official, including but not limited to the chief financial officer (CFO), that the payment amount for that quarter is accurate and is based on 100% of all completed calls; (4) require quarterly reporting obligations for other facilitiesbased long distance carriers in the call path, if any, and define these carriers as "Intermediate Carriers;" and (5) give parties flexibility to agree to alternative compensation arrangements (ACA) so that small Completing Carriers may avoid the expense of instituting a tracking system. The revisions adopted in the 2018 Report and Order significantly decreased the paperwork burden on carriers.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary. [FR Doc. 2024–05615 Filed 3–14–24; 8:45 am] BILLING CODE 6712–01–P

FEDERAL TRADE COMMISSION

[Docket No. C-4760]

Petition for Prior Approval of XCL Resources Holdings, LLC's Proposed Acquisition of Altamont Energy, LLC

AGENCY: Federal Trade Commission. **ACTION:** Announcement of Petition; Request for Comment.

SUMMARY: XCL Resources Holdings, LLC ("XCL") has petitioned the Federal Trade Commission ("FTC" or "Commission") for approval of its acquisition of Altamont Energy, LLC ("Altamont"), an oil and gas operator in the Uinta Basin, pursuant to the agreement reached with the FTC in the EnCap/EP Energy matter.

DATES: Comments must be received on or before April 15, 2024.

ADDRESSES: Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the SUPPLEMENTARY INFORMATION section below. Please write: "XCL/Altamont Petition for Prior Approval; Docket No. C–4760" on your comment, and file your comment online at *www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Mail Stop H-144 (Annex P), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Kenneth Libby (202–326–2694), Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to FTC Rule 2.41(f), 16 CFR 2.41(f), notice is hereby given that the public [redacted] version of the abovecaptioned petition has been filed with the Secretary of the Commission and is being placed on the public record for a period of thirty (30) days. After the period for public comments has expired, the Commission shall determine whether to approve the petition. In making its determination, the Commission will consider, among other information, all timely and responsive comments submitted in connection with this document.

The text of the public [redacted] version of the petition is provided below. An electronic copy of the text of the public [redacted] version of the petition can be obtained from the FTC website at this web address: https:// www.ftc.gov/legal-library/browse/casesproceedings/2110158-encapep-energymatter.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before April 15, 2024. Write "XCL/ Altamont Petition for Prior Approval; Docket No. C–4760" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *www.regulations.gov* website.

Because of the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *www.regulations.gov* website.

If you prefer to file your comment on paper, write "XCL/Altamont Petition for Prior Approval; Docket No. C–4760" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Mail Stop H–144 (Annex P), Washington, DC 20580.

Because your comment will be placed on the publicly accessible website at *www.regulations.gov*, you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not

include any sensitive personal information, such as your or anyone else's Social Security number: date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form. must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on www.regulations.gov—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http:// www.ftc.gov* to read this document and the news release describing this matter. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before April 15, 2024. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see https://www.ftc.gov/ site-information/privacy-policy.

April J. Tabor,

Secretary.

Text of Public [Redacted] Version of Petition for Prior Approval of XCL Resources Holdings, LLC's Proposed Acquisition of Altamont Energy, LLC

I. Executive Summary

XCL Resources Holdings, LLC ("XCL") plans to acquire Altamont Energy, LLC ("Altamont" and, together with XCL, the "Parties"), an oil and gas operator in the Uinta Basin. XCL seeks prior approval from the Federal Trade Commission (the "FTC" or the "Commission") to complete this proposed transaction pursuant to the agreement reached with the FTC in the EnCap/EP Energy matter.

The Proposed Transaction will not increase the capacity or share of XCL in any relevant market in any appreciable way; nor will it alter in any negative way the competitive landscape for supply of waxy crude oil to Salt Lake City refiners (or to any other refiner). It will provide Altamont, a small operator [REDACTED], the access to capital it needs. The transaction will allow the combined entity to increase production, execute drilling of new wells at a lower cost, and allow for other cost-lowering enhancements, ultimately offering more production at competitive prices downstream to buyers in and out of Salt Lake City.

