the Commission can bring its expertise and experience to bare, while also promoting transparency and accountability on merger remedies. Thus, if the Commission takes remedies off the table, it will find itself fighting a more complex battle in court, and effectively little by little relegates its judgment about what constitutes an acceptable remedy to the parties themselves and the judiciary.

Finally, categorically refusing to settle merger cases diminishes the effect of the FTC's finite enforcement resources. As already noted, litigating antitrust cases is expensive—in terms of the costs the Commission must bear for experts and other costs related to discovery and trial, but also in terms of staff's time. Such litigation can tie up staff for six to eight months or even longer.[27] Every litigation entails costly tradeoffs. Every case the Commission brings forecloses other potential merger cases or actions challenging anticompetitive conduct. Thus settlements, where they resolve the competitive concerns that a proposed transaction creates, save the Commission time and money that it can then deploy toward other matters. Settlements therefore must be on the table if the FTC is to protect competition efficiently and as fully as its resources allow.

Although I believe the Trump FTC must be open to settling merger cases, I am clear-eyed about the dangers of inadequate or unworkable settlements. The object of settlement is to protect competition as fully as would successful litigation without the expense and risk of litigation. It is not to paper over an anticompetitive transaction. Accordingly, I believe that the Commission should accept settlements in merger cases only when it is confident that the settlement will protect competition in the relevant market to the same extent that successful litigation would. Specifically, experience teaches that behavioral remedies should be treated with substantial caution. They are often difficult or impossible for the Commission to enforce effectively and can lock the Commission into the status of a monitor for individual firms rather than a guardian of competition across the entire economy. They are therefore disfavored.

Nor should the Commission ordinarily accept a structural remedy unless it involves the sale of a standalone or discrete business, or something very close to it, along with all tangible and intangible assets necessary (1) to make that line of business viable, (2) to give the divestiture buyer the incentive and ability to compete vigorously against the merged firm, and (3) to eliminate to the to the extent possible any ongoing entanglements between the divested business and the merged firm. The Commission must also be confident that the divestiture buyer has the resources and experience necessary to make that standalone business competitive in the market. Unless these conditions obtain, the Commission should proceed to litigation. When confronted with an anticompetitive merger, I will favor litigation to guarantee that competition will be protected rather than accepting an uncertain settlement.

Today's settlement satisfies these requirements. Staff conducted a thorough investigation and identified substantial anticompetitive effects likely to flow from the proposed transaction across three relevant markets.[28] Had the Commission proceeded to litigation, I am confident the Commission would have prevailed in demonstrating that the merger as originally filed would have violated section 7 of the Clayton Act. But the parties proposed divestitures in the three relevant markets,[29] and the divestitures satisfy the conditions of a successful structural remedy.[30] They involve the sale of standalone or discrete business units, or as close to it as possible, with all tangible and intangible assets necessary for a buyer to succeed in the market after the divestiture.[31] And the divestiture buyer has a long track record of acquiring assets in related markets and making them successful, as well as the financial resources to compete effectively after the divestiture.[32]

The upshot of today's Commission action for the American people and business community is that the Commission is willing to consider settlements in merger cases. But it must do so consistently with its mission to protect competition to the fullest extent possible, maximizing its resources, and in light of the lessons learned from remedies of the past. If the Commission is confident that a settlement will prevent a substantial lessening of competition as fully as would litigation, while sparing the Commission and the American people the expense and uncertainty of litigation, then it should accept that settlement.

But the Commission's standards for evaluating remedies should be exacting, and its strong preference should be for structural remedies over conduct remedies. The Commission must learn the lessons of unsuccessful past remedies and avoid returning to an era when it sometimes accepted weak remedies in lieu of the hard work of litigating to protect competition. Learning from the past, the Trump FTC should err in favor of litigating to protect competition where it believes it can prevail, rather than accepting a questionable settlement. But I am confident that accepting sound remedies in the right cases will allow the Commission to support a strong American economy that promotes human flourishing through competition and economic freedom.

