DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4821]

Food and Drug Administration's Best Practices for Food and Drug Administration Communication With Interested Parties: Draft Report for Public Comment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled ''Best Practices for FDA Communication with Interested Parties: Draft Report for Public Comment.'' This draft report and implementation plan respond to the Consolidated Appropriations Act of 2023, which directs FDA to issue a report on FDA's practices for broadly communicating with external interested parties and a plan for implementation of such best practices. In addition, FDA is to conduct a review of the types and methods of public communication that FDA uses to communicate and interact with medical product sponsors and other external interested parties; identify best practices for the efficient development, issuance, and use of such communications; and develop a plan for implementation of best practices for these communications. As directed, FDA is publishing and soliciting feedback on this draft report and implementation plan.

DATES: Submit either electronic or written comments on the draft report and implementation plan by February 3, 2025.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–4821 for ''Best Practices for FDA Communication with Interested Parties.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft report and plan.

FOR FURTHER INFORMATION CONTACT: Will Bet-Sayad, Office of External Affairs, Food and Drug Administration, *will.bet-sayad@fda.hhs.gov,* 301–796–4523.

SUPPLEMENTARY INFORMATION:

I. Background

Clear, concise, and timely communication with medical product sponsors and other interested parties, including the public, using Agency regulatory documents as well as a variety of other communication methods, is essential to the public health mission of FDA. FDA currently uses a wide range of communication methods (*e.g.,* website posting, online resource libraries, webinars and town halls, email, press releases and press conferences, social media, blogs, podcasts, guidance snapshots, graphics and short videos, conferences, meetings, workshops, focus groups, and public speeches) to reach external parties and the public. During the COVID–19 Public Health Emergency (PHE), FDA considered innovative approaches and novel communication methods to reach a broad audience in an expedited manner. Now that the PHE determined under section 319 of the Public Health Service Act (42 U.S.C. 247d) is over, FDA is internally discussing the lessons learned from that experience and reassessing our current best practices for communication to look for additional areas for improvement consistent with our statutory and regulatory framework.

In accordance with section 2505(b) of the Consolidated Appropriations Act (Pub. L. 117–328) of 2023, FDA's draft report and plan on ''Best Practices for FDA Communication with Interested Parties'' reviews the types and methods of public communication outside of guidance that FDA uses to communicate and interact with medical product

sponsors and other external parties and identifies our current best practices for the efficient development, issuance, and use of such communications. As a part of this draft report and plan, FDA is also considering opportunities to advance the use of innovative forms of communication, to streamline the processes for regulatory submissions, and to implement innovative communication development processes and to transition or update communication practices used during the COVID–19 PHE. Pursuant to section 2505(c) of the Consolidated Appropriations Act, in this **Federal Register** notice announcing the availability of this document, FDA is seeking public comment on this ''Best Practices for FDA Communication with Interested Parties: Draft Report for Public Comment.''

II. Request for Comments

FDA is soliciting comments on its ''Best Practices for FDA Communication with Interested Parties: Draft Report for Public Comment'' from interested parties. Specifically, we request feedback on the following areas of communication:

Communications Questions

1. Are there communication practices that other Federal agencies use to communicate with interested parties, such as regulated industry, that would be consistent with FDA's statutory and regulatory requirements and helpful for FDA to consider implementing?

2. Recognizing that FDA used many innovative communications processes and practices during the COVID–19 public health emergency, what types of communications were most beneficial/useful during the COVID–19 pandemic and why?

III. Electronic Access

Persons with access to the internet may obtain the draft report and plan at *https://www.fda.gov/about-fda/reports/reports-agency-policies-and-initiatives* or *https://www.regulations.gov.*

Dated: November 25, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–28229 Filed 12–2–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5653]

Food and Drug Administration Report and Plan on Best Practices for Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled ''Food and Drug Administration Report and Plan on Best Practices for Guidance'' (Report and Plan). FDA is publishing this Report and Plan in response to the Consolidated Appropriations Act, 2023, which directs FDA to issue a report identifying best practices for the efficient prioritization, development, issuance, and use of guidance documents and a plan for implementation of such best practices.

DATES: The announcement of the report and plan is published in the **Federal Register** on December 3, 2024.

ADDRESSES: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Report and Plan.

FOR FURTHER INFORMATION CONTACT: Julie Finegan, Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4252, Silver Spring, MD 20993–0002, 301–827–4830.

SUPPLEMENTARY INFORMATION:

I. Background

Clear, concise, and timely communication through guidance documents is essential to the public health mission of FDA. FDA guidance documents are prepared for FDA staff, industry, and the public to describe the Agency's interpretation of, or policy on, a regulatory issue. (21 CFR 10.115(b)). Specifically, FDA uses guidance documents to assist regulated industry, FDA staff, and the public in understanding the Agency's current thinking on policy, scientific, medical, and regulatory issues, such as: the design, manufacturing, and testing of regulated products; content and evaluation of applications for product approvals; and inspection and enforcement policies. Timely publication of guidance documents significantly benefits public health by providing transparency and valuable insight into approaches that may assist industry and other interested parties in complying with applicable statutes and regulations, ensuring consumer and patient safety, and developing new and innovative products to improve public health.

As part of FDA's Transparency Initiative, in 2011, FDA publicly released a comprehensive report entitled ''Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency'' (2011 GGP Report).[1] 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. Since 2011, FDA has made significant strides to implement the recommendations in the 2011 GGP Report and 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, and as explained in the Report and Plan, FDA has significantly increased the number of guidance documents it publishes annually.

As part of FDA's reassessment of its best practices for guidance and in accordance with section 2505(a) of the Consolidated Appropriations Act, 2023, FDA published a ''Draft Report and Plan on Best Practices for Guidance'' (Draft Report and Plan) on our website on December 28, 2023.[2] Pursuant to section 2505(c) of the Consolidated Appropriations Act, 2023 in a **Federal Register** notice announcing the availability of the Draft Report and Plan, FDA solicited public comment from a broad range of interested parties, including researchers; academic organizations; pharmaceutical, biotechnology, and medical device developers; clinical research

[1] FDA, ''Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency,'' available at *https://www.fda.gov/media/82644/download.*

[2] See *https://www.fda.gov/about-fda/reports/fda-reports-good-guidance-practices.* As explained in the Draft Report and Plan, FDA will issue a separate Report and Plan in accordance with Section 2505(b) of the Consolidated Appropriations Act, 2023.