II. Introduction

A. Background on the Order

Pursuant to Section 2.41(f) of the FTC Rules of Practice and Procedure ¹ and Section X(A) of the September 13, 2022, final decision and order *In the Matter of EnCap Investments L.P., a limited partnership, EnCap Energy Capital Fund XI, L.P., a limited partnership, Verdun Oil Company II LLC, a limited liability company, XCL Resources Holdings, LLC, a limited liability company, EP Energy Corporation, a corporation and EP Energy LLC, a limited liability company* (the "Order"),² XCL hereby petitions the Commission to approve its proposed acquisition of Altamont (the "Proposed Transaction").

As part of the Order, the Commission required that EnCap Investments L.P., EnCap Energy Capital Fund XI, L.P., Verdun Oil Company II LLC and XCL (collectively, "EnCap") obtain prior approval before acquiring any other producer of waxy crude oil with an output of over 2,000 barrels per day in any of the following Utah counties: Duchesne, Uintah, Utah, Grand, Emery, Carbon and Wasatch.³

B. The Proposed Transaction

On August 24, 2023, XCL signed a non-disclosure agreement with Altamont in contemplation of the Proposed Transaction. XCL subsequently began due diligence and negotiation of initial terms. On October 31, 2023, XCL and Altamont signed a deal term sheet and entered into an exclusivity agreement. XCL notified the FTC of the Proposed Transaction on November 5, 2023. On January 16, 2024, XCL and Altamont executed a Purchase and Sale Agreement in contemplation of the Proposed Transaction, which [REDACTED] makes closing conditional on obtaining approval from the Commission.4

Given that Altamont is a waxy crude oil producer in the Uinta Basin with an output of approximately [REDACTED] barrels per day, the Proposed Transaction is subject to the requirement for prior approval under the Order; and XCL hereby seeks such approval prior to closing the Proposed Transaction. As outlined *infra* in Section IV, the Proposed Transaction is procompetitive and does not raise any competitive concerns.

III. The Parties and the Transaction Rationale

A. The Parties

XCL is a privately held, Houstonbased independent oil and gas company focused on the acquisition and development of liquids-rich basins in the United States. XCL owns and operates approximately 135 horizontal wells across approximately 45,900 net acres in Duchesne and Uintah Counties, Utah, where it extracts black and yellow waxy crude oil and natural gas. XCL's low-cost, efficient operations strategy focuses on the development of horizontal wells and pioneering new production methods in the Uinta Basin. The company has three active rigs and is drilling 70 new wells per year on average in the Uinta Basin. A majority of XCL's production is exported to refiners on the U.S. Gulf Coast, due to supply saturation in Salt Lake City. See infra, Section IV(A).

XCL became a subsidiary of EnCap Investments L.P. ("EnCap Investments") in 2018, and EnCap Investments has provided the majority of the financial backing for XCL's projects and investments to date. EnCap Investments is a private equity firm specializing in investments in the energy industry, particularly oil and gas.

Altamont is a small operator with no active rigs and no material growth plans it can achieve without access to capital [REDACTED]. Altamont produces [REDACTED] barrels of waxy crude oil per day on average, and nearly all of that is purchased by Salt Lake City refiners. [REDACTED].

In 2018, Altamont acquired oil and gas assets from LINN Energy, Inc., an oil and gas exploration and production company. Altamont focused its operations in and around the Wasatch and Green River stacked formations in the Uinta Basin. Altamont completed drilling operations for four vertical wells in 2018 and 2019.

In 2021, Altamont [REDACTED] to drill eight horizontal wells. Those wells were begun in 2022 completed in 2023, with five wells beginning production in March and three wells beginning production in June, [REDACTED].⁵

Altamont hired Houlihan Lokey as its investment banker and began marketing itself for a sale in August 2023. Altamont and its bankers reached out to over 300 parties in search of potential bidders. [REDACTED].⁶ As the highest bidder, XCL was selected as buyer; and discussions kicked off shortly thereafter for the Potential Transaction. *See supra*, Section II(B).

