agency to publish the annual Guidance Agenda on the Internet only. Eliminating the *Federal Register* publication requirement would reduce the Agency’s burden and increase efficiency. Moreover, it would prevent confusion that could be created by potentially outdated information, which would also advance transparency. As discussed above, FDA now publishes Guidance Agendas on the Internet, which allows for greater transparency, easier updates, and more access to the Agency’s current guidance plans. Although FDA has made other updates to its GGP regulation since 2011, we have not updated the GGP regulation to provide for publication of the annual Guidance Agenda on the Internet only. Because technology has

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<sup>64</sup> 88 FR 15417 (Mar. 13. 2023).

<sup>65</sup> 88 FR 15417, 15418 (Mar. 13. 2023). For example, in October 2023, CDER announced that it had decided to allow two COVID-19-related guidances to expire (one on drug shortages and one on potency assays for monoclonal antibodies) on November 7, 2023, because CDER already issued draft replacement guidances; and CBER published notice of its decision to withdraw the guidance “Emergency Use Authorization for Vaccines to Prevent COVID-19.” 88 FR 72084 (Oct. 19, 2023); 88 FR 72489 (Oct. 20, 2023).

changed in the 23 years since the GGP regulation was finalized, there are other aspects of the GGP regulation that could be modernized and improved.

Therefore, as a part of this plan, FDA intends to consider amending our GGP regulation to allow for better methods of developing, issuing, and using guidance documents and for consistency with the current state of technology. Examples of such amendments could include amending the GGP regulation to:

- provide for publication of the annual Guidance Agenda on the Internet only.
- provide information to ease the process for individuals and firms to suggest topics for new guidance documents or to suggest that a particular guidance document be revised or withdrawn.
- make our guidance documents available on the “Search for FDA Guidance Documents” web page and make paper copies of guidance documents available only upon request.

## *2. Use of Level 1 Guidance “for Immediate Implementation”*

The 2011 GGP Report recommended that FDA make more use of its authority to issue Level 1 guidance “for immediate implementation”; however, to date, FDA has issued a small portion of Level 1 guidance “for immediate implementation,” and thus has not fully implemented this best practice. Although the 2011 Report did not address FDA’s authority to issue Level 2 guidance without prior public comment, FDA issues few standalone Level 2 guidance documents and often uses its authority to issue Level 2 guidance to provide minor updates to an existing guidance. As described in this report, the ability to issue Level 1 guidance “for immediate implementation” without prior public participation was a significant factor in FDA’s success in implementing many COVID-19 guidances in a short timeframe.

FDA intends to consider whether, consistent with the FD&C Act, there are additional categories of Level 1 documents for which, or circumstances under which, FDA should consider issuing Level 1 guidance “for immediate implementation.” FDA also intends to consider whether, consistent with the FD&C Act, there are additional categories of guidance that would meet the definition of Level 2 guidance and be appropriate for issuance using the procedures for Level 2 guidance documents.

## *3. Streamlining Processes for Regulatory Submissions to FDA through the Issuance of Guidance Documents*

As noted in this report, FDA has issued hundreds of guidance documents that directly or indirectly assist industry in making regulatory submissions to the Agency and assist in the Agency’s review of such submissions. FDA will continue to issue guidance documents that are intended to streamline the process for making regulatory submissions and will work toward finalizing those that are currently in draft. These plans may be reflected in our Guidance

Agendas. In addition, FDA intends to continue to develop templates and technical conformance guides to accompany its guidance documents as appropriate and as resources allow.

For example, under section 515C of the FD&C Act,<sup>66</sup> FDA may under certain circumstances approve or clear a Predetermined Change Control Plan (PCCP) that describes planned changes that may be made to a device and that would otherwise require a supplemental premarket approval application or a new premarket notification. CDRH plans to finalize the draft guidance “Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions”<sup>67</sup> and issue a new draft guidance on PCCPs, which would apply to all device types, in FY24.<sup>68</sup> CDRH has also previously issued a guidance to describe an optional pathway—the Safety and Performance Based Pathway<sup>69</sup>—for certain, well-understood device types, where a submitter would demonstrate that a new device meets FDA-identified performance criteria to demonstrate that the device is as safe and effective as a legally marketed device, instead of through direct comparison testing. CDRH continues to issue device-specific guidances with these performance criteria.

As noted in this report, FDA is continually preparing and issuing guidance to assist industry in making regulatory submissions to the Agency. Examples of such guidances listed in the current guidance agendas include: (1) CDER: “Early Alzheimer’s Disease: Developing Drugs for Treatment”; “Repackagers and Relabelers of Human Drugs: Labeling; Registration and Listing, Safety Reporting, Supply Chain Security, and Good Manufacturing Practice”; and “ANDA Submissions-Amendments to Abbreviated New Drug Applications Under GDUFA”; (2) CFSAN: “New Dietary Ingredient (NDI) Notifications and Related Issues: NDI Notification Procedures and Timeframes”; (3) CBER: “Standardized Format for Electronic Submission for Marketing Applications Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for Center for Biologics Evaluation and Research Submissions.”

#### *4. Provision of a Guidance Agenda for Certain Offices in the Office of the Commissioner*

As described in this report, most FDA Centers currently publish an annual Guidance Agenda. However, the guidance documents issued by FDA Offices in the Office of the Commissioner may not be reflected in those agendas. Many of these guidance documents are of significant interest to industry and the public, including those issued by the Office of the Chief

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<sup>66</sup> Section 3308 of the Food and Drug Omnibus Reform Act of 2022 (FDORA), enacted as part of the Consolidated Appropriations Act, 2023, added section 515C “Predetermined Change Control Plans for Devices” to the FD&C Act (Pub. L. 117-328).

<sup>67</sup> Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions (April, 2023), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial>.

<sup>68</sup> FDA, CDRH, “CDRH Proposed Guidances for Fiscal Year 2024 (FY2024)”, available at <https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2024fy2024>.

<sup>69</sup> FDA, CDRH, “Safety and Performance Based Pathway”, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway>.

Scientist (recently posted a list of possible topics for future guidance document development or revision during the next year), certain offices within the Office of Clinical Policy and Programs, and OCE. FDA is considering whether it should publish a Guidance Agenda for certain Offices in the Office of the Commissioner.