[FR Doc. 2025–10290 Filed 6–5–25; 8:45 am]

BILLING CODE 6750–01–P

[27] See, *e.g., FTC* v. *Tempur Sealy Int'l,* No. 4:24–CV–02508, 2025 WL 617735, at *9 (S.D. Tex. Feb. 26, 2025) (roughly seven months from filing of complaint and motion for preliminary injunction to district court ruling); *FTC* v. *Tapestry,* 755 F. Supp. 3d 386, 406 (S.D.N.Y. 2024) (roughly six months from filing of complaint and motion for preliminary injunction to district court ruling); *FTC* v. *Kroger Company,* No. 3:24–cv–00347–AN, 2024 WL 5053016, at *5 (D. Or. Dec. 10, 2024) (roughly ten months from filing of complaint and motion for preliminary injunction to district court ruling); *FTC* v. *Cmty. Health Sys.,* 736 F. Supp. 3d 335, 350 (W.D.N.C. 2024), opinion vacated, appeal dismissed sub nom. *FTC* v. *Novant Health,* No. 24–1526, 2024 WL 3561941 (4th Cir. July 24, 2024) (roughly four and a half months from filing of complaint and motion for preliminary injunction to district court ruling, and another month for appellate resolution after which parties abandoned transaction); *FTC* v. *IQVIA Holdings,* 710 F. Supp. 3d 329, 346 (S.D.N.Y. 2024) (just under six months from filing of complaint and motion for preliminary injunction to district court ruling). See also Farrell J. Malone & Ian C. Thresher, Leaving Time to Litigate: Lessons from Recent Merger Challenge, Antitrust Source (Oct. 2018) (''among the 13 cases that were litigated to a decision in 2011–2017, the average time from the filing of a complaint until a district court's decision on the merits has increased from 99 days in 2011 to as high as 221 days in 2017.'').

[28] Complaint, *In the Matter of Synopsys, Inc. and ANSYS, Inc.,* Matter No. 2410059, ¶¶ 5–18 (May 27, 2025).

[29] See Decision and Order, *In the Matter of Synopsys, Inc. and ANSYS, Inc.,* Matter No. 2410059 (May 27, 2025) (''Decision and Order''); Analysis of Agreement Containing Consent Orders, *In the Matter of Synopsys, Inc. and ANSYS, Inc.,* Matter No. 2410059, at 3–4 (May 27, 2025) (''AAOC'').

[30] See, *e.g.,* BC Remedies Statement, *supra* note 9.

[31] See Decision and Order.

[32] AAOC at 3–4.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–1150]

Hernia Mesh—Package Labeling Recommendations; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled ''Hernia Mesh—Package Labeling Recommendations.'' This draft guidance provides labeling recommendations for hernia mesh devices that are intended to help promote the safe and effective use of hernia mesh. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by August 5, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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–2025–D–1150 for ''Hernia Mesh—Package Labeling Recommendations.'' 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Hernia Mesh—Package Labeling Recommendations'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Nils Potter, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4526, Silver Spring, MD 20993–0002, 240–402–7130.

SUPPLEMENTARY INFORMATION:

I. Background

Hernia meshes represent a diverse group of medical devices intended for hernia repair in different anatomic regions and featuring a wide variety of physical and mechanical properties. The range of hernia mesh characteristics and properties can make it challenging, even for experienced healthcare providers, to choose the most appropriate hernia mesh for a given patient, while also taking into consideration patient-specific factors and surgical approach. Since January 1, 2019, FDA has received over 86,000 adverse event reports related to hernia mesh. The package labeling recommendations in this draft guidance are intended to help promote the safe and effective use of hernia mesh. In particular, the package labeling recommendations may provide for a more consistent format for disseminating certain clinically relevant information, making it easier for healthcare providers to find certain information needed to use these devices safely and for the purposes for which they are intended.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Hernia Mesh—Package Labeling Recommendations. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop any final guidance on this topic, FDA will consider comments on the applicability of Executive Order 14192, per OMB guidance M–25–20, and in particular, on any costs or cost savings.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by

downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Hernia Mesh—Package Labeling Recommendations'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00007030 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification	0910–0485

Dated: June 2, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–10275 Filed 6–5–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–3054]

M11 Technical Specification: Clinical Electronic Structured Harmonised Protocol; International Council for Harmonisation; Draft Technical Specification; and Template; 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 the revised draft technical specification entitled ''M11 Technical Specification: Clinical Electronic Structured Harmonised Protocol (CeSHarP)'' and a supplemental document entitled ''M11 Template.'' The revised draft technical specification and template were prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The revised draft technical specification recommends the use of an open, nonproprietary standard to enable electronic exchange of clinical protocol information. The template identifies headers, common text, and a set of data fields and terminologies that will be the basis for efficiencies in data exchange. These ICH documents create an international standard for the content and exchange of clinical trial protocol information facilitating review and assessment by regulators, sponsors, ethical oversight bodies, investigators, and other stakeholders. This revised draft technical specification and updated template revise and replace the draft versions of the same titles issued in December 2022.

DATES: Submit either electronic or written comments on the draft guidance by July 7, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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–2022–D–3054 for ''M11 Technical Specification: Clinical Electronic Structured Harmonised Protocol (CeSHarP).'' 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