B. The Transaction Rationale

With the acquisition of Altamont, XCL expects to realize substantial economic efficiencies in the development and production of oil in the Uinta Basin. XCL projects that the Proposed Transaction will not have any significant impact on its own growth or investment plans, but it will enable XCL to apply capital and its superior operating capabilities to Altamont properties, further XCL's cost-reduction objectives, and ultimately bring more product at competitive prices to its customers.

¹¹⁶ CFR 2.41(f).

² In the Matter of EnCap Investments L.P., a limited partnership, EnCap Energy Capital Fund XI, L.P., a limited partnership, Verdun Oil Company II LLC, a limited liability company, XCL Resources Holdings, LLC, a limited liability company, EP Energy Corporation, a corporation and EP Energy LLC, a limited liability company, Decision and Order, Docket No. C-4760, (F.T.C. Sept. 13, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/C4760 EnCapEPEnergyOrder.pdf (hereinafter, "Order"), at § X(A).

³ Order § X(A).

⁴ An executed copy of the Purchase and Sale Agreement between Altamont Energy LLC and Altamont Minerals LLC, collectively, as Seller and XCL AssetCo, LLC as Buyer, has been provided to the Commission in connection with this application.

⁵ [REDACTED].

^{6 [}REDACTED].

As the owner of acreage adjacent to Altamont's and an efficient, low-cost operator, XCL is uniquely positioned to generate numerous efficiencies from combining the contiguous acreage. For example, XCL will be able to lower operating costs by combining its water and gas infrastructure with Altamont's. Additionally, XCL will be able to optimize development plans to limit downtime in drilling and completion operations on the contiguous acreage. Reduced operating costs will enhance economic viability (*i.e.*, ability to maintain production and investment in lower commodity price environments) and increase competitive downstream pricing without adding significantly to XCL's share of the Uinta Basin production, output to the Sale Lake City refiners or the like. See infra, Section IV. [REDACTED].7

For Altamont specifically, the Proposed Transaction will provide an opportunity to generate value for their assets [REDACTED]. XCL plans to change this with the goal of tripling Altamont's production. [REDACTED].

IV. Competitive Analysis of the Transaction

A. Changes in the Market Structure

Since the FTC investigated the EPE Transaction, the competitive landscape in the Uinta Basin, including its supply into the Salt Lake City refiners, has changed significantly.⁸

Critically for purposes of the FTC's concern in 2021, the increase in waxy crude oil production in the Uinta Basin has saturated supply to the Salt Lake

City refiners. Current production levels dramatically exceed the capacity of the refiners, and Uinta Basin producers are selling a growing portion (in XCL's case, a majority) of their output outside the Salt Lake City area (primarily to the U.S. Gulf Coast). The Salt Lake City's refiners' demand for waxy crude oil remains capped at approximately 90,000 barrels per day,⁹ while Uinta Basin waxy crude oil production has reached 140,000 barrels per day and is continuing to grow.¹⁰ In addition, Salt Lake City refiners also source other types of crude from outside of the Uinta Basin. Moreover, three different owners of Salt Lake City refineries also source Uinta waxy crude for their other refineries outside of Utah. Both in Salt Lake City and at refineries on the Gulf Coast, waxy crude competes with various other crude grades as refineries optimize their crude feedstocks to maximize profits by producing the combination of products dictated by the market.11

In the Complaint, the Commission expressed concern that increased concentration in the Uinta Basin would result in higher prices and decreased supply to the Salt Lake City refiners.¹² But the supply today from the Uinta Basin well exceeds the demand for waxy crude oil from the Salt Lake refiners. This puts the Salt Lake City refiners in the position of driving prices, rather than the Uinta Basin oil producers doing so. Because the Uinta Basin oil producers need to pay higher transportation and other costs to access customers other than the Salt Lake City refiners, the refiners are able to demand low prices.

The Salt Lake City refiners also charge high prices for their finished product higher than in most of the United States—and realize the highest profits in the nation as compared to refiners in other locations. Finished product prices in Salt Lake City are independent of the sales price of waxy crude oil.¹³

As described above, the production of waxy crude oil in the Uinta Basin has grown (well beyond the demand of Salt Lake City refiners) and continues to grow, creating opportunities for entry and growth. In the last 24 months, at least four new oil producers. Scout Energy Partners, Wasatch Energy Management Operating ("WEM Operating"),¹⁴ Anschutz Corporation and Vaquero Energy have entered the Uinta Basin, initiated drilling operations and have wells that are producing. Additionally, several formerly dormant operators have resumed drilling activities, including Berry Corporation¹⁵ Caerus Uinta, and KGH Operating. Ovintiv, Inc., Uinta Wax Operating and Crescent Energy Company (the company that ultimately acquired EPE) remain large producers, while other competitors, including Middle Fork Energy Partners ¹⁶ as well as the new entrants mentioned above, have also built a significant presence, as measured by crude production.

The below chart shows the number of new horizontal wells that have been drilled by year since 2020 per producer, with a notable increase for most producers in 2023.

Producer	2020	2021	2022	2023
Altamont Energy	0	0	8	0
Anschutz Corp	0	0	0	2
Crescent Energy	9	41	30	24
Finley Resources	2	0	0	0
KGH Operating Co	0	0	1	1
Koda Resources	0	0	0	9
Ovintiv	3	26	14	54
Scout Energy	0	0	0	20
Uinta Wax	10	16	23	37
WEM Operating	0	0	0	6
XCL Resources	4	48	70	61

⁷ Altamont acreage shapefiles provided to XCL in the course of diligence. XCL acreage shapefiles created by XCL internally in the ordinary course. 2110158C4760EnCapEPEComplaint.pdf (hereinafter, "Complaint") ¶ 15.

⁹ Based on Utah Geological Survey data for 2022, available at *https://geology.utah.gov/docs/statistics/ petroleum3.0/pdf/T3.13a.pdf*. The Complaint estimated the capacity of the Salt Lake City refineries at 80,000 barrels per day. *See* Complaint ¶ 21.

¹⁰ Refinery Demand Data extracted by XCL from Utah Geological Survey. Production Data supplied to XCL by Utah Division of Oil Gas and Mining.

¹¹Based on U.S. Geological Survey, Table 3.13a "Utah Refinery Receipts of Crude Oil by St.ate of Origin, 1980–2022", available at *https://geology*. utah.gov/energy-minerals/info/energy-mineralstatistics/#toggle-id-3.

¹²Complaint ¶ 24.

¹³ Data obtained from Utah Office of Energy Development 2022 Utah Gasoline Prices Report, *https://energy.utah.gov/wp-content/uploads/Utah-Gasoline-Prices.pdf.*

¹⁴ [REDACTED]. WEM Operating began drilling in the Uinta Basin as an independent operator in 2023 and are not yet listed on the UDOGM website as an active producer yet (expected to be listed in 2024).

¹⁵ Primarily drilling vertical wells (so not included in the chart below).

¹⁶ Listed in the chart below as Koda Resources

⁸ Please note that, for the purposes of this submission only, XCL adopts the view of the market set forth by the Commission in the EnCap/EP Energy matter. See In the Matter of EnCap Investments L.P., a limited partnership, EnCap Energy Capital Fund XI, L.P., a limited partnership, Verdun Oil Company II LLC, a limited liability company, XCL Resources Holdings, LLC, a limited liability company, EP Energy Corporation, a corporation and EP Energy LC, a limited liability company, Docket No. C-4760 (F.T.C. Mar. 25, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/

Producer	2020	2021	2022	2023
Total	28	131	146	214

Source: Enverus Data [REDACTED].

The emergence of at least four new entrants in the last 24 months, combined with formerly small producers increasing their shares, indicates that competition is robust in the region.

B. Size and Positioning of the Target

As outlined *supra* in Section II(A)(2), Altamont is a small producer with limited capacity and output. Altamont's limited acreage is contiguous to XCL's, and the Parties' infrastructure is complementary, allowing XCL to optimize the combined entity's processes and lower costs. While XCL expects to realize significant cost savings from the Potential Transaction, the increase to XCL's production and share of the Uinta Basin will be modest. *See supra*, Section IV(A). XCL expects that the addition of Altamont's current production will only increase XCL's total production by 9% and market share of waxy crude oil supply to Salt Lake City by 4%, and not materially affect its development or investment plans.

The Parties also expect the Proposed Transaction to have a limited effect, if any, on the supply of waxy crude oil to the Salt Lake City refiners. As outlined *supra* in Section IV(A), the production of waxy crude oil in the Uinta Basin well exceeds the demand from the Salt Lake City refiners. Although XCL's waxy crude oil production has quadrupled since 2022, its supply to Salt Lake City refiners remains unchanged, at approximately [REDACTED] barrels per day. The Salt Lake City refiners have indicated to XCL that they do not intend to purchase any more oil from XCL, and XCL does not expect to increase its sales to them in any significant measure, even with the acquisition of Altamont. [REDACTED] the incremental output from Altamont is only 4% of the waxy crude oil sold to Salt Lake City refiners.

XCL estimates that the HHI index in the market for the supply of waxy crude oil to Salt Lake City refiners is currently 1,549 (pre-Proposed Transaction) and would increase to 1,647 (post-Proposed Transaction), for an HHI delta of 98 points.¹⁷ The chart below shows the pre and post-Proposed Transaction market shares and corresponding HHI components for the 12 top producers for supply of waxy crude to Salt Lake City refiners.¹⁸

Producer	Share of waxy crude supply to SLC (pre-transaction)	HHI component (pre-transaction)	Share of waxy crude supply to SLC (post-transaction)	HHI component (post-transaction)
XCL AssetCo, LLC Javelin Energy Partners Management, LLC Ovintiv USA, Inc Uinta Wax Operating, LLC FINLEY RESOURCES, INC Scout Energy Management, LLC Altamont Energy Operating LLC Berry Petroleum Company LLC MIDDLE FORK ENERGY UINTA, LLC Vaquero Uinta, LLC Greylock Production, LLC Caerus Uinta, LLC	[REDACTED] [REDACTED]	311 654 189 178 80 29 17 16 9 2 1 1	[REDACTED] [REDACTED]	475 654 189 178 80 29 N/A 16 9 2 1 0
Total ¹⁹	100%	1,549	100%	1,647

Neither the starting nor ending HHI figures indicate a highly concentrated market and the delta from the transaction is not a significant increase under the 2023 Merger Guidelines; instead, the delta reflects only a marginal increase in concentration. [REDACTED].²⁰ Additionally, the HHI calculations do not take into account the ample oversupply of waxy crude oil available to Salt Lake City refiners. The estimated HHIs also only include waxy crude oil sold to Salt Lake City (90,000 barrels per day) and not all crude oil sold to Salt Lake City (200,000 barrels per day).

C. Expected Competitive Effects

The Proposed Transaction will have no negative competitive effect on any relevant market. Since the Commission issued the Order, the competitive

¹⁸ Note the remaining (smaller) producers have a market share and HHI component that rounds to 0 and so have not been displayed. [REDACTED].

 $^{19}\,\rm Note$ that the percentages and HHI numbers are rounded and <1% is accounted for by the small producers not listed.

landscape has shifted in favor of Salt Lake City refiners, due to the increase in local output from existing suppliers (XCL and others) and the entry of new waxy crude oil producers; while the emergence of these producers shows that barriers to entry have weakened. Given the ample choice Salt Lake City refiners have, the small increase in capacity and output XCL would receive from the Altamont assets would have

¹⁷ Calculations based on latest available Utah Division of Oil, Gas and Mining (UDOGM) data as of January 2024 (July 2023), using production data for a 12-month period (August 2022-July 2023). Calculations use XCL actual sales to SLC and UDOGM production data for other Uinta Basin producers. Estimates assume 100% of production in the Uinta Basin is supplied to Salt Lake City for most producers, except for Ovintiv and Uinta Wax, which XCL is aware also supply a portion (which, for the purposes of this estimate XCL has assumed to be 10,000 barrels per day) to the Gulf Coast. XCL

is not aware of Uinta Basin producers other than itself, Ovintiv, and Uinta Wax that supply outside of Salt Lake City in any significant manner. SLC demand for waxy crude (for total size of market) obtained from UDOGM. [REDACTED].

²⁰ A typical horizontal well in Utah can make anywhere between 800–2,000 barrels per day in its first several months of production. However, by month 12, this typically will fall to under 500 barrels per day, and typically will fall below 300 barrels per day by month. *See* Appendix A (showing average daily production for Uinta Basin horizontal wells with first production since 2019). [REDACTED].

little effect.²¹ Additionally, both the size of the target and the value of the Proposed Transaction are a small fraction of the size of the EPE Transaction that resulted in the Order.

The Potential Transaction will, however, result in pro-competitive effects, allowing XCL to lower costs, grow production, and optimize its processes to deliver high-quality, competitively priced products to the downstream markets in Salt Lake City, the Gulf Coast, and elsewhere. XCL has demonstrated its desire and ability to significantly grow production on its existing position for the benefit of customers (and consumers) in all regions, and it is uniquely positioned to employ the same strategy on Altamont.

V. Request for Confidential Treatment

This petition, including its related documents, contains certain confidential and competitively sensitive business information relating to XCL, Altamont and the Proposed Transaction. Disclosure of such confidential information may prejudice XCL and Altamont, and cause harm to the ongoing competitiveness of both companies. Pursuant to Sections 2.41(f)(4) and 4.9(c) of the FTC's Rules of Practice and Procedure,²² XCL has redacted such information from the public version of this application, and requests confidential treatment for such redacted information under Section 4.10(a)(2) of the FTC's Rules of Practice and Procedure ²³ and Sections 552(b)(4) and (b)(7) of the Freedom of Information Act.²⁴ In the event that a determination is made that any material marked as confidential is not subject to confidential treatment, XCL requests that the FTC provide prompt notice of that determination and adequate opportunity to appeal such a decision.

Appendix A

Average Daily Production 2019–2023 for Uinta Basin Horizontal Wells With First Production in 2019 $^{\rm 25}$



²²16 CFR 2.41(f)(4), 4.9(c).

²¹ As noted above, for the purposes of this submission, XCL has adopted the Complaint's view of the market. However, XCL believes that market activity and competitive dynamics have demonstrated that waxy crude is not its own product market. It is a crude grade that is fungible with and competes with various other crude grades as refineries optimize their feedstock to align with

what the market dictates. Waxy crude has been run at many refineries outside of Salt Lake City and in the process, displaced alternative crude oils at those destinations. When analyzed in this broader market lens, the transaction has negligible impacts on any refining markets.

²³ 16 CFR 4.10(a)(2).

²⁴ 5 U.S.C. 552(b)(4), 552(b)(7).

²⁵ A minimum of 10 wells is required to produce a monthly average reducing noise in outer years. Data sourced from Enverus. [REDACTED].

A full color version of this chart is included as a Supporting Document in the docket for this matter on *www.regulations.gov.* [FR Doc. 2024–05297 Filed 3–14–24; 8:45 am] **BILLING CODE 6750–01–P**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-D-0664]

Evaluation of Thermal Effects of Medical Devices That Produce Tissue Heating and/or Cooling; 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 "Evaluation of Thermal Effects of Medical Devices That Produce Tissue Heating and/or Cooling." FDA is issuing this draft guidance document to describe relevant information that should be provided in premarket submissions to support the evaluation of thermal effects of medical devices that produce local, regional, and/or systemic changes in tissue temperature (*i.e.*, heating and/or cooling) due to their use. The recommendations in this draft guidance reflect current review practices and are intended to promote consistency and facilitate efficient review of thermal effects data in premarket submissions for these devices. 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 May 14, 2024 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– 2024–D–0664 for "Evaluation of Thermal Effects of Medical Devices that Produce Tissue Heating and/or Cooling." 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 "Evaluation of Thermal Effects of Medical Devices that Produce Tissue Heating and/or Cooling' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT:

Devashish Shrivastava, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4628, Silver Spring, MD 20993–0002, 301– 796–5459.

SUPPLEMENTARY INFORMATION:

I. Background

When a change in tissue temperature occurs because of device heating and/or cooling, there is a potential for adverse health effects, such as tissue damage or a negative impact on physiological functions. This draft guidance provides FDA's recommendations for evaluation of thermal effects for devices that produce changes in tissue temperature (heating and/or cooling) as an intended or unintended consequence of device use. The draft guidance describes when